

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Printed: 03/13/2008  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 000	<p><b>INITIAL COMMENTS</b></p> <p>The following reflects the findings of the California Department of Public Health during a Full Certification survey conducted October 2 through October 5, 2007. The Southwest Healthcare System is comprised of two hospitals under the same licensure (Inland Valley Medical Center and Rancho Springs Medical Center).</p> <p>The CFO and CNO were notified that Immediate Jeopardy was declared on October 2, 2007, at 6:05 p.m. The Immediate Jeopardy was identified due to the facility's failure to ensure the safe storage of food to prevent the potential for food borne illness in their patients. An acceptable plan of correction was received, and the CFO and CNO were notified that the Immediate Jeopardy was abated on October 3, 2007, at 8:25 a.m.</p> <p>The CFO was notified that Immediate Jeopardy was declared on October 4, 2007, at 5:35 p.m. The Immediate Jeopardy was identified due to the facility's failure to ensure the availability of an adequate supply of emergency medications needed to treat Malignant Hyperthermia (a life threatening medical emergency associated with the administration of general anesthesia) in accordance with the standards established by the Malignant Hyperthermia Association of the United States, resulting in the potential for harm and death in all patients receiving anesthetic agents known to cause Malignant Hyperthermia. An acceptable plan of correction was received, and the Director of QAPI was notified that the Immediate Jeopardy was abated on October 4, 2007, at 7:35 p.m.</p> <p>Representing the Department of Public Health; Tina Buchanan, HFEN; Janne Powell, HFEN;</p>	A 000	<p>Submission of this plan of correction is not an agreement that the facts are correct or an admission that the Hospital violated the rules.</p>	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>James Knox</i>	TITLE <b>CEO</b>	(X6) DATE <b>6/11/08</b>
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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 patients. (See Instructions.) Except for nursing homes, the findings stated 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.

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*DF*  
*DF*

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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92582</b>		
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A 000	Continued From page 1 Deanne Martzolf, HFEN; Sheldeen Grimes, HFEN; Morton Kligerman, MD, Medical Consultant; Shola Ayodele, RD, Nutrition Consultant; Kari Roosenberg, OTR/L, CHT, Rehabilitation Consultant; Mark Sanguinetti, PharmD, Pharmacy Consultant; and Dongjoon Song, PharmD, Pharmacy Consultant.  The average daily census was 181.  The sample size was 73 patients.  The following abbreviations are found in this document: 2400 - Midnight ADA - American Diabetic Association ASHSP - American Society of Health System Pharmacists A/O - Alert and Oriented BSC - Biological Safety Cabinet CEO - Chief Executive Officer CFO - Chief Financial Officer c/o - Complaint of CN - Charge Nurse CNO - Chief Nursing Officer CT - Computerized Tomography DNFS - Director of Nutrition and Food Services DPO - Director of Plant Operations ECG - Electrocardiogram ED - Emergency Department EMTALA - Emergency Medical Treatment and Labor Act ER - Emergency Room EVS - Environmental Services F - Fahrenheit FDA - Food and Drug Administration FSM - Food Services Manager FSW - Food Services Worker	A 000		

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A 000	Continued From page 2 ggt - drop/drip H/A - Headache Hg - Mercury HS - House Supervisor IC - Infection Control ICC - Infection Control Coordinator ICU - Intensive Care Unit ISMP - Institute for Safe Medication Practices IV - Intravenous IVMC - Inland Valley Medical Center IVP - Intravenous Push L&D - Labor and Delivery LSLF - Low sodium, low fat MAR - Medication Administration Record mg - Milligram MH - Malignant Hyperthermia MHAUS - Malignant Hyperthermia Association of the United States ml - Milliliter mm - Millimeter NDD - National Dysphagia Diet NDD 1 - Dysphagia Pureed Diet NDD 2 - Dysphagia Mechanically Altered Diet NDD 3 - Dysphagia Advanced Diet NIOSH - National Institute for Occupational Health and Safety NMT - Nuclear Medicine Technician NR - No Reaction N/V - Nausea and Vomiting OR - Operating Room OT - Occupational Therapy/Occupational Therapist oz - Ounce PA - Physician's Assistant PACU - Post Anesthesia Recovery Unit PI - Performance Improvement PM - Preventive Maintenance P&T - Pharmacy and Therapeutics Pt - Patient PT - Physical Therapy/Physical Therapist	A 000		

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A 000	Continued From page 3 QA - Quality Assurance QAPI - Quality Assurance/Performance Improvement R - Right RD - Registered Dietician RM - Risk Manager RN - Registered Nurse RSMC - Rancho Springs Medical Center RT - Respiratory Therapist SBP - Systolic Blood Pressure SPD - Sterile Processing Department ST - Speech Therapist/Speech Therapy TEE - Transesophageal Echocardiogram vs - Versus	A 000		
A 020	<b>482.11 COMPLIANCE WITH FEDERAL LAWS</b>  The hospital must ensure that specific Federal, State and local law requirements are met.  This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure compliance with one Federal regulation, and two State regulations by failing to:  a. Post a sign in the ER lobby at IVMC notifying patients of their rights to a medical screening examination on arrival to the ER as required by EMTALA (A021);  b. Ensure all supplemental services were licensed by the State prior to offering outpatient rehabilitation services to patients (A022), and;  c. Ensure general acute care beds were not converted to ICU beds without written approval (A022).	A 020	<b>B. Licensing of Supplemental Services</b>  1. With respect to licensure of supplemental services, the Chief Nursing Officer (CNO) completed applications for outpatient rehabilitation licensure and gave them to the CMS/DPH surveyor prior to departure from the facility on 10/05/07.  2. The CNO reviewed and confirmed that outpatient rehabilitation services were being provided in accordance with requirements.  3. To prevent the recurrence of this situation in the future, the organization, the COO or designee will consult with the California DPH office to review the hospital's license for any changes that need to be made. This step has been incorporated into the planning process for any new service.  Please see responses to A021 (ED Signage) and A022 (General Acute Care beds used for ICU patients).	10/05/07  10/05/07  10/05/07

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A 020	Continued From page 4 The cumulative effect of these systemic problems resulted in the failure of the governing body and CEO to ensure the provision of safe and effective patient care, in compliance with Federal and State laws and regulations.	A 020		
A 021	482.11(a) COMPLIANCE WITH FEDERAL LAWS  The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.  This Standard is not met as evidenced by: Based on observation and interview, the facility failed to ensure posting of a sign in the ER lobby at IVMC, in compliance with the federal EMTALA law, resulting in failure to notify patients of their right to a medical screening exam upon arrival to the ER.  Findings:  During a tour of the ER at IVMC on October 4, 2007, at 11:05 a.m., it was noted there was no sign in the lobby (where patients were waiting for examination and treatment) informing patients of their right to examination and treatment of an emergency medical condition, including labor.  The Director of the ER was present during the tour, and stated she would get the sign posted.  According to the Code of Federal Regulations, 42 CFR §489.20(q), the hospital is required to post conspicuously in any emergency department or in a place or places likely to be noticed by individuals entering the emergency department....a sign....specifying the rights of individuals....with respect to examination and	A 021	At the time of the survey it was noted that the sign informing patients of their rights to a Medical Screening exam was missing. The Director of Critical Care investigated and determined that the sign had been inadvertently removed by plant operations during construction.  The sign has been placed in a locked cabinet in the lobby of the Emergency Department that is visible to all patients.  The Director of Critical Care drafted and sent a memo to the Facilities Project Director that in the course of construction or other maintenance projects; the Director of Critical Care must approve any patient information that needs to be moved or removed.  The Manager of the Emergency Department (or designee) checks weekly to be sure that the sign remains posted in the lobby.	10/04/07  10/05/07  04/04/08  10/05/07 & ongoing



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A 022	<p>Continued From page 6</p> <p>multiple trauma secondary to a motor vehicle accident. According to RN 1, patient 914 had a respiratory arrest prior to a previously planned surgery, came to the ICU satellite on a ventilator, was weaned off the ventilator, and waiting to go back to surgery. RN 1 stated the patient in room 915 was admitted with a vertebral artery dissection, was in a very fragile neurological state, and needed to have the door closed and the lights off. RN 1 stated that when the door was closed, she could not visualize the patient or the cardiac monitor.</p> <p>RN 2 was interviewed on October 4, 2007, at 10:40 a.m. RN 2 stated she was an ICU staff member who usually worked in the ICU, but was floated to the ICU satellite unit for the day. RN 2 stated the patient in room 259 (Patient 916) was admitted for treatment of a gastrointestinal bleed and had received five units of packed red blood cells.</p> <p>On October 4, 2007, at 11 a.m., during an interview with both RNs assigned to the ICU satellite patients, they stated some of the critical care medications and equipment used in the ICU were not available on 2 East, "but we can call the ICU for help if needed." The RNs stated ICU staff cover for lunches and other breaks to ensure nurse to nurse to patient ratios are maintained.</p> <p>During an interview with the Director of ICU, on October 4, 2007, at 11:40 a.m., she stated when the ICU was full patients were placed in a satellite ICU on the second floor.</p> <p>The facility's license to operate was reviewed on October 4, 2007. The license, with an effective date of September 7, 2006, and an update in August 2007, indicated the facility was licensed</p>	A 022	<p>2. When a Medical-Surgical patient's condition changes so that the patient requires ICU level of care, the CNO/designee must assign two ICU-competent nurses to be physically present on the unit. If more than one Medical-Surgical patient requires ICU level of care while waiting for an ICU bed to become available, the CNO/designee is responsible for assigning additional ICU-competent nurses as necessary to maintain the appropriate RN-to-patient ratio related to the ICU level of care.</p> <p>3. When a bed becomes available in the ICU and patients waiting for an ICU bed are being cared for outside of the ICU, the patients' healthcare team (Medical Staff and Nursing Leadership with support from Administration) work collaboratively to assess and prioritize each patient waiting for an ICU bed. The patient with the greatest clinical priority is moved to the open ICU bed.</p> <p>4. Should there be an instance when more than one Medical-Surgical patient requires ICU level of care, the CNO/designee may have the patients moved closer together to maximize the use of nursing and equipment resources.</p> <p>5. The Director of Nurses and PI Director developed a patient tracking tool to monitor the ongoing efforts taken on behalf of the ICU patient cared for in a non-ICU setting. This tool is designed to document the ongoing assessment of the patient, the patient's clinical condition and the status of ICU bed availability.</p> <p>E. The Chief Nursing Officer/designee updated the nursing staff on the procedure for handling patients who meet criteria for an ICU bed when the ICU beds are full.</p>	06/06/08  06/06/08  06/06/08  06/10/08  06/10/08

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A 022	Continued From page 7 for 8 ICU beds and 104 unspecified general acute beds. There was no written documentation that the Department had approved converting any of the 104 general acute beds for other uses.  On October 5, 2007, at 10 a.m., during an interview with the CNO, she stated she thought they could place overflow ICU patients in the medical/surgical unit, as they were allowed to use 5% of the bed capacity for a classification other than designated on the license.  According to Title 22, Regulation 70805, spaces approved for specific uses at the time of licensure can not be converted to other uses without the written approval of the Department.	A 022	Monitoring: 1. The CNO, or designee is responsible for monitoring the situation and actions taken when there is an ICU patient being cared for in a non-ICU setting. 2. The CNO provides a monthly report to the PI/RM Committee, which is responsible for analyzing the information for any potential opportunities for improvement and for identifying follow-up action as appropriate. The report is also forwarded to the MEC monthly and to the Board of Governors quarterly.  The Hospital nevertheless respectfully disagrees that the citation describes a violation of this rule. The Hospital has a license, which is all that is required by this subsection.	06/06/08 & ongoing
A 043	<b>482.12 GOVERNING BODY</b>  The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.  This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the governing body was effective and accountable for the conduct of the hospital as an institution, by failing to ensure;  a. Adequate staff and resources were available to fulfill all managerial functions of the two hospitals (A057);  b. The development, implementation and maintenance of an effective QAPI program	A 043	A. Action Steps: The Governing Board takes its responsibility and accountability for the conduct of the Hospital as an institution very seriously. On a routine basis service line Directors, CNO, COO, and CEO all present the Governing Board with updates to advise them of current operations, proposed changes and quality/safety metrics. For example, Core Measures updates are presented to Governing Board on a bi-monthly basis along with drill-downs into specific areas for improvement and action steps to drive that improvement. The results are tracked and trended for Governing Body review/ discussion, and intervention. As a result of these activities the Core Measure results for SWHCS have demonstrated a significant improvement over the last 4 quarters.	Ongoing

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A 043	Continued From page 8 (A084)(A267)(A274)(A284)(A286)(A315)(A316);  c. Patients rights were protected and promoted when restraints were used (A156)(A158)(A165)(A168)(A169);  d. The medical staff was accountable for the quality of care provided to patients in the hospital (A347)(A500);  e. The provision of safe and effective nursing care (A386)(A394)(A397)(A398)(A404);  f. The provision of safe and effective pharmaceutical services (A500)(A505)(A507);  g. The provision of safe and effective radiological services (A284)(A529)(A537);  h. The provision of safe and effective dietary services (A619)(A622)(A628)(A630)(A631)(A726);  i. The provision of a safe and sanitary environment for patients (A749);  j. The provision of safe and effective surgical services (A284)(A537)(A749)(A951)(A1004), and;  k. The provision of safe and effective rehabilitation services (A022)(A267)(A438)(A453)(A724)(A1132).  The cumulative effect of these systemic problems resulted in the failure of the governing body to operate both campuses of the facility in a manner that was safe and effective, and met the needs of the patients.	A 043	B. Monitoring: Bi-monthly Board meetings address the effectiveness of the outcomes related to operations, quality and safety metrics.  Please see responses to A022, A057, A084, A156, A158, A165, A168, A169, A267, A274, A284, A286, A315, A316, A347, A386, A394, A397, A398, A404; A438, A453, A500, A505, A507; A529, A537, A619, A622, A628, A630, A631, A724, A726, A749, A951, A1004, and A1132	Ongoing
A 057	482.12(b) CHIEF EXECUTIVE OFFICER	A 057		

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A 057	<p>Continued From page 9</p> <p>The governing body must appoint a chief executive officer who is responsible for managing the hospital.</p> <p>This Standard is not met as evidenced by: Based on interview, the CEO failed to effectively manage the facility, by failing to ensure adequate staff and resources were available to fulfill all managerial functions of the two hospitals.</p> <p>The CEO held the department directors responsible for the activities of their departments at both campuses, with managers at each campus who reported to the directors. This resulted in a complicated line of communication of patient care issues from the staff to the directors, a break down in communication up and down the administrative chain of command, and multiple failures in provided services.</p> <p>The department directors had responsibilities beyond reasonable expectations for a single person, resulting in failure to carry out their duties adequately.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. During the survey, the Director of ER, the Director of Surgical Services, the Director of PI, and the IC Coordinator stated they had difficulties overseeing their respective services at the two hospitals.</li> <li>2. The Emergency Department was toured on October 3, 2007, at 9 a.m. During the tour, the RN Director of Emergency Services stated,</li> </ol>	A 057	<p>The CEO led reorganization of leadership/management structure to provide higher level manager/leader presence on the clinical units and in key ancillary areas. This also reduced scope-of-personnel-responsibility levels to a more manageable level that provides more clear and concise opportunities for feedback, brainstorming, problem-solving, etc. As a result of the reorganization, Managers are in place on each clinical unit to supervise and facilitate initiatives that relate to all hospital processes, including but not limited to, PI and IC processes. Additionally, Directors have been relieved of many day to day operational concerns and are more available to mentor and oversee initiatives that cross multiple departments.</p> <p>Please see more detailed responses to A263, A315, and A316.</p> <p>The Hospital has a new CEO.</p> <p>Monitoring: Effectiveness of leadership structure will be demonstrated by the annual employee engagement survey, which is completed in late May to early June by the Gallup Corporation. This survey provides specific information on a department by department basis of the employees' perception of the organization's success in the following areas:</p> <ol style="list-style-type: none"> <li>1. I know what's expected of me at work</li> </ol>	<p>01/15/08</p> <p>03/18/08</p> <p>Early June 2008 &amp; Annually</p>

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A 057	<p>Continued From page 10</p> <p>although she was a 40 hour a week employee, in order to keep up with the work her usual work hours were 7 a.m. to 8 p.m. every day, and that it was difficult to manage departments at two campuses.</p> <p>3. During a tour of the Surgical Suite of RSMC on October 2, 2007, at 2:30 p.m., the Director of Surgical Services stated, although she was a 40 hour a week employee, in order to keep up with the work, her work hours were close to 12 hours a day. She stated she was not able to perform all of her duties unless she worked the extra hours.</p> <p>4. The Director of PI was interviewed on October 5, 2007, at 10:07 a.m. She stated she was responsible for the PI activities at the RSMC and IVMC campuses. When asked about covering all PI activities at both hospitals, she stated she "saw a gap in the process." She stated it was difficult to keep up with two hospitals, and she had so much to do, she could only get the top priorities done. The PI Director stated she was able to get the required data collected and entered, and attend meetings, but she did not have time to get out to the floors in the facilities and network with the staff to determine if there were QAPI issues that needed to be addressed.</p> <p>5. The IC staff (consisting of the CNO and the ICC), was interviewed on October 5, 2007, at 1:12 p.m. During the interview, the ICC stated she made daily rounds, attended construction rounds and meetings, and called for corrective action when needed at IVMC, but not at RSMC. The ICC stated the IC activities at RSMC consisted of review of culture results. The CNO stated they used to have two IC employees, but one left the facility, and they had not replaced that position. The CNO stated there was no way one</p>	A 057	<p>2. I have the materials and equipment to get the job done</p> <p>3. I have the opportunity to do my best</p> <p>4. I am recognized for good work</p> <p>5. My manager cares about me</p> <p>6. There is someone who encourages my development</p> <p>7. At work my opinion seems to count</p> <p>8. The mission or purpose of my organization makes me feel my job is important</p> <p>9. My fellow employees are committed to doing quality work</p> <p>10. I have a best friend at work</p> <p>11. In the last 6 months someone has talked to me about my progress</p> <p>12. This past year I have had opportunities at work to learn and grow</p> <p>The Hospital nevertheless respectfully disagrees that the citation describes a violation of this rule. Section 482.12(b) requires the governing body to appoint a single CEO and delegate to that CEO the responsibility for managing the Hospital. Because the Hospital's governing body has appointed and single CEO and given the CEO the responsibility to manage the hospital, this requirement was met.</p>	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>		
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A 057	Continued From page 11 person could do complete surveillance at both campuses, so the IC Coordinator was doing, "only the essentials," at RSMC.	A 057			
A 084	482.12(e)(1) CONTRACTED SERVICES  The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.  This Standard is not met as evidenced by: Based on observation, interview and record review, the governing body failed to ensure that nuclear medicine, laboratory, and dialysis services performed under a contract were undergoing the same QAPI process as other hospital services, resulting in the potential for these services to become unsafe and ineffective.  Findings:  1. The Nuclear Medicine service area of RSMC was toured on October 4, 2007 at 10:15 a.m. The area where radio nuclides (substance used for specialized radiology testing) were stored was inspected. At that time, the technician stated that the radio nuclides were supplied and discarded through a contract with Cardinal Health. The NMT was questioned regarding QA of the service provided by Cardinal Health. The NMT stated the doses of radio nuclide were tested, by Cardinal Health, for activity level at each of the two hospitals. She stated complete QA was	A 084	1. CARDINAL HEALTH A. Administration requested and received a letter from Cardinal Health on the date of the survey and provided it to the surveyor. The letter outlines the quality control procedures in place at the Cardinal Health nuclear pharmacy. These quality control procedures included sterility procedures, purity testing, and instrumentation quality control.  B. The Director of Imaging collaborated with representatives from Cardinal Health including the Pharmacy Manager (Colton, CA) and the Regional Zone Director to develop an acceptable plan for Cardinal Health to provide the hospital with quality control information on an ongoing basis.  C. The Cardinal Health Regional Zone Director also met with the representatives from DPH to review requirements as stated in 42 CFR §482.12 (e).  D. On an annual basis, Cardinal Health provides the hospital with a letter regarding ongoing quality assurance efforts along with copies of the following: a. California Board of Pharmacy Inspection Reports b. Retail Pharmacy Permit c. Sterile Compounding Permit d. DPH inspection report for radioactive materials license e. Radiochemical purity testing requirements	10/05/07  Beginning 11/2007 and ongoing.  05/2008  06/09/08	

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A084	Continued From page 12	A084	<p>Continued from page 12 of 174</p> <p>E. The Director of Imaging Services is responsible for reviewing the annual report received from Cardinal Health and presenting it for discussion at the Department of Imaging for analysis, action planning and follow-up as appropriate.</p> <p>2. MAYO CLINIC A. The Director of Laboratory requested quality reports to be provided on a monthly basis by Mayo Medical Laboratories. This report will contain specific quality metrics, the call log and matrices illustrating the external proficiency testing results for Mayo Medical Laboratories.</p> <p>(Plan of Correction continues on page 13).</p>	<p>06/09/08 &amp; ongoing</p> <p>04/02/08</p>

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A 084	<p>Continued From page 12 performed by Cardinal and supplied a copy of the agreement showing Cardinal's QA policy. No evidence of a review of Cardinal's QA as part of the hospital's QA process could be provided.</p> <p>The Director of PI was interviewed on October 4, 2007 at 12 p.m. She stated that Cardinal provided a licensed service and was responsible for their own QA, and that the hospital's QAPI program did not receive or review this information.</p> <p>2. The Laboratory at RSMC was toured on October 5, 2007 at 9 a.m. The Director of Clinical Laboratory Services was questioned regarding QAPI activities for contracted laboratory services. She stated that although histology (preparation of microscopic slides) was performed at University of California, Irvine, the QAPI was done at the two hospitals. However, certain specimens were sent to the Mayo Clinic laboratory for analysis, and QAPI data was not being forwarded to the two hospitals.</p> <p>3. During a tour of the ICU at RSMC on October 2, 2007, at 10:32 a.m., an RN was observed in ICU room 3 performing dialysis on a patient. The RN was asked to explain the process he went through when arriving at the hospital to dialyze a patient. The RN stated he signed in at the nurses station and got the key to the storage area where the dialysis machine was kept. The RN stated he did not tell the nursing supervisor he was in the facility, did not show his nursing license to anybody, and had never had his performance evaluated by the facility staff.</p> <p>During an interview with the ICU Director at IVMC on October 4, 2007, at 8:35 a.m., the Director stated the facility had a contract with a dialysis company named Davita. The Director stated the</p>	A 084	<p>B. The Director of Laboratory is responsible for reporting on Mayo Medical Laboratories' services through the monthly Hospital Department of Laboratory committee. Any and all QA issues identified will be discussed at the Hospital Department of Laboratory meetings and solutions to these issues will be worked on and documented in meeting minutes.</p> <p>3. DAVITA DIALYSIS SERVICES The Director of Resource Management met with Davita Dialysis Services representatives to clarify expectations of contracted staff.</p> <p>The Director of Resource Management placed competency binders in each House Supervisor Office for competency/license/certification validation of contracted staff.</p> <p>The Director of Resource Management established a new process that addresses tracking/signing in of contracted staff, maintenance and verification of licensure, certifications and competencies. New process establishes ability to provide annual performance evaluations on contracted staff. The process is as follows: a. A binder is kept in the House Supervisor's office at each site containing copies of licenses, certifications and competencies of all dialysis nurses employed by Davita that come to the Hospital to provide dialysis for patients.</p>	04/02/08 & Ongoing  02/28/08  03/07/08  04/02/08

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A 084	<p>Continued From page 13</p> <p>agreement with Davita was to have the nurse's licenses and competencies intact. The Director stated she had never checked the licenses or competencies of the dialysis nurses that came to either facility.</p> <p>During an interview with the HS at IVMC on October 4, 2007, the HS stated every time a registry nurse went to either facility, they had to report to the nursing office to check in. The HS stated if the registry nurse was at the facility for the first time, the HS was responsible for looking at the nurse's credentials, reviewing the competency packet provided by the registry, and verifying the nurse's license on line. The HS stated the performance of every registry nurse was evaluated at the end of every shift by facility staff. The HS stated the dialysis nurses did not check into the nursing office, so the HS on duty was not involved in reviewing their competencies, checking their license, or evaluating their performance. The HS stated she did not know what process the dialysis nurses followed. The HS stated there was no mechanism for the HS on duty to know when a dialysis nurse was in the facility providing care to a patient.</p> <p>During an interview with the CNO at IVMC on October 5, 2007, at 1 p.m., the CNO stated the dialysis nurses came to the facility, accessed the dialysis equipment located in their equipment closet, reported to the floor where they would be doing dialysis, checked the physician's order, and performed the dialysis treatment. The CNO stated the facility did not check the dialysis nurse's licenses or competencies, or evaluate their performance. The CNO agreed the dialysis nurses were under a contract like the registry nurses. The CNO stated she never thought about monitoring the dialysis nurses like she did</p>	A 084	<p>b. A binder of Davita's Policy and Procedures is kept in the House Supervisor's office at each site.</p> <p>c. The dialysis nurse must check in with the House Supervisor when he/she arrives and sign in the log book in the office.</p> <p>d. The House Supervisor must obtain an online verification of the dialysis nurse's license each time the dialysis nurse comes to the Hospital and confirm the presence of current competencies and evaluation.</p> <p>e. The primary nurse or the charge nurse will complete an evaluation of the dialysis nurse annually.</p> <p>f. The nursing staff, Davita manager, and House Supervisors were educated on this process.</p> <p>The Director of Resource Management sent facility orientation manuals to Davita Dialysis Services with new process instructions.</p> <p>The Director of Resource Management or designee is responsible for conducting an annual audit of Davita beginning June 2008, including verifying business license, proof of insurance, employee files for competencies, orientation, HIPAA compliance, annual physical, and required licensure and certifications.</p> <p>The Director of Resource Management is responsible for reporting on services provided by Davita Dialysis Services to Performance Improvement/Risk Management Committee.</p>	04/08/08  04/08/08 & Ongoing  04/08/08 & Ongoing

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A 084	Continued From page 14 the registry nurses, then stated, "we certainly can."	A 084		
A 115	482.13 PATIENT RIGHTS  A hospital must protect and promote the rights of each patient.  This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure patients were allowed to exercise their right to be free from unnecessary physical and chemical restraints, by failing to:  a. Ensure patients were free from restraints as a means of staff convenience (A156);  b. Ensure restraints were discontinued at the earliest possible time (A158);  c. Ensure the least restrictive restraint was used to protect the patient and others from harm (A165);  d. Ensure there were written physician's orders for restraints used on patients (A168);  e. Ensure orders for the use of restraints were not written on an as needed basis (A169).  The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the protection and promotion of each patient's rights while in the hospital.	A 115	See corrective actions under Tags A156, A158, A165, A168, and A169.	
A 156	482.13(e) PATIENT RIGHTS: RESTRAINT OR SECLUSION	A 156		

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A 156	Continued From page 15  All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.  This Standard is not met as evidenced by: Based on observation, interview and record review, the hospital failed to ensure nine of 15 sampled patients in physical restraints (Patients 208, 213, 214, 210, 215, 201, 205, 207, and 402) were free from restraints as a means of staff convenience, resulting in the inappropriate use of restraints and violation of the rights of the patients.  Findings:  The hospital's Policy and Procedure dated 4/06, titled, "Restraints, Application of safety and behavior restraints," indicated a restraint could be used if needed to improve the patient's well-being, patient rights and dignity would be respected and maintained during restraint use, and restraints would not be used as a means of coercion, discipline, convenience or retaliation by staff.  1. On October 3, 2007, at 9 a.m., Patient 208 was observed in her hospital room at RSMC, sitting in a chair next to her bed.  Record review for Patient 208 was conducted on October 3, 2007, at 9:15 a.m. The patient was	A 158	The Chief Nursing Officer reviewed and reinforced education on the current restraint policy and directed that the House Supervisors and the Charge Nurses include discussion of any restrained patients (including reason, alternatives attempted, type of restraint, length of time in restraints) at daily patient care rounds at 0830 and 2030 at each hospital.  The Chief Nursing Officer reviewed and revised restraint policy and procedure to add instructions about the use of medications and chemical restraints, as well as to enhance the section describing alternatives to restraint that have been tried before imposing restraints. The restraint policy and procedure revisions were approved on 04/9/08  The Education Department conducted staff education, emphasizing the requirement of assessing and trying less restrictive alternatives before imposing restraints, of using types of restraint that are the least restrictive intervention possible, of obtaining a physician's order for every restraint, and of discontinuing restraints at the earliest time possible.  The Chief Nursing Officer is providing physician education on the restraint policy at every Medical Staff Department meeting during the 2nd quarter 2008, with attention to the criteria for ordering the least restrictive intervention possible after other less restrictive alternatives had been tried, to the prohibition on	12/15/08 07 OK to change per TJC Michele Burns, DNS & Pam Diven, PI 11/3/08 10:38 AM 04/09/08 04/30/08 05/30/08

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A 156	<p>Continued From page 16</p> <p>admitted to the hospital through the emergency room on September 30, 2007, after falling at home. The nursing Admission Data Base dated October 1, 2007, at 12:50 a.m., stated, "N/V, fell at home, had laceration, forehead, hematoma R knee, dizziness."</p> <p>On October 1, 2007, at 8:40 a.m., a nurse documented, "Pt. confused. Pulled foley cath out..." At 10 a.m., the licensed nurse documented, "...Posey vest placed. Pt. unstable on feet and confused. Attempts to get OOB." At 10:30 p.m., a nurse documented, "Called physician, pt. with periods of confusion, trying to get out of bed with order may put posey vest. Posey vest applied also by a.m. nurse for safety."</p> <p>On the restraint order form dated October 1, 2007, at 10:30 a.m., a licensed nurse check marked under Observed Behaviors, Memory Deficit, Disorientation and Agitation/Combative Behavior. Under Alternatives/interventions attempted or considered today, a licensed nurse check marked, Companionship: Family, friend or volunteer at bedside, educate re: clinical condition. Supervision: Increased nursing rounds, monitor call-light / mark for quick response. Change or eliminate offending medications or bothersome treatments....</p> <p>There was no documented evidence in the record that companionship was provided, increased nursing rounds were provided or an assessment was conducted for a bothersome treatment such as a foley catheter, in an effort to keep from restraining the patient.</p> <p>On October 2, 2007, at 8:30 a.m., a nurse documented, "Pt. A/Ox3. Placed in chair for ...with posey." At 7:30 p.m., a nurse documented,</p>	A 156	<p>ordering restraints PRN, and to the requirement to sign telephone orders within 24 hours. Additionally, the Chief Nursing Officer is sending education information on the restraint policy to each physician office during April-May 2008.</p> <p>Monitoring: The PI Director is responsible for auditing 100% of restraint episodes to check for compliance with the restraint policy.</p> <p>The PI Director and CNO are responsible for reporting trends and variances from restraint policy to P/IRM monthly as indicated.</p> <p>The Hospital nevertheless respectfully disagrees with these citations. The Medicare rule states that a "restraint does not include devices...to protect the patient from falling out of bed..." 42 CFR § 482.13(e)(1)(C). Because there was documentation in the medical records that the cited patients were confused and trying to get out of bed, and the devices were ordered to prevent them from getting out of bed and falling, they do not constitute "restraints" that are covered by this rule.</p>	<p>October 2007 and ongoing</p> <p>05/08 &amp; ongoing</p>

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A 156	<p>Continued From page 17</p> <p>"Received patient alert, oriented to room and place with periods of confusion...with posey vest on..."</p> <p>On the restraint order form, dated October 2, 2007, at 10:10 a.m., a licensed nurse check marked under Observed Behaviors, Memory Deficit, Disorientation. Under Alternatives/interventions attempted or considered today, a licensed nurse check marked, Supervision: Increased nursing rounds, monitor call-light / mark for quick response.</p> <p>There was no documented evidence at 8:30 a.m., that Patient 208 had a need for a vest restraint when she was alert and oriented and there was no documented evidence that nursing rounds were increased, in an effort to keep from restraining the patient.</p> <p>On October 3, 2007, at 10:05 a.m., the director of the unit stated, "We need to document more. The documentation is not showing a good enough picture."</p> <p>2. A closed record review for Patient 213 was conducted at IVMC on October 4, 2007. The patient was admitted on September 25, 2007, with complaints of weakness, and dementia. At 7:30 p.m., a licensed nurse documented, "Physician sees Pt. Pt. up walking around room. Encouraged to lay in bed while physician will do examination. Cooperative/exam performed per MD." At 8:40 p.m., a licensed nurse documented, "Pt. increased confusion-called physician-orders received." At 8:45 p.m., a licensed nurse documented, "Posey vest applied.....side rails up x 2..."</p> <p>A review of the restraint order form dated</p>	A 156		

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A 156	<p>Continued From page 18</p> <p>September 25, 2007, showed under Observed Behaviors, a licensed nurse check marked, Memory Deficit, Disorientation and Unable to follow instructions. Under Alternatives/interventions attempted or considered today, a licensed nurse check marked, Supervision: Increased nursing rounds, monitor call-light / mark for quick response. Modify Environment: Lighting, noise, room assignment, bedside commode, call light. Reality Orientation / Psychosocial Interventions: Involve in conversations, convey sense of calm, explain procedures, relaxation techniques, verbally redirect behavior. Diversion / Physical Activity: TV, radio, music, ambulation, involve patient in ADLs.</p> <p>On September 25, 2007, 11 p.m., a nurse documented the patient had a posey vest in place for patient safety, however there was no documented evidence that the patient was unsafe while ambulating around the room. It was unclear why the posey vest was needed.</p> <p>A review of the restraint order form dated September 26, 2007, at 8 a.m., showed, under Observed Behaviors, a licensed nurse check marked, Memory Deficit, Disorientation, agitated and unable to follow instructions. Under Alternatives/interventions attempted or considered today, a licensed nurse check marked, Supervision: Increased nursing rounds, monitor call-light / mark for quick response. Modify Environment: Lighting, noise, room assignment, bedside commode, call light. Reality Orientation / Psychosocial Interventions: Involve in conversations, convey sense of calm, explain procedures, relaxation techniques, verbally redirect behavior. Diversion / Physical Activity: TV, radio, music, ambulation, involve patient in</p>	A 156		

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Printed: 03/13/2008  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 156	<p>Continued From page 19 ADLs.</p> <p>There was no documented evidence that the patient was agitated or unable to follow instructions, increased nursing rounds were provided, the environment was modified, reality orientation / psychosocial interventions were provided or the patient received diversion / physical activity, in an effort to keep from restraining the patient.</p> <p>On September 27, 2007, at 7:50 a.m., a licensed nurse documented the patient was alert, confused, and a Posey vest was on for safety.</p> <p>A review of the restraint order form dated September 27, 2007 at 8 a.m., showed, under Observed Behaviors, a licensed nurse check marked, Memory Deficit, Disorientation, unable to follow instructions and disoriented, danger to self, unsteady. Under Alternatives/interventions attempted or considered today, a licensed nurse check marked, Companionship: Family, friend or volunteer at bedside, education re: clinical condition. Modify Environment: Lighting, noise, room assignment, bedside commode, call light. Reality Orientation / Psychosocial Interventions: Involve in conversations, convey sense of calm, explain procedures, relaxation techniques, verbally redirect behavior. Diversion / Physical Activity: TV, radio, music, ambulation, involve patient in ADLs. Creative alternatives: frequent reorientation to person place, time.</p> <p>There was no documented evidence that the patient was a danger to self or unsteady, or that companionship, a modified environment, reality orientation, diversion or creative alternatives were provided. It was unclear why the posey vest was needed, in an effort to keep from restraining the</p>	A 156		

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A 156	<p>Continued From page 20 patient.</p> <p>3. On October 4, 2007, at 2:30 p.m., an interview was conducted with Patient 214's spouse at IVMC. The spouse stated, "Nobody talks to me about too much."</p> <p>The patient was observed laying flat in bed, bilateral wrist restraints on and bilateral side rails up. The patient was observed with eyes closed and snoring.</p> <p>At 2 :40 p.m., a record review for Patient 214 was conducted. The patient was an 81 year old admitted to the hospital on September 27, 2007, from home.</p> <p>A review of the patient's record was conducted. A licensed nurse documented that Patient 214, had orders for wrist restraints from September 28, 2007 through October 4, 2007.</p> <p>On September 28, 2007, the physician ordered ativan 0.5 mg, IV to be given every four hours when needed for agitation. On September 29, 2007 the physician wrote orders to discontinue ativan and ordered haldol 2 mg IV to be given every 4 hours when needed for agitation.</p> <p>There was no documented evidence in the record that the, "Alternatives / interventions attempted or considered today," were provided by hospital staff. And there was no documented evidence that Patient 214 needed wrist restraints while he was asleep. It was unclear why the chemical and physical restraints were needed for this patient.</p> <p>On October 4, 2007 at 3:35 p.m., an interview was conducted with the director of the telemetry unit. When asked about the physician's orders</p>	A 156		

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A 156	<p>Continued From page 21 for bilateral wrist restraints and haldol 0.5 mg., the director did not offer an explanation.</p> <p>4. The record of Patient 210, a closed record was reviewed at IVMC on October 4, 2007. Patient 210 was admitted to the hospital on September 22, 2007, due to seizures and an altered level of consciousness. Due to another seizure in the ER, the patient was intubated and placed on a ventilator. By September 23, 2007, at 9 a.m., Patient 210 extubated herself (removed the airway tube) and was placed on oxygen at 2 liters per minute via nasal cannula. Throughout the notes the patient was identified as agitated, confused and not following instructions.</p> <p>On September 28, 2007, at 2 p.m., Patient 210 was transferred to the medical floor. There was a restraint order sheet dated September 28, 2007. The physician signed the order sheet, with no type of restraints checked. On September 28, 2007, at 10 a.m., a nurse documented, "Patient out of bed, placed in bed, patient anxious about wrist restraints." At 2 p.m., a nurse documented, "Patient in room with sitter and posey vest." At 9 p.m., a nurse documented, "Patient pulling at posey attempting to get out of bed." There was no evidence of the patient being unsafe when getting out of bed. It was unclear why the restraints were needed. There was no evidence of an attempt to remove the posey vest when the sitter was present.</p> <p>On October 4, 2007, at 2:45 p.m., the Unit Director for 2 East was interviewed. The director stated, "Without knowing the situation, it looked like the staff was just trying to keep her safe."</p> <p>5. Patient 215 was admitted to the hospital on September 29, 2007, with diagnoses that</p>	A 156		

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A 156	<p>Continued From page 22</p> <p>included hypertension and urinary tract infection. There were orders for a vest and wrist restraints (right &amp; left).</p> <p>During the tour of the unit on October 4, 2007, at 2:50 p.m., Patient 215 was observed in bed with the head of the bed elevated. The patient's eyes were closed, and had the vest and both wrist restraints on. The wrist restraints were not tied, as the patient was receiving passive range of motion to the lower extremities.</p> <p>There was a physician's order dated October 3, 2007, at 9:10 p.m., for "Benadryl 12.5mg (antihistamine) IVP times 1 now, may repeat every 4 hours 1 time only." A review of the nurses note dated October 3, 2007, at 8:30 p.m., indicated, "Instructed patient not to get out of bed because she may fall &amp; injure herself. Patient appears agitated as manifested by her instant attempts to sit up and head to the edge of the bed. Dr. notified and ordered Benadryl 12.5mg IV times one now and may repeat in 4 hours times one only." There was no evidence that the patient was unsafe when getting out of bed. It was unclear why the restraints were needed.</p> <p>On October 4, 2007, at 3:40 p.m., the Unit Director for 2 East, was interviewed. The Director reviewed the record and stated, "I do not know why the doctor ordered the Benadryl, since there was an order for restraints."</p> <p>6. On October 2, 2007, at 10:15 a.m., during a tour of the medical surgical unit at RSMC, Patient 201 was observed in bed. The head of the bed was up and the patient was observed with a vest restraint on and all 4 side rails up. During this tour, the unit charge nurse was asked about the vest restraint and 4 bed rails, and stated, "She is confused and tries to get out of bed."</p>	A 156		

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A 156	Continued From page 23  The record for Patient 201 was reviewed on October 2, 2007. The patient was admitted to the hospital on September 28, 2007, with diagnoses that included pneumonia, cardiomyopathy, and congestive heart failure. The nursing section of the restraint order form indicated the patient had a memory deficit, disorientation and agitated/combative behavior. In the section titled "Clinical justification for and intent of restraint", the nurse checked, "I have reviewed and concur with the nursing assessment. Restraints are indicated for the patient's safety." For the type of restraint, 4 side rails, soft limb restraints (left & right), and vest were all checked off." As of the review of the record, the physician had not signed the orders.  There was another restraint order sheet dated October 1, 2007, at 11:30 a.m., with an order for a vest, both wrist restraints and 4 side rails. The order was still not signed by the physician as of October 2, 2007, at 10:45 a.m. There was no documentation of an assessment by nursing addressing the use of these restraints, or other less restrictive methods that would prevent injury.  On October 2, 2007, at 10:31 a.m., the RM was interviewed. The RM stated, "The orders are to be signed by the physician within a 24 hour period. I will get the nurse to call the doctor now."  7. The record for Patient 205 was reviewed at RSMC on October 2, 2007. Patient 205 was admitted on September 28, 2007, with diagnoses that included dehydration, failure to thrive, and a 50 pound weight loss in two months. The patient was receiving nutrition via a gastrostomy tube during the night and was assisted with a regular texture diet during the day. The restraint	A 156		

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A 156	<p>Continued From page 24</p> <p>assessment and order sheet dated September 30, 2007, at 7:39 p.m., indicated Patient 205 was forgetful. The physician checked the box indicating he "reviewed and concurred with the nursing assessment. Restraints are indicated to prevent the disruption of necessary patient treatment and for the patient's safety." The type of restraint was a vest. Again on October 1, 2007, at 10:35 a.m., the observed behavior was "Memory deficit, disorientation and forgetful." The area of the vest restraint was checked, due to the "prevention of the disruption of necessary patient treatment and for patient safety." There was no indication in the record the patient was unsafe, or what assessment led to the decision to use a vest restraint vs. siderails.</p> <p>On October 3, 2007, at 9:10 a.m., a visit was made to the patient's room. The patient was noted to have the head of the bed elevated, with a vest restraint on and all 4 side rails were in the up position. The unit manager was interviewed during the tour and stated, "The side rails are used to keep him safe or from crawling out of bed."</p> <p>8. Patient 207 was admitted on September 29, 2007. Record review on October 3, 2007, indicated the patient had dementia, and congestive heart failure.</p> <p>On October 3, 2007, at 10:20 a.m., the patient was observed in bed with 4 side rails in the up position and the vest restraint in place.</p> <p>The nurse's note dated September 29, 2007, at 9 p.m., indicated, "Admitted patient from ER, awake and confused. Reoriented patient to his room, on tele and vital signs done. Will continue to monitor." At 10:15 p.m., "Patient trying to pull out</p>	A 156		

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A 156	<p>Continued From page 25</p> <p>IV &amp; Foley catheter, patient confused. Paged doctor."At 10:23 p.m., "Dr. called back and he ordered restraints." The nurse's section of the restraint order sheet dated September 29, 2007, had check marks on, "Memory deficit, disorientation and unable to follow directions." The form was not signed, timed or dated by the nurse. In the order section, there were check marks under, "I have reviewed and concur with the nursing assessment. Restraints are indicated to prevent the disruption of necessary patient care and for patient safety." Checked on this section of the order sheet was, "4 side rails, soft limb restraints (right and left) and vest restraint." There was a telephone order dated September 29, 2007, at 10:23 p.m., "Haldol 2 mg (antipsychotic) IV every 6 hours PRN (as needed) for agitation." There was no documentation in the record by staff of the assessment for the use of three restraints (wrist, 4 side rails &amp; vest), including the medication (Haldol). There was no assessment addressing the attempts to use less restrictive devices prior to placing the patient in three different restraints.</p> <p>On October 3, 2007, at 10:10 a.m., the risk manager was interviewed. The Manager reviewed the record for Patient 207 and stated, "They did not use the Haldol. I see in the record the staff did place a 1:1 staff person outside the room."</p> <p>9. The record for Patient 402 was reviewed at RSMC on October 2, 2007. The nurse's notes dated September 24, 2007, at 9 p.m., stated, "Patient climbed out of bed and was unsteady on her feet walking to the bathroom. Assistance given in this activity. At her families request, a posey vest was applied because they said that she will forget to call for help and fell last time she was here. Dr. was informed of this. He ordered</p>	A 156		

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A 156	<p>Continued From page 26</p> <p>for a posey vest to be used." The record showed daily physician's orders for a vest and bilateral limb restraints due to agitated behavior and disorientation.</p> <p>The nurse's notes, starting September 24, 2007, to the date of survey, indicated the restraints were removed when the husband was at the bedside, and reapplied when he left. The nurse's notes indicated the patient's behavior with the husband present and the restraints off was, "cooperative."</p> <p>During an interview with the medical surgical unit CN on October 3, 3007, at 11:22 a.m., the CN stated the reason for the restraints was confusion and attempts to get out of bed when unsteady. The CN stated Patient 402 was not restrained when her husband was with her.</p> <p>Resident 402 was observed laying in bed on October 3, 2007, at 11:25 a.m. The patient was calm, awake and alert. The PT was at the bedside attempting to get the patient up for assistance with ambulation. The Patient was refusing to get out of bed, stating she would do it later.</p> <p>The patient's husband was interviewed at that time, and he stated he wanted the patient to be restrained so she wouldn't get out of bed and fall. The husband stated she was calm while he was there, but he didn't trust her to stay in bed when he wasn't there to watch her.</p> <p>There was no evidence in the record that the facility attempted means to keep the patient safe other than restraining her, when it was evident she was calm when another person was in the room with her.</p>	A 156		
A 158	482.13(e) PATIENT RIGHTS: RESTRAINT OR	A 158		

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A 158	<p>Continued From page 27 <b>SECLUSION</b></p> <p>Restraint or seclusion must be discontinued at the earliest possible time.</p> <p>This Standard is not met as evidenced by: Based on observations, interviews and record reviews, the hospital failed to ensure restraints were discontinued at the earliest possible time for seven of 15 sampled patients in restraints (Patients 213, 214, 215, 415, 417, 402, and 418), resulting in the potential for patients to be restrained longer than clinically indicated.</p> <p>Findings:</p> <p>1. On October 4, 2007, a closed record for Patient 213 was reviewed at IVMC. The patient was admitted to the facility on September 25, 2007, with complaints of weakness, and dementia.</p> <p>A licensed nurse documented on September 25, 2007, through September 27, 2007, the patient had a Posey vest in place. There was no documented evidence the licensed nurse made attempts to end the use of restraints at the earliest possible time.</p> <p>2. On October 4, 2007, at 2:30 p.m., an interview was conducted with Patient 214's spouse at IVMC. The spouse stated, "Nobody talks to me about too much."</p> <p>The patient was observed laying flat in bed, with bilateral wrist restraints on and bilateral side rails</p>	A 158	<p>The Chief Nursing Officer reviewed and reinforced education on the current restraint policy and directed that the House Supervisors and the Charge Nurses include discussion of any restrained patients (including reason, alternatives attempted, type of restraint, length of time in restraints) at daily patient care rounds at 0830 and 2030 at each hospital.</p> <p>The Chief Nursing Officer reviewed and revised restraint policy and procedure to add instructions about the use of medications and chemical restraints, as well as to enhance the section describing alternatives to restraint that have been tried before imposing restraints. The restraint policy and procedure revisions were approved on 04/9/08</p> <p>The Education Department conducted staff education, emphasizing the requirement of assessing and trying less restrictive alternatives before imposing restraints, of using types of restraint that are the least restrictive intervention possible, of obtaining a physician's order for every restraint, and of discontinuing restraints at the earliest time possible.</p> <p>The Chief Nursing Officer is providing physician education on the restraint policy at every Medical Staff Department meeting during the 2nd quarter 2008, with attention to the criteria for ordering the least restrictive intervention possible after other less restrictive alternatives had been tried, to the prohibition on</p>	<p>12/15/08 6/13/08 10:38 AM OK TO CHANGE PER TLC E M... P... DNS - P... Div... 01 6-13-08 10:38 AM Ⓟ</p> <p>04/09/08</p> <p>04/30/08</p> <p>05/30/08</p>

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A 158	<p>Continued From page 28</p> <p>up. The patient was observed with his eyes closed and snoring.</p> <p>At 2:40 p.m., a record review for Patient 214 was conducted. The patient was an 81 year old admitted to the hospital on September 27, 2007, from home.</p> <p>A review of the patient's record was conducted. A licensed nurse documented Patient 214 had orders for wrist restraints from September 28, 2007 through October 4, 2007.</p> <p>On September 28, 2007, the physician ordered ativan 0.5 mg, IV to be given every four hours when needed for agitation. On September 29, 2007 the physician wrote orders to discontinue ativan and ordered haldol 2 mg IV to be given every 4 hours when needed for agitation.</p> <p>There was no documented evidence in the nurse's notes that the "Alternatives / interventions attempted or considered today" were provided by hospital staff. And there was no documented evidence that Patient 214 needed wrist restraints while he was asleep, but the restraints were not discontinued.</p> <p>On October 4, 2007 at 3:35 p.m., an interview was conducted with the director of the telemetry unit. When asked if there was documented evidence that the hospital made attempts to end the use of restraints at the earliest possible time, the director was unable to provide further information.</p> <p>3. During a tour of the 2 East at IVMC, on October 4, 2007, at 2:50 p.m., Patient 215 was observed in bed asleep. The head of the bed was elevated and the patient had a posey vest on and</p>	A 158	<p>ordering restraints PRN, and to the requirement to sign telephone orders within 24 hours. Additionally, the Chief Nursing Officer is sending education information on the restraint policy to each physician office during April-May 2008.</p> <p>Monitoring: The PI Director is responsible for auditing 100% of restraint episodes to check for compliance with the restraint policy.</p> <p>The PI Director and CNO are responsible for reporting trends and variances from restraint policy to PI/RM monthly as indicated.</p> <p>The Hospital nevertheless respectfully disagrees with these citations. The Medicare rule states that a "restraint does not include devices...to protect the patient from falling out of bed..." 42 CFR § 482.13(e)(1)(C). Because there was documentation in the medical records that the cited patients were confused and trying to get out of bed, and the devices were ordered to prevent them from getting out of bed and falling, they do not constitute "restraints" that are covered by this rule.</p>	<p>October 2007 and ongoing</p> <p>05/08 &amp; ongoing</p>

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A 158	<p>Continued From page 29</p> <p>wrist restraints (untied) on both wrists. The PT was providing passive range of motion to the patient.</p> <p>A review of the record for Patient 215 was done on October 4, 2007. Patient 215 was admitted to the hospital on September 29, 2007, with diagnoses that included hypertension and urinary tract infection. The restraint order form dated October 3, 2007, had orders for wrist restraints (left &amp; right) and vest, due to patients inability to follow directions. There was a physician's order dated October 3, 2007, at 9:10 p.m. for, "Benadryl 12.5mg (antihistamine) IVP times one now and repeat every 4 hours times one only." The nurse's progress note dated October 3, 2007, at 8:30 p.m. indicated, "Instructed patient not to get out of bed because she may fall and injure herself. Patient appeared agitated manifested by her instant attempts to sit up and head to the edge of the bed. Dr. notified and ordered benadryl 12.5mg IV times one and repeat times one only. .... Patient is incontinent of urine and on air mattress. Two point soft restraints and posey are on for patient's safety. Patient less agitated after benadryl 12.5mg IV given., but remains still a little restless. Restraints and posey remain for patient safety."</p> <p>There was no documentation in the record the staff attempted to discontinue the use of restraints.</p> <p>4. The record for Patient 415 was reviewed at RSMC on October 3, 2007. The restraint order forms dated June 23, 27, and 30, and July 1, 6, 13, and 14, 2007, did not include when the restraints could be discontinued. There was no indication that, on these dates, the staff was observing for a change in the patient's status that would lead to the discontinuation of restraints.</p>	A 158			

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A 158	Continued From page 30  5. The record for Patient 417 was reviewed on October 3, 2007, at RSMC. The restraint order forms dated July 14, 15, 16, and 17, 2007, did not include when the restraints could be discontinued. There was no indication that, on these dates, the staff was observing for a change in the patient's status that would lead to the discontinuation of restraints.  6. The record for Patient 402 was reviewed on October 2, 2007, at RSMC. The restraint order forms dated September 25, 26, and 29, 2007, did not include when the restraints could be discontinued. There was no indication that, on these dates, the staff was observing for a change in the patient's status that would lead to the discontinuation of restraints.  7. The record for Patient 418 was reviewed on October 4, 2007, at IVMC. The restraint order forms dated September 12, 16, 17, and 18, 2007, did not include when the restraints could be discontinued. There was no indication that, on these dates, the staff was observing for a change in the patient's status that would lead to the discontinuation of restraints.	A 158		
A 165	482.13(e)(3) PATIENT RIGHTS: RESTRAINT OR SECLUSION  The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.	A 165	The Chief Nursing Officer reviewed and reinforced education on the current	12/15/08 07

6/13/08  
1038AA  
①

OK to change per Tlc &  
Melissa Burns, DNS &  
Pam Diven, PI

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A 165	<p>Continued From page 31</p> <p>This Standard is not met as evidenced by: Based on observation, interview and record review, the hospital failed to ensure the use of the least restrictive type of restraining device needed to protect the patient or others from harm for six of 15 sampled patients in restraints (Patients 213, 214, 402, 415, 417, and 418), resulting in the potential for patients to be restrained more than clinically indicated.</p> <p>Findings at IVMC:</p> <p>1. A closed record review for Patient 213 was conducted on October 4, 2007. The patient was admitted on September 25, 2007, with complaints of weakness, and dementia. At 7:30 p.m., a licensed nurse documented, "Physician sees Pt. Pt. up walking around room. Encouraged to lay in bed while physician will do examination. Cooperative/exam perform per MD. At 8:40 p.m., the licensed nurse documented, "Pt. increased confusion-called physician-orders received. At 8:45 p.m., the licensed nurse documented, "Posey vest applied.....side rails up x 2..."</p> <p>On the restraint order form dated September 24, 2007, under Observed Behaviors, the licensed nurse checked, Memory Deficit, Disorientation and Unable to follow instructions. Under Alternatives/interventions attempted or considered today, the licensed nurse checked, Supervision: Increased nursing rounds, monitor call-light / mark for quick response. Modify Environment: Lighting, noise, room assignment, bedside commode, call light. Reality Orientation / Psychosocial Interventions: Involve in conversations, convey sense of calm, explain procedures, relaxation techniques, verbally redirect behavior. Diversion / Physical Activity: TV, radio, music, ambulation, involve patient in</p>	A 165	<p>restraint policy and directed that the House Supervisors and the Charge Nurses include discussion of any restrained patients (including reason, alternatives attempted, type of restraint, length of time in restraints) at daily patient care rounds at 0830 and 2030 at each hospital.</p> <p>The Chief Nursing Officer reviewed and revised restraint policy and procedure to add instructions about the use of medications and chemical restraints, as well as to enhance the section describing alternatives to restraint that have been tried before imposing restraints. The restraint policy and procedure revisions were approved on 04/9/08</p> <p>The Education Department conducted staff education, emphasizing the requirement of assessing and trying less restrictive alternatives before imposing restraints, of using types of restraint that are the least restrictive intervention possible, of obtaining a physician's order for every restraint, and of discontinuing restraints at the earliest time possible.</p> <p>The Chief Nursing Officer is providing physician education on the restraint policy at every Medical Staff Department meeting during the 2nd quarter 2008, with attention to the criteria for ordering the least restrictive intervention possible after other less restrictive alternatives had been tried, to the prohibition on</p>	04/09/08	04/30/08	05/30/08

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A 165	<p>Continued From page 32 ADLs.</p> <p>From September 25, 2007, through September 27, 2007, when the patient was discharged home, it was documented the patient had a posey vest in place for patient safety. There was no documented evidence that the patient was unsafe, and in need of restraints.</p> <p>There was no documented evidence that increased nursing rounds were provided, the environment was modified, reality orientation / psychosocial interventions were provided or the patient received diversion / physical activity to ensure the least restrictive means of restraints were used.</p> <p>2. On October 4, 2007, at 2:30 p.m., an interview was conducted with Patient 214's spouse. The spouse stated, "Nobody talks to me about too much."</p> <p>The patient was observed laying flat in bed, with eyes closed and snoring. Bilateral wrist restraints were observed on and bilateral side rails were up.</p> <p>At 2:40 p.m., a record review for Patient 214 was conducted. The patient was a 81 year old admitted to the hospital on September 27, 2007, from home.</p> <p>A review of the patient's record was conducted. A licensed nurse documented that Patient 214, had orders for wrist restraints from September 28, 2007 through October 4, 2007.</p> <p>On September 28, 2007, the physician ordered ativan 0.5 mg, IV to be given every four hours when needed for agitation. On September 29,</p>	A 165	<p>ordering restraints PRN, and to the requirement to sign telephone orders within 24 hours. Additionally, the Chief Nursing Officer is sending education information on the restraint policy to each physician office during April-May 2008.</p> <p>Monitoring: The PI Director is responsible for auditing 100% of restraint episodes to check for compliance with the restraint policy.</p> <p>The PI Director and CNO are responsible for reporting trends and variances from restraint policy to PI/RM monthly as indicated.</p> <p>The Hospital nevertheless respectfully disagrees with these citations. The Medicare rule states that a "restraint does not include devices...to protect the patient from falling out of bed...." 42 CFR § 482.13(e)(1)(C). Because there was documentation in the medical records that the cited patients were confused and trying to get out of bed, and the devices were ordered to prevent them from getting out of bed and falling, they do not constitute "restraints" that are covered by this rule.</p>	<p>October 2007 and ongoing</p> <p>05/08 &amp; ongoing</p>	

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A 165	<p>Continued From page 33</p> <p>2007, the physician wrote orders to discontinue ativan and ordered haldol 2 mg IV to be given every 4 hours when needed for agitation.</p> <p>There was no documented evidence in the nurse's notes that "Alternatives / interventions attempted or considered today" were provided by hospital staff to ensure the least restrictive means of restraints would be provided. And there was no documented evidence that Patient 214 needed wrist restraints while he was asleep.</p> <p>On October 4, 2007 at 3:35 p.m., an interview was conducted with the director of the telemetry unit. When the surveyor asked about the physician's orders for bilateral wrist restraints and haldol 0.5 mg., the director did not offer any explanation.</p> <p>3. The record for Patient 402 was reviewed at RSMC on October 2, 2007. The nurse's notes dated September 24, 2007, at 9 p.m., stated, "Patient climbed out of bed and was unsteady on her feet walking to the bathroom. Assistance given in this activity. At her families request, a posey vest was applied because they said that she will forget to call for help and fell last time she was here. Dr. was informed of this. He ordered for a posey vest to be used." The record showed daily physician's orders for a vest and bilateral limb restraints due to agitated behavior and disorientation.</p> <p>The nurse's notes, dated September 24, 2007, through the date of survey, indicated the restraints were removed when the husband was at the bedside, and reapplied when he left. The nurse's notes indicated the patient's behavior with the husband present and the restraints off was, "cooperative."</p>	A 165			

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A 165	<p>Continued From page 34</p> <p>During an interview with the medical surgical unit CN on October 3, 3007, at 11:22 a.m., the CN stated the reason for the restraints was confusion and attempts to get out of bed when unsteady. The CN stated Patient 402 was not restrained when her husband was with her.</p> <p>Resident 402 was observed laying in bed on October 3, 2007, at 11:25 a.m. The patient was calm, awake and alert. The PT was at the bedside attempting to get the patient up for assistance with ambulation. The Patient was refusing to get out of bed, stating she would do it later.</p> <p>The patient's husband was interviewed at that time, and he stated he wanted the patient to be restrained so she wouldn't get out of bed and fall. The husband stated she was calm while he was there, but he didn't trust her to stay in bed when he wasn't there to watch her.</p> <p>There was no evidence in the record to indicate why two different forms of restraint had to be used on Patient 402.</p> <p>There was no evidence in the record that the facility attempted means to keep the patient safe other than restraining her, when it was evident she was calm when another person was in the room with her.</p> <p>4. The record for Patient 415 was reviewed on October 3, 2007, at RSMC. The restraint order forms dated June 25, 26, 27, and 29, and July 10, 12, 13 and 14, 2007, indicated orders for soft limb restraints and a vest restraint. There was no evidence in the record to indicate why two different forms of restraint had to be used on</p>	A 165		

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A 165	Continued From page 35 Patient 415. There was no evidence in the record indicating the facility was attempting to use the least restrictive means of restraint needed to provide care to the patient.  5. The record for Patient 417 was reviewed on October 3, 2007, at RSMC. The restraint order form dated July 13, 2007 indicated 4 side rails, soft limb restraints, and a vest restraint were to be used. There was no evidence in the record to indicate why three different types of restraint had to be used on Resident 417.  The restraint order forms dated July 14 and 15, 2007, indicated soft limb restraints were to be used. There was no evidence indicating why two different types of restraint had to be used on Patient 417. There was no evidence in the record indicating the facility was attempting to use the least restrictive means of restraint needed to provide care to the patient.  6. The record for Patient 418 was reviewed on October 3, 2007, at IVMC. The restraint order form dated September 13, 2007 listed 4 side rails, soft limb restraints, and a vest restraint to be used. There was no evidence in the record to indicate why three different types of restraint had to be used on Resident 418. There was no evidence in the record indicating the facility was attempting to use the least restrictive means of restraint needed to provide care to the patient.	A 165		
A 168	482.13(e)(5) PATIENT RIGHTS: RESTRAINT OR SECLUSION  The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order	A 168	Plan of Correction begins on next page.	

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A 168	Continued From page 36 restraint or seclusion by hospital policy in accordance with State law.  This Standard is not met as evidenced by: Findings:  Based on observation, interview and record review, the hospital failed to ensure there were written physician's orders for restraints for eight of 15 sampled patients in restraints (Patients 208, 201, 210, 913, 416, 417, 415, and 418), resulting in the potential for patients to be restrained inappropriately, without the knowledge or consent of the physician.  The hospital's Policy and Procedure dated 4/06, titled: "Restraints/Application of safety and behavior restraints", indicated, "Only on order from a physician or other licensed independent practitioner can a restraint be instituted...Should it be necessary, a registered nurse may place a patient in restraints and get a telephone order subsequent to placing the patient in restraints." The policy indicated the restraint order form was used for all restraint orders, and the physician's order was renewed at least every 24 hours and the physician must sign telephone orders within 24 hours.  1. A review of the record for Patient 208 at RSMC on October 3, 2007, at 9 a.m., indicated Patient 208 was admitted to the hospital on September 30, 2007, for complaints of feeling dizzy and falling four times at home.  Patient 208 was observed sitting up in a chair	A 168	The Chief Nursing Officer reviewed and reinforced education on the current restraint policy and directed that the House Supervisors and the Charge Nurses include discussion of any restrained patients (including reason, alternatives attempted, type of restraint, length of time in restraints) at daily patient care rounds at 0830 and 2030 at each hospital.  The Chief Nursing Officer reviewed and revised restraint policy and procedure to add instructions about the use of medications and chemical restraints, as well as to enhance the section describing alternatives to restraint that have been tried before imposing restraints. The restraint policy and procedure revisions were approved on 04/9/08  The Education Department conducted staff education, emphasizing the requirement of assessing and trying less restrictive alternatives before imposing restraints, of using types of restraint that are the least restrictive intervention possible, of obtaining a physician's order for every restraint, and of discontinuing restraints at the earliest time possible.  The Chief Nursing Officer is providing physician education on the restraint policy at every Medical Staff Department meeting during the 2nd quarter 2008, with attention to the criteria for ordering the least restrictive intervention possible after other less restrictive alternatives had been tried, to the prohibition on	12/15/08 <i>OK to change per TLC &amp; Melissa Burns, DNP &amp; Pam Divan, PI</i> 11/3/08 1038A  04/09/08  04/30/08  05/30/08
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A 168	<p>Continued From page 37 next to her bed.</p> <p>A review of the physician's orders for non-behavior restraints dated October 1, 2007, and October 3, 2007, indicated the physician failed to sign the orders.</p> <p>A review of the nurse's notes dated October 1, 2007, and October 3, 2007, indicated the was in a posey vest restraint.</p> <p>2. During a tour of the unit at RSMC on October 2, 2007, Patient 201 was observed in bed. The head of the bed was raised, with all 4 side rails up and a vest restraint was on. According to the Unit Charge Nurse, Patient 201 was confused and had made attempts to get out of bed.</p> <p>Patient 201 was admitted to the hospital on September 28, 2007, with diagnoses that included congestive heart failure, pneumonia and cardiomyopathy. The record for Patient 201 was reviewed on October 2, 2007. There was a physician's order sheet dated September 29, 2007, at 7:50 a.m., signed by the nurse for, "4 side rails, soft wrist restraints (left &amp; right) and vest Posey." There was no physician signature on the order sheet.</p> <p>3. The closed record for Patient 210 at IVMC was reviewed on October 4, 2007. Patient 210 was admitted through the ER due to an onset of seizures. While in the ER, Patient 210 when into respiratory distress, requiring intubation and ventilator assistance.</p> <p>The restraint order sheet had physician's orders dated September 22, 2007, for soft wrist restraints, which had not been signed by the physician.</p>	A 168	<p>ordering restraints PRN, and to the requirement to sign telephone orders within 24 hours. Additionally, the Chief Nursing Officer is sending education information on the restraint policy to each physician office during April-May 2008.</p> <p>Monitoring: The PI Director is responsible for auditing 100% of restraint episodes to check for compliance with the restraint policy.</p> <p>The PI Director and CNO are responsible for reporting trends and variances from restraint policy to PI/RM monthly as indicated.</p> <p>The Hospital nevertheless respectfully disagrees with these citations. The Medicare rule states that a "restraint does not include devices...to protect the patient from falling out of bed...." 42 CFR § 482.13(e)(1)(C). Because there was documentation in the medical records that the cited patients were confused and trying to get out of bed, and the devices were ordered to prevent them from getting out of bed and falling, they do not constitute "restraints" that are covered by this rule.</p>	<p>October 2007 and ongoing</p> <p>05/08 &amp; ongoing</p>
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A 168	<p>Continued From page 38</p> <p>The order sheet dated September 23, 2007, at 6 a.m., had check marks checked for, "Soft wrist restraints" which were not signed by the physician.</p> <p>The restraint order sheet dated September 24, 2007, at 6:30 p.m., for "4 side rails and soft wrist restraints" was not signed by the physician.</p> <p>4. On October 4, 2007, at 8:30 a.m., the Intensive Care Unit (ICU) at Inland Valley Hospital was toured. Patient 913 was observed in bed with soft restraints in place to both wrists.</p> <p>On October 4, 2007, the clinical record for Patient 913 was reviewed. The record contained numerous restraint order forms which were reviewed. The following was noted:</p> <p>a. A form dated October 1, 2007, at 9:30 a.m., had no documentation in the section for observed behaviors. In addition, the section to be completed by the physician contained check marks for progress notes, and type of restraints, but was unsigned by the physician.</p> <p>b. A form dated October 2, 2007, at 9:30 a.m., contained check marks in the sections for progress notes, type of restraint and when to discontinue restraint, but was unsigned by the physician.</p> <p>c. A form dated October 4, 2007, at 6 a.m., contained check marks in the sections for progress notes, type of restraint, and when to discontinue restraint. The form was unsigned by the physician and the form lacked the name of the nurse who obtained the telephone order and the physician who was contacted.</p>	A 168		

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A 168	<p>Continued From page 39</p> <p>During an interview with the Director of ICU on October 4, 2007, at 10:10 a.m., she stated the physician must evaluate the patient and sign every 24 hours. The Director stated it was not unusual for the RN to check the boxes which were to be completed by the physician.</p> <p>5. The record for Patient 416 was reviewed at RSMC on October 3, 2007. The restraint order forms dated July 11 and 12, 2007, did not have a physician's signature.</p> <p>6. The record for Patient 417 was reviewed at RSMC on October 3, 2007. The restraint order forms dated July 3, 16, and 17, 2007, did not have a physician's signature.</p> <p>7. The record for Patient 415 was reviewed on October 3, 2007. The restraint order form dated June 22, 2007, was not signed by the physician until after the patient was discharged from the hospital (July 14, 2007). The restraint order was authenticated by the physician electronically on August 14, 2007.</p> <p>The restraint order form dated June 25, 2007, was not signed by the physician until after discharge (July 14, 2007). The order was authenticated by the physician electronically on August 3, 2007.</p> <p>The restraint order form dated June 26, 2007, was not signed by the physician. The order was authenticated by the physician electronically on August 14, 2007.</p> <p>The restraint order form dated July 3, 2007, was signed by the physician on July 5, 2007, 2 days later.</p>	A 168		

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A 168	Continued From page 40 8. The record for Patient 418 at IVMC was reviewed on October 4, 2007. The restraint order form dated September 12, 2007, was not signed by the physician.	A 168	The Chief Nursing Officer reviewed and reinforced education on the current restraint policy and directed that the House Supervisors and the Charge Nurses include discussion of any restrained patients (including reason, alternatives attempted, type of restraint, length of time in restraints) at daily patient care rounds at 0830 and 2030 at each hospital.	12/15/08	OK to change per T/C & M... B... DNS A... Diver, P
A 169	482.13(e)(6) PATIENT RIGHTS: RESTRAINT OR SECLUSION  Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).  This Standard is not met as evidenced by: Based on interview and record review, the hospital failed to ensure orders for the use of restraints were not written on an as needed basis for one of 15 sampled patients in restraints (Patient 210), resulting in the potential for the patient to be restrained unnecessarily and inconsistently.  Findings:  The facility policy for Restraints was reviewed on October 4, 2007. The Policy, entitled, "NUR - R1: Restraints, Application of Safety and Behavior Restraints," stated, "If an order is written as a PRN order, the physician is immediately contacted and advised that any restraint order must be specific and time-limited."  The record of Patient 210, a closed record at IVMC, was reviewed on October 4, 2007. Patient 210 was admitted to the hospital on September 22, 2007, for seizures and an altered level of consciousness. Due to another seizure in the Emergency Room, the patient was intubated (a	A 169	The Chief Nursing Officer reviewed and revised restraint policy and procedure to add instructions about the use of medications and chemical restraints, as well as to enhance the section describing alternatives to restraint that have been tried before imposing restraints. The restraint policy and procedure revisions were approved on 04/9/08  The Education Department conducted staff education, emphasizing the requirement of assessing and trying less restrictive alternatives before imposing restraints, of using types of restraint that are the least restrictive intervention possible, of obtaining a physician's order for every restraint, and of discontinuing restraints at the earliest time possible.  The Chief Nursing Officer is providing physician education on the restraint policy at every Medical Staff Department meeting during the 2nd quarter 2008, with attention to the criteria for ordering the least restrictive intervention possible after other less restrictive alternatives had been tried, to the prohibition on ordering restraints PRN, and to the requirement to sign telephone orders within 24 hours. Additionally, the Chief Nursing Officer is sending education information on the restraint policy to each physician office during April-May 2008.	6-13-08 1038A 04/09/08 04/30/08 05/30/08	

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A 169	Continued From page 41 tube placed into the mouth and down the trachea to assist with airway management) and placed on a ventilator. By September 23, 2007, at 9 a.m., Patient 210 extubated (pulled the tube out) herself and was placed on oxygen at 2 liters per minute via nasal cannula. The patient remained agitated, confused and was not following instructions.  The patient was transferred to 2 West on September 28, 2007. There was a restraint order sheet dated September 28, 2007, at 10 a.m. The physician dated, timed and signed the order form. On this order form there was no area checked by the physician as to the type of restraint to be used.  The Non-Behavioral Restraint order form dated September 29, 2007, showed restraints were to be used, "For Patient Safety." The order was signed by the physician with the date and time. In the upper right area of the order, it was written, "PRN," and signed by the physician.  On October 4, 2007, at 2:45 p.m., the Unit Director for 2 East was interviewed. The Director stated, "Without knowing the patient and the situation, it looked like the physician misunderstood the situation."	A 169	Monitoring: The PI Director is responsible for auditing 100% of restraint episodes to check for compliance with the restraint policy.  The PI Director and CNO are responsible for reporting trends and variances from restraint policy to PI/RM monthly as indicated.  The Hospital nevertheless respectfully disagrees with these citations. The Medicare rule states that a "restraint does not include devices...to protect the patient from falling out of bed...." 42 CFR § 482.13(e)(1)(C). Because there was documentation in the medical records that the cited patients were confused and trying to get out of bed, and the devices were ordered to prevent them from getting out of bed and falling, they do not constitute "restraints" that are covered by this rule.	October 2007 and ongoing  05/08 & ongoing	
A 263	482.21 QAPI  The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.  The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including	A 263	See corrective actions under Tags A267, A274, A284, A286, A315, A316, A529, A537,		

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A 263	<p>Continued From page 42 those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.</p> <p>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</p> <p>This Condition is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure the development, implementation, and maintenance of an effective QAPI program, by failing to:</p> <p>a. Develop, track, and report on quality indicators for the Rehabilitation Services of PT, OT, and ST for 9 months (A267);</p> <p>b. Ensure PI activities of the Dietetic Services were submitted to the PI committee (A274);</p> <p>c. Ensure policies for decontamination of surgical instruments were followed (A284);</p> <p>d. Ensure there was a system in place that supplies used for cardiac and radiological procedures were not outdated and unsafe for use (A284)(A537);</p> <p>e. Track medical errors and adverse patient events through the PI process, with no mechanism for tracking ED misreads of x-rays (A286) (A529);</p>	A 263		

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A 263	Continued From page 43  f. Ensure adequate resources were allocated for measuring, assessing, improving, and sustaining safe and effective performance of patient care (A315), and;  g. Ensure adequate resources were allocated for reducing risk to patients (A316).  The cumulative effect of these systemic problems resulted in the failure of the governing body to ensure the PI program focused on safe and effective patient care, improving health outcomes, and preventing and reducing medical errors.	A 263		
A 267	482.21(a)(2) QAPI QUALITY INDICATORS  The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.  This Standard is not met as evidenced by: Based on staff interview and review of the facilities' policies and procedures and performance improvement committee meeting minutes, health system failed to develop, track and report on quality indicators for the rehabilitation services of physical therapy, occupational therapy and speech therapy during the 9 months preceding the survey.  Findings:  During an interview begun at 3:13 pm..... on October 3, 2007 the director of physical therapy	A 267	A. Action Plan: The Rehabilitation Manager has developed, tracked and reported clinical indicators for PT/OT and Speech Therapy. The clinical indicators have been developed, tracked, and reported. PI indicators include review of whether the following actions have been done for each patient: assessment of pain; PT/OT/ST interdisciplinary plan of care performed; PT/OT/ST plan of care signed by MD prior to treatment; and PT/OT/ST goals are objective and if not achieved, the reason is documented.  Responsible Party: Rehabilitation Manager	01/01/08

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A 267	<p>Continued From page 44</p> <p>stated that he had become the director in April 2007. The director stated that data regarding physical therapy and occupational therapy documentation had been collected since that time. The director was unaware of any speech therapy performance improvement activities. The director stated that he participated in a subcommittee of the performance improvement committee on a quarterly basis and was to report data at those meetings. The director stated that he had not reported performance improvement data for physical therapy, occupational therapy or speech therapy to the committee since becoming the director in April 2007.</p> <p>Review of the system's performance improvement plan revealed, "The Governing Board requires the medical and organization's staff to implement and report activities for identifying and evaluating opportunities to improve patient care and services throughout the organization."</p> <p>During an interview begun at 3:35 pm..... on October 3, 2007, the director of quality stated that each department was responsible for developing their own performance improvement projects. The performance improvement committee was responsible to monitor the quality of performance improvement projects initiated by each department.</p> <p>During an interview begun at 4:20 pm..... on October 3, 2007, the director of quality stated that physical therapy, occupational therapy and speech therapy had not reported any data on quality improvement indicators the the performance improvement committee during calendar year 2007.</p>	A 267	<p>Monitoring:</p> <p>The Director of Quality/Performance Improvement confirms that each Department has developed, tracked and reported clinical indicators. If a department does not have indicators, the Director of Quality/Performance Improvement works with the Director and Department staff to assure appropriate indicators are developed, tracked and reported. The Department head is responsible for reviewing the results of QAPI reviews monthly and the department head reports on a quarterly basis at the Operational Performance Improvement Committee (OPIC) meeting. These results are then reported to the Governing Board as part of the core measures and drill downs as appropriate.</p>	Ongoing
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A		A 274	<p>continued from page 46 to the Governing Body. All QAPI activities and progress are further discussed and tracked during the Department's monthly leadership meetings held monthly on the third Friday of the month.</p> <p>The Diet Order Accuracy Study and Patient Test Tray Audit have been transitioned to quarterly random audits because the Department achieved 99% compliance for the last six months.</p>	04/01/08

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ (X6) DATE \_\_\_\_\_

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 patients. (See Instructions.) Except for nursing homes, the findings stated 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.

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A 284 A 284	Continued From page 46 482.21(c)(1) QAPI IMPROVEMENT PRIORITIES  The hospital must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and, affect health outcomes and quality of care.  This Standard is not met as evidenced by: Based on observation, interview and record review, the hospital's performance improvement plan failed to set priorities for its improvement activities that focused on high risk, high volume, or problem prone areas. There was no system in place to ensure that policies for decontamination of surgical instruments were being followed in the OR at RSMC. There was no system in place to ensure that supplies used for cardiac and radiological procedures at RSMC and IVMC were not outdated, and safe for use. These failures resulted in the potential for injury and infection in patients undergoing surgical, cardiac and radiological procedures.  Findings:  1. The SPD at RSMC was toured on October 2, 2007, at 3:20 p.m. Tech 1 was observed washing instruments, and was interviewed about the procedure she followed. The tech stated the washing sink held about six quarts of water, and when she mixed the solution for decontamination of surgical instruments in this sink, she added, "a few squirts," of Ultrazyme cleaner to the water. The tech stated there was no measured amount	A 284 A 284	A. Action Plan: The Director of Perioperative Services changed the GI tech and SPD Tech job specific competencies to reflect that all enzymatic cleaners must be diluted per manufacture instructions using exact measurements of water and enzymatic cleaner. All GI techs, SPD techs and RN GI staff at both facilities have signed the revised job description competency. All GI and SPD personnel were updated on the enzymatic cleaner changes at the October 2007 staff meetings and OR board meetings. The policy on SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies was revised to reflect "all enzymatic cleaners are diluted per manufactures instruction." Random audits are currently done to check the validity of this practice.  All SPD and GI staff at Inland Valley and Rancho Springs Medical Centers were updated on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the revised SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies.  Director of Perioperative Services or designee is conducting random audits to ensure compliance. Results of the audits are reported to the OPIC	10/31/07          10/31/07          10/31/07 & ongoing

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A 284	<p>Continued From page 47 of solution added to the water, sometimes she added more, and sometimes she added less. A review of the manufacturer's recommendations on the Ultrazyme bottle indicated one ounce (one pump) of cleaner should be added to each gallon of water.</p> <p>The tech was not aware of the need to accurately measure the amount of enzymatic cleaner to be added to a known amount of water. She stated she could not recall being educated about this, or having her competency checked at her last skills day or evaluation.</p> <p>The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. They both stated that the mixing of the cleaner was not part of the annual competency evaluation for the SPD technicians.</p> <p>2. During the tour, the other side of the instrument pre wash area was identified as the area for washing TEE probes (used to do a cardiac ultrasound from inside the esophagus). The SPD tech stated the cardiology techs were responsible for cleaning these instruments. The tech stated Cidex was used as the enzymatic cleaner for this procedure. The tech identified a bottle of test strips used to verify the concentration of the cleaner after mixing. The date on the bottle of test strips indicated they had expired.</p> <p>The hospital policy on cleaning TEE probes was reviewed on October 2, 2007. The policy indicated the probes should be cleaned with one to two ounces of enzymatic cleaner per gallon of water. However, the bottle of Cidex specified one ounce of cleaner per gallon of water. The tech stated the old cleaner was mixed with one to two ounces of solution per gallon of water, and the</p>	A 284	<p>Committee to assure that corrective action is sufficient to assure staff comply with requirements.</p> <p>Director of Imaging / Lead RN Cardiac Cath reviewed and revised the policy and procedure related to sterilization of TEE probes. The Lead RN reviews all inventory for outdates on the first week of each month. In addition, the Imaging Managers conduct bi-weekly random inspections that include a review of expiration dates. The Imaging Department maintains a log to confirm that the require audits are conducted and the results of checking the expired items. The Director of Imaging reviews the log at least quarterly to confirm that the required inventories and random inspections are occurring and the results of the inventories and reviews.</p> <p>Physical Inventory Inspection log and inventory report from inventory computer system reviewed weekly by Lead RN.</p> <p>The Cardio Manager revised the TEE cleaning logbook to include a column requiring documentation of Cidex test strip expiration date, which is to be filled in prior to use of the Cidex. Policy and procedure has been revised to reflect this practice. All staff involved in the cleaning of TEE equipment have been educated to this new procedure. The Cardio Manager reviews the log book on a monthly basis to assure compliance with the new procedures.</p>	<p>10/27/07</p> <p>10/27/07 &amp; ongoing</p> <p>04/02/08</p>	

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A 284	<p>Continued From page 48 policy was outdated.</p> <p>3. In the same area, a cart was placed with a towel on top. The clean endoscopes were observed curled up on the towel. The clinical lead for Surgical Services stated the old cabinet for hanging the endoscopes had to be discarded, and they were awaiting approval of the capital budget to purchase a new one. In the meantime, the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.</p> <p>4. The Endoscopy Lab (used for scoping procedures of the stomach and colon) at IVMC was toured on October 4, 2007, at 3:30 p.m. The Endo technician was questioned regarding the cleaning of the endoscopes. The tech stated the first step involved soaking the scopes and cleaning them with an enzymatic cleaning solution. The cleaner present in the cleaning area was V. Mueller Dual Enzy Clean, and the instructions called for one to two pumps (ounces) per gallon of water. The technician described he would fill the sink with water and add about 10 pumps of solution to the sink water. He stated he did not remember how he was taught the mixing procedure. He stated he did not recall having this part of his job checked with his annual competencies or his evaluation.</p> <p>5. The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10 a.m. There were multiple wrapped angi catheters and other equipment, for use in</p>	A 284	<p>The Cardio Manager added this item as a quality indicator under the PI Program and results of the reviews are reported to the PI Committee.</p> <p>Responsible Party: Cardio Manager</p> <p>Monitoring: Checked monthly and added to PI program as a Quality Indicator</p>	04/02/08 & ongoing	

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A 284	Continued From page 49 the Special Procedures/Cardiac Cath suite, stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angiocaths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angiocaths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.  The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired supplies available for use.  6. The Radiology Suite at IVMC was toured on October 4, 2007, at 2 p.m. Examination of the supplies in the room revealed one Vista 8 french endovascular catheter with an expiration date of September 2007, indicating that the period for safe use had ended 4 days prior. Three biliary stents (used to catheterize the gall bladder) were also expired September 2007. The staff was unable to explain why the expired instruments were stored with the supplies for patient use.	A 284		
A 286	482.21(c)(2) QAPI TRACKING  Performance improvement activities must track medical errors and adverse patient events.  This Standard is not met as evidenced by: Based on interview and record review, the facility failed to track medical errors and adverse patient	A 286	Physician representatives from the Departments of Imaging and Emergency and the PI Director reviewed the policy, "Patient Contact after Discharge from the ED" (ED P#16) the decision was made to draft a new policy specific to the Medical Staff concerning variances in x-ray readings between Emergency Physicians and Radiologists. The new policy establishes a process to identify when there is a variance in the interpretation	

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A 286	<p>Continued From page 50</p> <p>events through the PI process, with no mechanism for tracking ED misreads of x-rays. This resulted in the failure to notify the ER physician of radiology misreads for two of 73 sampled patients (Patients 411 and 414), and the potential for inappropriate diagnosis and treatment of all patients receiving x-rays in the ED after radiology hours.</p> <p>Findings:</p> <p>The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.</p> <p>1. The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on</p>	A 286	<p>of imaging studies. When such a variance is identified:</p> <ol style="list-style-type: none"> <li>1. Appropriate action is taken to alert a physician when a variance is identified that could impact the patient's plan of care.</li> <li>2. The Medical Staff, as part of their ongoing efforts to improve the quality of care provided, review each variance on a regular basis to identify opportunities for improvement.</li> </ol> <p>On 12/10/2007, the hospital implemented a digital imaging system referred to as "PACS" that provides better capabilities to track the variance.</p> <p>Under the new process:</p> <ol style="list-style-type: none"> <li>1. The ED physician or PA reviews the exam and enters in PACS an internal note of their findings for each exam reviewed. Treatment is initiated as appropriate and the patient/representative is advised of the preliminary findings.</li> <li>2. The radiologist reviews the exam for a final interpretation and result reporting.               <ol style="list-style-type: none"> <li>a. If the Radiologist reading is different than the preliminary ED read, the Radiologist informs the on-duty ED physician about the variance so appropriate clinical action can be taken if necessary.</li> <li>b. The Radiologist documents the variance (where the official interpretation differs from the ED preliminary finding) in the final dictated report, and who was notified.</li> </ol> </li> </ol>	12/10/07
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A 286	<p>Continued From page 51</p> <p>October 4, 2007, at 1 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>2. A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>3. The policy governing both facilities titled, "Patient Contact After Discharge From the ED," was reviewed on October 3, 2007. The policy stated the following;</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist to see what the ED physician concluded;</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of the ED physician on duty;</p>	A 286	<p>c. The Radiologist copies the case information to the ED – QA Worklist in the PACS system. This worklist serves as the tracking log for potential ED "misreads."</p> <p>3. The on-duty ED physician reviews the patient's chart and takes appropriate clinical action to.</p> <p>a. Contact the patient or their representative to inform them of the final interpretation and any change in their plan of care.</p> <p>b. Document the action taken in the patient's medical record.</p> <p>4. The variance readings are tracked by ED physician and type of exam to address trends and identify areas for improvement or change in practice.</p> <p>5. Variance rates and results of the reviews are reported to ED Committee, OPIC Committee and the Governing Board at part of the QAPI process.</p> <p>The PACS software company was contacted in February to assist in configuring the system to enable the required ED – QA Worklist tab. The PACS software company configured the tabs for the ED-QA Worklist. The function was tested and found to be functioning. The ED physicians and Radiologists were given reminders of the revised process. Additional written reminders were posted in the physician areas in the ED and Imaging departments.</p> <p>Responsible Party: ED and Imaging Department Chairs</p>	04/01/08
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A 286	Continued From page 52 d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;  e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for three reasons: 1. Documentation in the patient's medical record, 2. Serves as a log for performance improvement activities, and, 3. Can provide feedback to the initial ED physician;  f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then: 1. The physician would give the letter to the ED Director or designee, 2. A copy of the letter would be attached to the patient's medical record, 3. The original letter would be mailed certified, return receipt, and, 4. When the ED Director received the return receipt, it would be attached to the patient's medical record.  During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."  During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated	A 286	1. The ED Department Chair (or designee) provides oversight to the review of variances to consider trends or clusters of: a. Variance involving the same provider. b. Variances of similar types of exams. 2. The ED physicians review the variances to identify opportunities for improvement. Significant variances will be routed to the ED committee for discussion and action as appropriate. 3. Routine variance reporting will be incorporated into the ED Department peer review process for analysis and follow-up action as indicated. At a minimum, this will be done twice annually. 4. Variance reviews are incorporated into the provider's reappointment profile.	04/01/08

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A 286	<p>Continued From page 53</p> <p>she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>4. During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).</p> <p>During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there</p>	A 286		

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A 286	Continued From page 54 was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or Patient 414 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."	A 286		
A 315	<b>482.21(e)(4) EXECUTIVE RESPONSIBILITIES</b>  The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that adequate resources are allocated for measuring, assessing, improving and sustaining the hospital's performance.  This Standard is not met as evidenced by: Based on observation, interview and record review, the governing body and medical staff failed to assure adequate resources were allocated for measuring, assessing, improving, and sustaining the hospital's performance, resulting in failure to notify the ER physician of radiology misreads for two of 73 sampled patients (Patients 411 and 414), the potential for inappropriate diagnosis and treatment of all patients receiving x-rays in the ED after radiology hours, and infection for surgical and radiology patients at both hospitals, and all patients at	A 315	The Executive responsibility and accountability to ensure adequate resources are allocated for QAPI are taken very seriously. During the last six months, the Governing Board, along with the Senior Administrative Team, has planned for and restructured leadership positions to ensure appropriate front line management with a span of control that will facilitate accomplishing the goals safe and effective patient care. As a result of the reorganization, Managers were put in place on each clinical unit to supervise and facilitate initiatives that relate to all hospital processes, including but not limited to, PI and IC processes. Additionally, Directors, have been relieved of many day to day operational concerns and are more available to mentor and oversee initiatives that cross multiple departments.  Person Responsible: Governing Board, CEO	N/A

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A 315	<p>Continued From page 55 RSMC.</p> <p>Findings:</p> <p>During the survey, it was noted the Director of ER, the Director of Surgical Services, the Director of PI, and the IC Coordinator had difficulties overseeing their respective services at the two hospitals, as evidenced by:</p> <p>1. The Emergency Department was toured on October 3, 2007, at 9 a.m. During the tour, the RN Director of Emergency Services stated her usual work hours were 7 a.m. to 8 p.m. every day, and that it was difficult to manage departments at two campuses.</p> <p>The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.</p> <p>The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He</p>	A 315	<p>Monitoring: Bi-monthly Board meetings will address the effectiveness of the outcomes related to operations, quality and safety metrics.</p> <p>See also corrective actions under Tags A267, A274, A284, and A286.</p>	

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A 315	<p>Continued From page 56</p> <p>was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on October 4, 2007, at 1:00 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>The policy governing both facilities titled, "Patient Contact After Discharge From the ED," was reviewed on October 3, 2007. The policy stated the following:</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist</p>	A 315		

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A 315	<p>Continued From page 57 to see what the ED physician concluded;</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of the ED physician on duty;</p> <p>d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;</p> <p>e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for 3 reasons:</p> <ol style="list-style-type: none"> <li>1. Documentation in the patient's medical record,</li> <li>2. Serves as a log for performance improvement activities, and,</li> <li>3. Can provide feedback to the initial ED physician;</li> </ol> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director of designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> <li>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</li> </ol> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from</p>	A 315		

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A 315	<p>Continued From page 58</p> <p>physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).</p> <p>During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at</p>	A 315		
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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 315	<p>Continued From page 59</p> <p>3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or Patient 414 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."</p> <p>2. During a tour of the Surgical Suite of RSMC on October 2, 2007, at 2:30 p.m., the Director of Surgical Services stated her work hours were close to 12 hours a day, and she was not able to perform all of her duties unless she worked the extra hours.</p> <p>The SPD at RSMC was toured on October 2, 2007, at 3:20 p.m. Tech 1 was observed washing instruments, and was interviewed about the procedure she followed. The tech stated the washing sink held about six quarts of water, and when she mixed the solution for decontamination of surgical instruments in this sink, she added, "a few squirts," of Ultrazyme cleaner to the water. The tech stated there was no measured amount of solution added to the water, sometimes she added more, and sometimes she added less. A review of the manufacturer's recommendations on the Ultrazyme bottle indicated one ounce (one pump) of cleaner should be added to each gallon of water.</p>	A 315		
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A 315	<p>Continued From page 60</p> <p>The tech was not aware of the need to accurately measure the amount of enzymatic cleaner to be added to a known amount of water. She stated she could not recall being educated about this, or having her competency checked at her last skills day or evaluation.</p> <p>The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. They both stated that the mixing of the cleaner was not part of the annual competency evaluation for the SPD technicians.</p> <p>During the tour, the other side of the instrument pre wash area was identified as the area for washing TEE probes (used to do a cardiac ultrasound from inside the esophagus). The SPD tech stated the cardiology techs were responsible for cleaning these instruments. The tech stated Cidex was used as the enzymatic cleaner for this procedure. The tech identified a bottle of test strips used to verify the concentration of the cleaner after mixing. The date on the bottle of test strips indicated they had expired.</p> <p>The hospital policy on cleaning TEE probes was reviewed on October 2, 2007. The policy indicated the probes should be cleaned with one to two ounces of enzymatic cleaner per gallon of water. However, the bottle of Cidex specified one ounce of cleaner per gallon of water. The tech stated the old cleaner was mixed with one to two ounces of solution per gallon of water, and the policy was outdated.</p> <p>In the same area, a cart was observed with a towel on top. Clean endoscopes were observed curled up in the towel. The clinical lead for Surgical Services stated the old cabinet for</p>	A 315		

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A 315	<p>Continued From page 61</p> <p>hanging the endoscopes had to be discarded, and they were awaiting approval of the capital budget to purchase a new one. In the meantime, the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.</p> <p>The Endoscopy Lab (used for scoping procedures of the stomach and colon) at IVMC was toured on October 4, 2007, at 3:30 p.m. The Endo technician was questioned regarding the cleaning of the endoscopes. The tech stated the first step involved soaking the scopes and cleaning them with an enzymatic cleaning solution. The cleaner present in the cleaning area was V. Mueller Dual Enzy Clean, and the instructions called for one to two pumps (ounces) per gallon of water. The technician described he would fill the sink with water and add about 10 pumps of solution to the sink water. He stated he did not remember how he was taught the mixing procedure. He stated he did not recall having this part of his job checked with his annual competencies or his evaluation.</p> <p>3. The Director of PI was interviewed on October 5, 2007, at 10:07 a.m. When asked about covering all PI activities at both hospitals, she stated she "saw a gap in the process." She stated it was difficult to keep up with two hospitals, and she had so much to do, she could only get the top priorities done. The PI Director stated she was able to get the required data collected and entered, and attend meetings, but she did not have time to get out to the floors in the facilities and network with the staff to</p>	A 315		

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A 315	<p>Continued From page 62</p> <p>determine if there were QAPI issues that needed to be addressed.</p> <p>4. The IC staff (consisting of the CNO and the ICC), was interviewed on October 5, 2007, at 1:12 p.m. During the interview, the ICC stated she made daily rounds, attended construction rounds and meetings, and called for corrective action when needed at IVMC, but not at RSMC. The ICC stated the IC activities at RSMC consisted of review of culture results. The CNO stated they used to have two IC employees, but one left the facility, and they had not replaced that position. The CNO stated there was no way one person could do complete surveillance at both campuses, so the IC Coordinator was doing, "only the essentials," at RSMC.</p> <p>The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10 a.m. There were multiple wrapped angiocatheters and other equipment, for use in the Special Procedures/Cardiac Cath suite, stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angiocaths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angiocaths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.</p> <p>The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired supplies available for use.</p> <p>The Radiology Suite at IVMC was toured on</p>	A 315		



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A 316

Continued From page 64

A 316

Findings:

1. During the survey, it was noted that the Director of ER, the Director of Surgical Services, the Director of PI, and the IC Coordinator had difficulties overseeing their respective services at the two hospitals.
2. The Emergency Department was toured on October 3, 2007, at 9 a.m. During the tour, the RN Director of Emergency Services stated her usual work hours were 7 a.m. to 8 p.m. every day, and that it was difficult to manage departments at two campuses.

The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.

The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.

Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray

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A 316	<p>Continued From page 65</p> <p>rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on October 4, 2007, at 1 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>The policy governing both facilities titled, "Patient Contact After Discharge From the ED," was reviewed on October 3, 2007. The policy stated the following:</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist to see what the ED physician concluded;</p>	A 316		

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A 316	<p>Continued From page 66</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of the ED physician on duty;</p> <p>d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;</p> <p>e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for 3 reasons:</p> <ol style="list-style-type: none"> <li>1. Documentation in the patient's medical record,</li> <li>2. Serves as a log for performance improvement activities, and,</li> <li>3. Can provide feedback to the initial ED physician;</li> </ol> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director of designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> <li>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</li> </ol> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she</p>	A 316		

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A 316	<p>Continued From page 67</p> <p>thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a prelliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).</p> <p>During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was</p>	A 316		
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A 316	<p>Continued From page 68</p> <p>obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or 414 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."</p> <p>3. During a tour of the Surgical Suite of RSMC on October 2, 2007, at 2:30 p.m., the Director of Surgical Services stated her work hours were close to 12 hours a day, and that she was not able to perform all of her duties unless she worked the extra hours.</p> <p>The SPD at RSMC was toured on October 2, 2007, at 3:20 p.m. Tech 1 was observed washing instruments, and was interviewed about the procedure she followed. The tech stated the washing sink held about six quarts of water, and when she mixed the solution for decontamination of surgical instruments in this sink, she added, "a few squirts," of Ultrazyme cleaner to the water. The tech stated there was no measured amount of solution added to the water, sometimes she added more, and sometimes she added less. A review of the manufacturer's recommendations on the Ultrazyme bottle indicated one ounce (one pump) of cleaner should be added to each gallon of water.</p>	A 316		

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A 316	<p>Continued From page 69</p> <p>The tech was not aware of the need to accurately measure the amount of enzymatic cleaner to be added to a known amount of water. She stated she could not recall being educated about this, or having her competency checked at her last skills day or evaluation.</p> <p>The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. They both stated that the mixing of the cleaner was not part of the annual competency evaluation for the SPD technicians.</p> <p>During the tour, the other side of the instrument pre wash area was identified as the area for washing TEE probes (used to do a cardiac ultrasound from inside the esophagus). The SPD tech stated the cardiology techs were responsible for cleaning these instruments. The tech stated Cidex was used as the enzymatic cleaner for this procedure. The tech identified a bottle of test strips used to verify the concentration of the cleaner after mixing. The date on the bottle of test strips indicated they had expired.</p> <p>The hospital policy on cleaning TEE probes was reviewed on October 2, 2007. The policy indicated the probes should be cleaned with one to two ounces of enzymatic cleaner per gallon of water. However, the bottle of Cidex specified one ounce of cleaner per gallon of water. The tech stated the old cleaner was mixed with one to two ounces of solution per gallon of water, and the policy was outdated.</p> <p>In the same area, a cart was placed with a towel on top. The clean endoscopes were observed curled up on the towel. The clinical lead for Surgical Services stated the old cabinet for hanging the endoscopes had to be discarded,</p>	A 316		
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A 316	<p>Continued From page 70</p> <p>and they were awaiting approval of the capital budget to purchase a new one. In the meantime, the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.</p> <p>The Endoscopy Lab (used for scoping procedures of the stomach and colon) at IVMC was toured on October 4, 2007, at 3:30 p.m. The Endo technician was questioned regarding the cleaning of the endoscopes. The tech stated the first step involved soaking the scopes and cleaning them with an enzymatic cleaning solution. The cleaner present in the cleaning area was V. Mueller Dual Enzy Clean, and the instructions called for one to two pumps (ounces) per gallon of water. The technician described he would fill the sink with water and add about 10 pumps of solution to the sink water. He stated he did not remember how he was taught the mixing procedure. He stated he did not recall having this part of his job checked with his annual competencies or his evaluation.</p> <p>4. The Director of PI was interviewed on October 5, 2007, at 10:07 a.m. When asked about covering all PI activities at both hospitals, she stated she "saw a gap in the process." She stated it was difficult to keep up with two hospitals, and she had so much to do, she could only get the top priorities done. The PI Director stated she was able to get the required data collected and entered, and attend meetings, but she did not have time to get out to the floors in the facilities and network with the staff to determine if there were QAPI issues that needed</p>	A 316		
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 316	Continued From page 71 to be addressed.  5. The IC staff (consisting of the CNO and the ICC), was interviewed on October 5, 2007, at 1:12 p.m. During the interview, the ICC stated she made daily rounds, attended construction rounds and meetings, and called for corrective action when needed at IVMC, but not at RSMC. The ICC stated the IC activities at RSMC consisted of review of culture results. The CNO stated they used to have two IC employees, but one left the facility, and they had not replaced that position. The CNO stated there was no way one person could do complete surveillance at both campuses, so the IC Coordinator was doing, "only the essentials," at RSMC.	A 316		
A 338	482.22 MEDICAL STAFF  The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of care provided to patients by the hospital.  This Condition is not met as evidenced by: Based on observation, interview and record review, the facility to ensure the medical staff was responsible for the quality of care provided to patients, by failing to:  a. Ensure the two ED medical groups were accountable for the quality of care provided to patients receiving after hours diagnostic x-rays (A347);  b. Ensure integration of services between the emergency Medicine department and imaging	A 338	The medical staff operates under bylaws approved by the governing body and is responsible for the quality of care provided. Medical Staff Leaders and the Medical Executive Committee have worked with the hospital staff to address their responsibility for quality of care provided to patients at the hospital. See response at Tags A168, A286, A347, A500, A1004.	

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A 338	<p>Continued From page 72 department (A1103);</p> <p>c. Ensure implementation of a policy and procedure for follow up on x-ray reading discrepancies between the radiologists and emergency medicine physician (A1104);</p> <p>d. Ensure there were written physician's orders for restraints used on patients (A168);</p> <p>e. Ensure the post-anesthesia follow-up report contained adequate documentation of cardiopulmonary status and level of consciousness(A1004), and;</p> <p>f. Ensure a long acting narcotic was not used for the treatment of addiction contrary to the Uniform Controlled Substance Act - California State Law (A500).</p> <p>The cumulative effect of these systemic problems resulted in the failure of the medical staff to ensure the provision of safe medical care to patients in the hospital.</p>	A 338		
A 347	<p>482.22(b) MEDICAL STAFF ACCOUNTABILITY</p> <p>The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.</p> <p>The medical staff must be organized in a manner approved by the governing body.</p> <p>If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.</p> <p>The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or,</p>	A 347	<p>Physician representatives from the Departments of Imaging and Emergency and the PI Director reviewed the policy, "Patient Contact after Discharge from the ED" (ED P#16) the decision was made to draft a new policy specific to the Medical Staff concerning variances in x-ray readings between Emergency Physicians and Radiologists. The new policy establishes a process to identify when there is a variance in the interpretation of imaging studies. When such a variance is identified:</p>	

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A 347	<p>Continued From page 73</p> <p>when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.</p> <p>This Standard is not met as evidenced by: Based on interview and record review, the governing body failed to ensure the two Emergency Medical Groups (a different group at each campus), providing services as members of the medical staff, were accountable for the quality of medical care provided to patients. This failure resulted in the potential for inappropriate diagnosis and treatment for emergency patients receiving diagnostic x-rays after hours.</p> <p>Findings:</p> <p>The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.</p> <p>1. The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She</p>	A 347	<p>1. Appropriate action is taken to alert a physician when a variance is identified that could impact the patient's plan of care.</p> <p>2. The Medical Staff, as part of their ongoing efforts to improve the quality of care provided, review each variance on a regular basis to identify opportunities for improvement.</p> <p>On 12/10/2007, the hospital implemented a digital imaging system referred to as "PACS" that provides better capabilities to track the variance.</p> <p>Under the new process:</p> <p>1. The ED physician or PA reviews the exam and enters in PACS an internal note of their findings for each exam reviewed. Treatment is initiated as appropriate and the patient/representative is advised of the preliminary findings.</p> <p>2. The radiologist reviews the exam for a final interpretation and result reporting.</p> <p>a. If the Radiologist reading is different than the preliminary ED read, the Radiologist informs the on-duty ED physician about the variance so appropriate clinical action can be taken if necessary.</p> <p>b. The Radiologist documents the variance (where the official interpretation differs from the ED preliminary finding) in the final dictated report, and who was notified.</p>	12/10/07	

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A 347	<p>Continued From page 74</p> <p>stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on October 4, 2007, at 1:00 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>2. A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>3. The policy governing both facilities titled, "Patient Contact After Discharge From the ED,"</p>	A 347	<p>c. The Radiologist copies the case information to the ED - QA Worklist in the PACS system. This worklist serves as the tracking log for potential ED "misreads."</p> <p>3. The on-duty ED physician reviews the patient's chart and takes appropriate clinical action to.</p> <p>a. Contact the patient or their representative to inform them of the final interpretation and any change in their plan of care.</p> <p>b. Document the action taken in the patient's medical record.</p> <p>4. The variance readings are tracked by ED physician and type of exam to address trends and identify areas for improvement or change in practice.</p> <p>5. Variance rates and results of the reviews are reported to ED Committee, OPIC Committee and the Governing Board at part of the QAPI process.</p> <p>The PACS software company was contacted in February to assist in configuring the system to enable the required ED - QA Worklist tab. The PACS software company configured the tabs for the ED-QA Worklist. The function was tested and found to be functioning. The ED physicians and Radiologists were given reminders of the revised process. Additional written reminders were posted in the physician areas in the ED and Imaging departments.</p> <p>Responsible Party: ED and Imaging Department Chairs</p>	04/01/08
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A 347	<p>Continued From page 75 was reviewed on October 3, 2007. The policy stated the following;</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist to see what the ED physician concluded;</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of the ED physician on duty;</p> <p>d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;</p> <p>e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for 3 reasons:</p> <ol style="list-style-type: none"> <li>1. Documentation in the patient's medical record,</li> <li>2. Serves as a log for performance improvement activities, and,</li> <li>3. Can provide feedback to the initial ED physician;</li> </ol> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director of designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> </ol>	A 347	<p>Monitoring:</p> <ol style="list-style-type: none"> <li>1. The ED Department Chair (or designee) provides oversight to the review of variances to consider trends or clusters of: <ol style="list-style-type: none"> <li>a. Variance involving the same provider.</li> <li>b. Variances of similar types of exams.</li> </ol> </li> <li>2. The ED physicians review the variances to identify opportunities for improvement. Significant variances will be routed to the ED committee for discussion and action as appropriate.</li> <li>3. Routine variance reporting will be incorporated into the ED Department peer review process for analysis and follow-up action as indicated. At a minimum, this will be done twice annually.</li> <li>4. Variance reviews are incorporated into the provider's reappointment profile.</li> </ol>	04/01/08

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A 347	<p>Continued From page 76</p> <p>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</p> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>4. During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p>	A 347		

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A 347	Continued From page 77 d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).  During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or 417 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."	A 347		
A 385	<b>482.23 NURSING SERVICES</b>  The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.  This Condition is not met as evidenced by:	A 385	The Chief Nursing Officer reviewed the Hospital's plans to ensure nursing leadership in the absence of the CNO. The plan includes: • Chief Nursing Officer • Director of Nursing • Nursing Directors and Managers over every nursing department	11/10/07



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A 386	Continued From page 79  This Standard is not met as evidenced by: Based on interview, the facility failed to provide the nursing staff with a clear plan for nursing leadership in the absence of the CNO and department directors/managers, resulting in delays in writing 5150's, pronouncing patient deaths, resolving conflicts, and verification of registry RN's authorization to work.  Findings:  During an interview with the ER CN at RSMC on October 3, 2007, the CN stated the facility had undergone changes in nursing leadership recently due to, "budget cutbacks." The CN stated they used to have 24 hour HS coverage at each facility, but with the changes, they now only had one HS covering both facilities (separated by > 5 miles) Monday through Friday from 7 a.m. to 7 p.m. The CN stated since this change occurred, the CN's were having problems with 5150's (application for a psychiatric evaluation) being written, pronouncement of patient deaths, conflict resolution with staff and patients/visitors, and verification of registry RN's so they can start their shift. She stated all of these things were taking longer since the change. The CN stated the HS could only be in one building at a time, and it was very difficult having them travel back and forth to cover both facilities.	A 386	<ul style="list-style-type: none"> <li>• Chief Nursing Officer</li> <li>• Director of Nursing</li> <li>• Nursing Directors and Managers over every nursing department</li> <li>• Nursing Directors for Resource Management, Case Management, Education</li> <li>• House Supervisors on site at each facility at a minimum whenever there is not one of the above physically present at a site</li> </ul> <p>The Chief Nursing Officer has directed that additional staff be trained to provide assistance with evaluating 5150's, pronouncing patients and providing conflict resolution assistance.</p> <p>The Chief Nursing Officer attends the monthly Charge RN meeting which provides opportunity for feedback about meeting nursing leadership requirements/needs.</p>	02/01/08  02/01/08 & ongoing
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A 386	Continued From page 80 During an interview with the HS at IVMC on October 4, 2007, at 4:25 p.m., the HS stated they were having difficulty doing all of the functions they did in the past when they covered only one facility. She stated they were in the process of, "Turning over," some of the responsibilities to the CN's. The HS stated there was no plan prior to making the change, so they were, "Making it up as we go."	A 386		
A 394	482.23(b)(2) LICENSURE OF NURSING STAFF  The nursing service must have a procedure in place to ensure that hospital nursing personnel for whom current licensure is required have a valid and current licensure.  This Standard is not met as evidenced by: Based on observation and interview, the nursing service failed to ensure each RN providing dialysis services through a contracted agency had a valid and current license, resulting in the potential for unlicensed persons to provide nursing care to dialysis patients.  Findings:  During a tour of the ICU at RSMC on October 2, 2007, at 10:32 a.m., an RN was observed in ICU room 3 performing dialysis on a patient. The RN was asked to explained the process he went through when arriving at the hospital to dialyze a patient. The RN stated he signed in at the nurse's station and got the key to the storage area where the dialysis machine was kept. The RN stated he did not tell the nursing supervisor he was in the facility, did not show his nursing	A 394	The Director of Resource Management established a new process that addresses tracking/signing in of contracted staff, maintenance and verification of licensure, certifications and competencies. New process establishes ability to provide annual performance evaluations on contracted staff. The process is as follows: a. A binder is kept in the House Supervisor's office at each site containing copies of licenses, certifications and competencies of all dialysis nurses employed by Davita that come to the Hospital to provide dialysis for patients. b. A binder of Davita's Policy and Procedures is kept in the House Supervisor's office at each site. c. The dialysis nurse must check in with the House Supervisor when he/she arrives and sign in the log book in the office. d. The House Supervisor must obtain an online verification of the dialysis nurse's license each time the dialysis nurse comes to the Hospital and confirm the	04/02/08

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A 394	<p>Continued From page 81</p> <p>license to anybody, and had never had his performance evaluated by the facility staff.</p> <p>During an interview with the ICU Director at IVMC on October 4, 2007, at 8:35 a.m., the Director stated the facility had a contract with a dialysis company named Davita. The Director stated the agreement with Davita was to have the nurse's licenses and competencies intact. The Director stated she had never checked the licenses or competencies of the dialysis nurses that came to either facility.</p> <p>During an interview with the HS at IVMC on October 4, 2007, the HS stated every time a registry nurse went to either facility, they had to report to the nursing office to check in. The HS stated if the registry nurse was at the facility for the first time, the HS was responsible for looking at the nurse's credentials, reviewing the competency packet provided by the registry, and verifying the nurse's license on line. The HS stated the performance of every registry nurse was evaluated at the end of every shift by facility staff. The HS stated the dialysis nurses did not check into the nursing office, so the HS on duty was not involved in reviewing their competencies, checking their license, or evaluating their performance. The HS stated she did not know what process the dialysis nurses followed. The HS stated there was no mechanism for the HS on duty to know when a dialysis nurse was in the facility providing care to a patient.</p> <p>During an interview with the CNO at IVMC on October 5, 2007, at 1 p.m., the CNO stated the dialysis nurses came to the facility, accessed the dialysis equipment located in their equipment closet, reported to the floor where they would be doing dialysis, checked the physician's order, and</p>	A 394	<p>presence of current competencies and evaluation.</p> <p>e. The primary nurse or the charge nurse will complete an evaluation of the dialysis nurse annually.</p> <p>f. The nursing staff, Davita manager, and House Supervisors were educated on this process.</p> <p>The Director of Resource Management sent facility orientation manuals to Davita Dialysis Services with new process instructions.</p> <p>The Director of Resource Management or designee is responsible for conducting an annual audit of Davita beginning June 2008, including verifying business license, proof of insurance, employee files for competencies, orientation, HPPA compliance, annual physical, and required licensure and certifications.</p> <p>The Director of Resource Management is responsible for reporting on services provided by Davita Dialysis Services to Performance Improvement/Risk Management Committee.</p>	<p>04/08/08</p> <p>04/08/08 &amp; ongoing</p> <p>04/08/08</p>

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 394	Continued From page 82 performed the dialysis treatment. The CNO stated the facility did not check the dialysis nurse's licenses or competencies, or evaluate their performance. The CNO agreed the dialysis nurses were under a contract like the registry nurses. The CNO stated she never thought about monitoring the dialysis nurses like she did the registry nurses, then stated, "we certainly can."	A 394		
A 397	<p><b>482.23(b)(5) PATIENT CARE ASSIGNMENTS</b></p> <p>A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.</p> <p>This Standard is not met as evidenced by: Based on interview and record review, the facility failed to ensure the competence of the ICU nursing staff to recover post operative patients prior to making such assignments, resulting in the potential for post operative complications to occur without timely recognition and treatment.</p> <p>Findings:</p> <p>During a tour of the PACU at RSMC on October 2, 2007, at 2:30 p.m., the Clinical Lead of the preoperative area stated the patients coming to surgery from ICU went back to ICU for recovery. The Clinical Lead stated the ICU patients did not spend any time in the PACU, and they were recovered by the ICU nursing staff. She stated there was a tracheostomy (a hole placed through the neck and into trachea to assist with airway</p>	A 397	<p>Policy review determined that there was no current policy for recovery of patients in the ICU. In April of 2008 a policy and competency was established to include the Aldrete Score and Malignant Hyperthermia.</p> <ol style="list-style-type: none"> <li>1. The purpose of this policy is to assure that all patients recovering from a general anesthetic in the ICU will have the same standard of care across the continuum.</li> <li>2. The new policy outlines the guidelines for use of the Aldrete Score, criteria for hemodynamic monitoring and Malignant Hyperthermia to be consistent with the Post Anesthesia Recovery Room.</li> <li>3. All staff were educated to the new policy and completed the Malignant Hyperthermia competency in the LMS system.</li> <li>4. Monthly chart audits will be conducted on patients that are recovered in the ICU.</li> <li>5. All current staff will be updated on this competency and on a yearly basis. This competency will become part of the new hire orientation process.</li> </ol>	04/09/08

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A 397	<p>Continued From page 83 .</p> <p>management and breathing) done on a patient that came from ICU that day, and the patient went back to ICU for recovery from anesthesia.</p> <p>During an interview with the OR Director at IVMC on October 4, 2007, at 3:10 p.m., the Director stated the neurosurgery patients went directly back to ICU for postoperative recovery, and other ICU patients were recovered in the ICU postoperatively depending on the circumstances.</p> <p>During an interview with ICU RN 1 at IVMC on October 5, 2007, at 9:32 a.m., the RN stated she received patients from the OR immediately following surgery, and monitored the patients during their recovery from anesthesia. RN 1 stated she did not know what an Aldrete Score (a score used to determine how much recovery from anesthesia has occurred) was. RN 1 stated she did not know what MH was, or what medication was used to treat it.</p> <p>The Director of ICU was present during the interview, and stated the anesthesiologist did a class on MH for the ICU nurses one time, and all of the nurses watch the video of the class.</p> <p>During an interview with ICU CN 1 on October 5, 2007, at 9:39 a.m., the ICU CN stated patients came directly back to the ICU from surgery if they were on a ventilator (machine used to aid in breathing) or if they had a neurosurgical procedure done. ICU CN 1 stated she did not remember seeing a video on MH, but, "I believe there was something about that in skills day." ICU CN 1 stated she did not know what the treatment for MH was, but she would get the medication from the pharmacy (the medication was located in the PACU). ICU CN 1 stated she did not know what an Aldrete score was.</p>	A 397	Responsible Party: ICU Managers and Director.	04/09/08
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A 397	<p>Continued From page 84</p> <p>During an interview with ICU RN 2 on October 5, 2007, at 9:45 a.m., ICU RN 2 stated she received neurosurgery patients immediately from surgery, and she monitored the patient for recovery from anesthesia. The RN stated she was trained to recover patients by an experienced ICU nurse. The RN stated she did not know what an Aldrete score was. The RN stated she had heard of MH, but she did not know what medication was used for it's treatment, where to get the medication, or how to use the medication.</p> <p>During a review of orientation and competency information on October 5, 2007, at 12:30 p.m., it was noted the ICU documents did not contain information on recovering patients from anesthesia. The orientation and competency verification done by the nurses in PACU included location and use of the MH cart, documentation requirements for the PACU, knowledge of medications specific to the PACU (including dantrolene used for MH), and a specific section on the causes, S/S, and treatment of MH. The orientation and competency verification done by the ICU nurses did not contain this information.</p> <p>Review of documents from a class done by the anesthesiologist (located with the PACU orientation and competency information) indicated, "Though MH most frequently occurs in the OR....it can develop outside of the OR....after a triggering agent is given. That is why it is crucial that nurses who work in areas like ICU....know how to recognize the signs of this disorder and initiate early treatment."</p>	A 397		
A 398	<p>482.23(b)(6) SUPERVISION OF CONTRACT STAFF</p> <p>Non-employee licensed nurses who are working</p>	A 398		

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A 398	<p>Continued From page 85</p> <p>in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.</p> <p>This Standard is not met as evidenced by: Based on observation and interview, the CNO failed to ensure supervision and evaluation of the performance of nurses providing dialysis services through a contracted agency, resulting in the potential for ineffective, unsafe care for patients receiving dialysis.</p> <p>Findings:</p> <p>During a tour of the ICU at RSMC on October 2, 2007, at 10:32, an RN was observed in ICU room 3 performing dialysis on the patient. The RN was asked to explain the process he went through when arriving at the hospital to dialyze a patient. The RN stated he signed in at one the nurses station and got the key to the storage area where the dialysis machine was kept. The RN stated he did not tell the nursing supervisor he was in the facility, did not show his nursing license to anybody, and had never had his performance evaluated by the facility staff.</p> <p>During an interview with the ICU Director at IVMC on October 4, 2007, at 8:35 a.m., the Director stated the facility had a contract with a dialysis company named Davita. The Director stated the</p>	A 398	<p>The Director of Resource Management established a new process that addresses tracking/signing in of contracted staff, maintenance and verification of licensure, certifications and competencies. New process establishes ability to provide annual performance evaluations on contracted staff. The process is as follows:</p> <ol style="list-style-type: none"> <li>A binder is kept in the House Supervisor's office at each site containing copies of licenses, certifications and competencies of all dialysis nurses employed by Davita that come to the Hospital to provide dialysis for patients.</li> <li>A binder of Davita's Policy and Procedures is kept in the House Supervisor's office at each site.</li> <li>The dialysis nurse must check in with the House Supervisor when he/she arrives and sign in the log book in the office.</li> <li>The House Supervisor must obtain an online verification of the dialysis nurse's license each time the dialysis nurse comes to the Hospital and confirm the presence of current competencies and evaluation.</li> <li>The primary nurse or the charge nurse will complete an evaluation of the dialysis nurse annually.</li> <li>The nursing staff, Davita manager, and House Supervisors were educated on this process.</li> </ol>	04/02/08

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A 398	<p>Continued From page 86</p> <p>agreement with Davita was to have the nurse's licenses and competencies intact. The Director stated she had never checked the licenses or competencies of the dialysis nurses that came to either facility.</p> <p>During an interview with the HS at IVMC on October 4, 2007, the HS stated every time a registry nurse went to either facility, they had to report to the nursing office to check in. The HS stated if the registry nurse was at the facility for the first time, the HS was responsible for looking at the nurse's credentials, reviewing the competency packet provided by the registry, and verifying the nurse's license on line. The HS stated the performance of every registry nurse was evaluated at the end of every shift by facility staff. The HS stated the dialysis nurses did not check into the nursing office, so the HS on duty was not involved in reviewing their competencies, checking their license, or evaluating their performance. The HS stated she did not know what process the dialysis nurses followed. The HS stated there was no mechanism for the HS on duty to know when a dialysis nurse was in the facility providing care to a patient.</p> <p>During an interview with the CNO at IVMC on October 5, 2007, at 1 p.m., the CNO stated the dialysis nurses came to the facility, accessed the dialysis equipment located in their equipment closet, reported to the floor where they would be doing dialysis, checked the physician's order, and performed the dialysis treatment. The CNO stated the facility did not check the dialysis nurse's licenses or competencies, or evaluate their performance. The CNO agreed the dialysis nurses were under a contract like the registry nurses. The CNO stated she never thought about monitoring the dialysis nurses like she did</p>	A 398	<p>The Director of Resource Management sent facility orientation manuals to Davita Dialysis Services with new process instructions.</p> <p>The Director of Resource Management or designee is responsible for conducting an annual audit of Davita beginning June 2008, including verifying business license, proof of insurance, employee files for competencies, orientation, HPPA compliance, annual physical, and required licensure and certifications.</p> <p>The Director of Resource Management is responsible for reporting on services provided by Davita Dialysis Services to Performance Improvement/Risk Management Committee.</p>	04/08/08  04/08/08 & ongoing  04/08/08 & ongoing

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A 398	Continued From page 87 the registry nurses, then stated, "we certainly can."	A 398		
A 404	482.23(c) ADMINISTRATION OF DRUGS  Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.  This Standard is not met as evidenced by: Based on record review and the observation of medication administration on October 4, 2007 medications were not administered in accordance with the orders of the practitioner responsible for the patient's care.  Patients 702 and 709 received the wrong dose of medication. Patient 801 received medication even though the physician's order stated it should have been held. Patient 802 had a delay of over an hour in receiving medication to treat sever pain. Patient 711 did not receive one dose of intravenous Reglan (a drug used for several different reasons such as nausea, vomiting etc)  Findings:  1. During a review Patient 702's emergency room record at the RSMC campus on October 2, 2007 beginning at 10:20 p.m. it was noted that on October 1, 2007 at 7 p.m. the physician ordered	A 404	The Chief Nursing Officer reviewed and revised the Medication Administration policy.  The Chief Nursing Officer reviewed the Hand-off Communication policy and found it to be appropriate for practice.  The Chief Nursing Officer directed that ED staff be re-educated in regards to the Hand-Off communication process specific to expectation during rest/meal periods.  The Chief Nursing Officer had "Beyond Blame," a video on safe medication practice by the Institute for Safe Medication Practice, shown to Housewide Charge Nurses who serve as frontline resources to nursing staff.  The Chief Nursing Officer had "Beyond Blame," a video on safe medication practice, shown to front line staff to further enhance safe clinical practice. This included nursing staff in Medical-Surgical-Telemetry, ICU, ED, Women's Services, and Surgical Services.  The Chief Nursing Officer established a competency regarding medication administration practice and begun	03/31/08  03/31/08  03/31/08  01/31/08  04/30/08  03/31/08

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A 404	Continued From page 88 Dilaudid (a potent opiate narcotic used for the relief of pain) 2 mg intravenously every 2 hours for mild pain, 3 mg intravenously every 2 hours for moderate pain and 4 mg every hours for severe pain. Documentation in the medical record section entitled "nursing procedure: medication" revealed a dose 1 mg of Dilaudid was administered at 1:15 a.m. on October 2, 2007. The nurse (Nursing Staff A) who administered the 1 mg dose was not available for interview at the time of the record review. Nursing Staff A was interviewed on October 3, 2007 at 4:45 p.m. She confirmed that there was no physician's order to administer Dilaudid 1 mg. She reported that the patient had previously received Dilaudid 3 mg but appeared to have not to have tolerated the dose so she gave only 1 mg. She realized later that the physician had ordered Dilaudid 2 mg. She sated she should have called or spoken with the physician for an order for a lower dose.  2. During the observation of medication administration on October 4, 2007 at 9:08 a.m. at the IVMC the medication nurse administered Lovenox 80 mg (a drug used to prevent blood clotting) subcutaneously to Patient 709. When the observations of the medication administration where reconciled with the physician orders at 10 a.m. on October 4, 2007 it was noted that the physician had ordered Lovenox 150 mg not 80 mg. A review of the medication administration record showed 80 mg of Lovenox had been administered every 12 hours since it was ordered on September 30, 2007 at 4:45 p.m. A close review of the order showed that the Lovenox dose appeared to have been written over and initialed. Pharmacy Staff C provided an original copy of the order from September 30, 2007 which showed that he prescriber had originally ordered Lovenox	A 404	checking nurse competencies in April 2008 in Medical-Surgical-Telemetry, ICU, ED, Women's Services, and Surgical Services.  The Chief Nursing Officer had the "Beyond Blame" safe medication practice video incorporated into New Hire Patient Care services orientation.  The Chief Nursing Officer provided re-education to physician staff regarding the writing of complete medication orders and the proper method for changing orders. Ongoing physician re-education will occur through the remainder of the 2nd quarter of 2008.  Nursing department Managers are responsible for making rounds and observing medication passes to ensure compliance with policy. Audits are conducted on a monthly basis and reported to Medication Safety Cmte quarterly.	02/28/08  04/30/08 & ongoing  04/30/08

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A 404	<p>Continued From page 89</p> <p>80 mg. At some unknown date and time the prescriber wrote over and changed the original dose. When interviewed at 10 a.m. on October 4, 2007, Pharmacy Staff C agreed that the current dose of Lovenox was 150 mg but that the prescriber should have discontinued the previous order and written an order for the new dose. The prescriber inappropriate changing of the order directly contributed to the wrong dose of Lovenox being given for an undetermined time,</p> <p>3. During record review on October 4, 2007 beginning at 2 p.m. in the intensive care unit of the IVMC it was noted that Patient 801 had an order to receive labetalol (a drug used to treat high blood pressure) intravenously. The order specified to hold the labetalol if the systolic blood pressure was below 140. Documentation in the medication administration section of the nursing progress notes showed Patient 801's blood pressure was below 140 beginning at 12:50 a.m. on October 1, 2007. The labetalol continued to be administered until 1:06 a.m. (an additional 16 minutes) at which time Patient 801's blood pressure was noted to be 47/23 and a "code blue was called". Documentation in the medical record showed the labetalol was not held until the code blue was called. Nursing Staff B who administered the medication ws off duty at the time of the review and was interviewed by phone at 3 p.m. on October 4, 2007. Nursing Staff B confirmed that the labetalol had continued to be administered even the blood pressure was below 140.</p> <p>4. During the reconciliation of observations made during the medication administration the October 4, 2007. It was noted at 9:50 a.m. that one scheduled dose of Reglan had not been</p>	A 404		

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A 404	Continued From page 90 administered to Patient 711 at 10 p.m. on October 3, 2007. The nurse who had failed to administer the medication was not available for interview. At 10 a.m. on October 4, 2007; Pharmacy Staff C reviewed the facility's record of drugs removed from the facility's automated drug delivery system and confirmed that Reglan had not been administered to Patient 711.  5. During a review of Patient 802's emergency room record at IVMC beginning at 4 p.m. on October 4, 2007 it was noted that the emergency room physician ordered 2 mg of Dilaudid at 11:20 a.m. on October 4, 2007. The Dilaudid was ordered for a pain level of 7 of 10. The Dilaudid was not administered until 12:46 p.m. (1 hour and 26 minutes after being ordered). When interviewed on October 4, 2007 at 4:30 p.m., Nursing Staff C reported she had been at lunch when the order had been written. When she returned from lunch, she was assigned three patients - one with chest pain, one with congestive heart failure and Patient 802 who had abdominal pain. Due to the clinical need of the first two patients she reported she needed to assess and provide care to these patients first. She did confirm that waiting over an 1 hour and 20 minutes was too long to wait for pain control.	A 404		
A 438	482.24(b) FORM AND RETENTION OF RECORDS  The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.	A 438	The Rehabilitation Manager developed a new procedure for the admission of outpatients so that a copy of each patient's Consent to Treat is placed in the patient's rehabilitation chart.	01/24/08

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A 438	Continued From page 91	A 438	Under the new charting process, all Rehabilitation disciplines chart in one patient chart rather than in separate charts.	01/24/08
	<p>This Standard is not met as evidenced by: Based on observation, staff interview and review of the facility's clinical records and policies and procedures, IVMC failed to ensure that all components of the clinical records for 6 of 6 patients receiving outpatient therapy services. (Patients 506, 507, 508, 509, 510 and 511) were readily accessible.</p> <p>Findings:</p> <p>Review of Patient 506's clinical record begun at 12:56 pm. on October 4, 2007 revealed no consent for treatment.</p> <p>Review of Patient 507's clinical record begun at 1:11 pm. on October 4, 2007 revealed no consent for treatment. The clinical record documentation indicated that the patient had received speech therapy services from February 23, 2007 up to and through the date of the survey. The clinical record did not contain a physician's order for speech therapy services provided between June 7, 2007 and August 6, 2007.</p> <p>Review of Patient 508's clinical record begun at 1:55 pm. on October 4, 2007 revealed no consent for treatment.</p> <p>Review of Patient 509's clinical record begun at 2:03 pm. on October 4, 2007 revealed no consent for treatment.</p> <p>Review of Patient 510's clinical record begun at 2:06 pm. on October 4, 2007 revealed no consent for treatment. The clinical record documentation</p>		<p>The Rehabilitation Manager has implemented a new tracking log for assuring that the current plan of care is signed; each outpatient visit triggers the clerical assistant to verify the status of the plan of care.</p> <p>The Rehabilitation Manager reviewed and revised Admin Policy #102 to address the process of including a copy of the conditions of admission in the patient's rehabilitation services chart.</p> <p>The Rehabilitation Manager provided education to therapy staff on the revised process.</p> <p>The Rehabilitation Manager is responsible for checking the outpatient charts monthly to confirm they are complete. This audit has been added to the PI program as a Quality Indicator, and results are reported quarterly at PI committee.</p> <p>The Hospital nevertheless respectfully disagrees that much of this citation describes a violation of the rule. The fact that portions of active outpatient records were kept where the therapists had access to them and consolidated when they were scanned into the electronic medical records system does not mean that the records violated the rule.</p>	01/24/08 01/24/08 01/24/08 01/24/08 & ongoing

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A 438	<p>Continued From page 92</p> <p>indicated that the patient had received occupational therapy services from December 2006 up to and through the date of the survey. The clinical record did not contain physician's orders for occupational therapy services provided between December 13, 2006 and January 8, 2007, February 2, 2007 and April 11, 2007 and August 11, 2007 and September 20, 2007.</p> <p>Review of Patient 511's clinical record begun at 2:11 pm. on October 4, 2007 revealed no consent for treatment. The clinical record documentation indicated that the patient had received occupational therapy services from June 2007 up to and through the date of the survey. The clinical record did not contain physician's orders for occupational therapy services provided between September 17, 2007 and October 3, 2007.</p> <p>During an interview begun at 2:27 pm. on October 4, 2007 the director of physical therapy acknowledged that Patient 507's clinical record did not contain a physician's order for speech therapy services provided between June 7, 2007 and August 6, 2007.</p> <p>During an interview begun at 2:35 pm. on October 4, 2007 speech therapist 1 acknowledged that Patient 507's clinical record did not contain a physician's order for speech therapy services provided between June 7, 2007 and August 6, 2007.</p> <p>During an interview begun at 2:38 pm. on October 4, 2007 the director or physical therapy acknowledged that Patient 510's clinical record did not contain physician's orders for occupational therapy services provided between December 13, 2006 and January 8, 2007, February 2, 2007 and April 11, 2007 and August 11, 2007 and</p>	A 438	The citation itself describes that the consents for treatment were retrieved and presented to the surveyor during the survey, indicating that they were readily retrievable.		

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A 438	Continued From page 93 September 20, 2007. The director acknowledged that Patient 511's clinical record did not contain physician's orders for occupational therapy services provided between September 17, 2007 and October 3, 2007. The director acknowledged that the clinical records of Patients 506, 507, 508, 509, 510 and 511 did not contain signed consents for treatment. The director stated that the rehabilitation services maintained separate charts for each discipline providing services to a patient. The records were consolidated at the time they were scanned into the electronic medical records system.  During an interview begun at 3:04 pm. on October 4, 2007 speech therapist 1 stated that she had reviewed other clinical records for Patient 511 and was unable to locate a physician order for occupational therapy services provided between September 17, 2007 and October 3, 2007.  During an interview begun at 4:13 pm. on October 4, 2007 the director of physical therapy and the director of quality presented signed consents for treatment for Patients 506, 507, 508, 509, 510 and 511. The directors stated that the consents had been located in the medical records office at RSMC.	A 438		
A 451	482.24(c)(1) MEDICAL RECORD SERVICES  All patient medical record entries must be complete.	A 451		
A 453	This Standard is not met as evidenced by: 482.24(c)(1) MEDICAL RECORD ENTRIES AUTHENTICATED	A 453		

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A 453	<p>Continued From page 94</p> <p>All patient medical record entries must be authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</p> <p>This Standard is not met as evidenced by: Based on interview and record review, the facility failed to ensure the treating therapist authenticated all entries in the clinical record for 1 of 2 patients (Patient 508) receiving outpatient physical therapy at IVMC, resulting in the inability to identify the therapist who provided services to the patient.</p> <p>Findings:</p> <p>A review of Patient 508's clinical record on October 4, 2007, at 1:55 p.m., revealed a physical therapy evaluation and plan of care dated August 17, 2007. The evaluation and plan of care were not authenticated to facilitate identification of the therapist completing the entry.</p> <p>During an interview with the Director of Physical Therapy on October 4, 2007, at 2:38 p.m., the director acknowledged that Patient 508's clinical record contained an unsigned physical therapy evaluation and plan of care dated August 17, 2007. The director stated that all clinical record entries were to be signed by the professional making the entry.</p> <p>A review of the facility's policies and procedures on October 4, 2007 revealed a policy titled "Physical Therapy -- Initial Patient</p>	A 453	<p>The Manager of Rehabilitation Services re-educated physical therapy department staff on the process and importance of authenticating their documentation during the October and November staff meetings.</p> <p>In October 2007, the Manager of Rehabilitation Services had a retrospective chart review done of 30 charts that included all pertinent documentation data points. This review evidenced a 100% compliance rate in the authentication of rehabilitation related documentation. This information was reported at the November 2007 Organizational Performance Improvement Committee.</p> <p>The Manager of Rehabilitation Services has had signature authentication via chart review added to the quarterly PI report.</p>	<p>10/17/07 &amp; 11/14/07</p> <p>11/30/07</p> <p>11/30/07</p>

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A 453	Continued From page 95 Assessment/Reassessment." The policy listed the components of a complete evaluation including "Physical therapist's signature and date."	A 453		
A 490	<p><b>482.25 PHARMACEUTICAL SERVICES</b></p> <p>The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.</p> <p>This Condition is not met as evidenced by: Based on observations, staff interviews and record review, the pharmaceutical services provided by the facility did not meet the needs of the patients.</p> <p>The facility emergency supply of medications for the treatment of Malignant Hyperthermia (a life threatening medical emergency) did not meet the standards established Malignant Hyperthermia Association of the United States. See A 951 pertaining to the failure to maintain emergency medication in accordance with standards of medical practice and patient care. Patient 705 was administered a long acting narcotic product contrary to the warnings of the manufacture and national organizations for</p>	A 490	See corrective action at Tags A500, A505, A507, and A951	

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A 490	<p>Continued From page 96 patient safety. See A 500 The facility failed to have a system to ensure that droperidol (a drug to treat nausea) was used in a manner consistent with manufacturer's and Food and Drug Administration warnings. (Patient 705, 711 and 703) See A 500 Patient 706 was administered a long acting narcotic for the treatment of addiction contrary to the Uniform Controlled Substance Act - California State Law. see A 500 The RSMC used the same "Laminar Flow Biological Safety Cabinet" (BSC) for the preparation of both hazardous drugs and intravenous admixtures. Not all written policies and procedures for the procurement, storage, distribution, dispensing and uses of drugs and chemicals are developed by the committee specified in state law. see A 500 The facility lacked guidelines, protocols or policies, procedures for the use of high risk medication (norepinephrine) that ensured this medication would be used in a safe, consistent and objective manner. (Patient 708) see A 500 The facility protocol for the use of propofol (a drug used for anesthesia and sedation) allowed the drug to remain in use longer than currently recommended by the Food and Drug Administration. The use of propofol solution for longer than 6 hours placed patients at an increased risk for a bacterial infection. Patient 708 see A 500 Outdated and otherwise unusable drugs where available for patient use. see A 505 The facility's policy for automatically stopping medications did not ensure medications would be stopped after the pre-determined time established by the medical staff. See A 507 The cumulative effect of the systemic problems</p>	A 490		

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A 490	Continued From page 97 resulted in the hospital provision of pharmaceutical services in an unsafe environment.	A 490		
A 500	<b>482.25(b) CONTROL AND DISTRIBUTION OF DRUGS</b>  In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.  This Standard is not met as evidenced by: Based on observations, staff interviews and record review, drugs and biologicals were not controlled and distributed in accordance with the applicable; standards of practice, consistent with state law and in a manner to promote patient safety.  Patient 705 was administered a long acting narcotic product contrary to the warnings of the manufacture and national organizations for patient safety. The facility failed to have a system to ensure that droperidol (a drug to treat nausea) was used in a manner consistent with manufacturer's and Food and Drug Administration warnings. (Patient 705, 711 and 703) Patient 706 was administered a long acting narcotic for the treatment of addiction contrary to the Uniform Controlled Substance Act - California State Law. The RSMC used the same "Laminar Flow	A 500	<b>2. DROPERIDOL (Inapsine)</b> The Pharmacy Director reviewed the black box warning regarding the use of Droperidol.  The P&T Committee reviewed and discussed the use of Droperidol including the information provided by the FDA black box warning and current literature on this topic.  The Chief of Staff (acting), the Chair of the Pharmacy and Therapeutics Committee, and the Pharmacy Director made the decision to remove Droperidol from the Hospital Formulary.  Implementation: 1. The P&T Committee Chair signed and had an informational memorandum circulated to the physician and non-physician staff notifying them that Droperidol had been removed from the Hospital Formulary. 2. Clinical Directors in the Pharmacy and Nursing areas provided direct education to the staff that orders for Droperidol must not be honored as it is not on the Hospital Formulary. The Pharmacy or Nursing staff must contact the ordering physician, advise him/her of the Formulary change, and request that the physician provide an order for an alternate medication.	10/05/07  12/18/07  06/09/08  06/10/08  06/10/08

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A 500	Continued From page 98 Biological Safety Cabinet" (BSC) for the preparation of both hazardous drugs and intravenous admixtures. Not all written policies and procedures for the procurement, storage, distribution, dispensing and uses of drugs and chemicals are developed by the committee specified in state law. The facility lacked guidelines, protocols or policies, procedures for the use of high risk medication (norepinephrine) that ensured this medication would be used in a safe, consistent and objective manner. (Patient 708) The facility protocol for the use of propofol (a drug used for anesthesia and sedation) allowed the drug to remain in use longer than currently recommended by the Food and Drug Administration. The use of propofol solution for longer than 6 hours placed patients at an increased risk for a bacterial infection. Patient 708  1. During a review of Patient 705's closed medical record from RSMC on October 3, 2007 beginning at 7:50 a.m. it was noted that on September 12, 2007 at 9:25 p.m. the physician ordered Dilaudid (a narcotic used to treat pain) intravenously every 3 hours as needed and Duragesic patch 25 mcg every 72 hours. Duragesic is a transdermal (through the skin) or topical product which deliver a consist dose of the very potent narcotic fentanyl for the relief of chronic and severe pain. Patient 705 was an 79 year old patient who was admitted to the facility on September 4, 2007 for complaints of back pain and generalized weakness as well as some dizziness and nausea. Prior to the start of the Duragesic patch and the as needed Dilaudid she	A 500	1. & 3. FENTANYL (Duragesic) PATCH  The Medical Staff was advised of the CMS survey findings. The issues were discussed at the PI/RM Committee and at MEC on 10/11/2007. This information included aspects of medication administration specific to physicians. The report was forwarded to the Board of Governors on 10/15/2007.  The P&T Committee wrote and approved a policy defining the appropriate criteria and contraindications for prescribing fentanyl transdermal patches. The policy (Pharmacy #F5, Fentanyl Transdermal Patches) addresses the issues identified in the FDA-approved product information. The Pharmacy Director educated the pharmacy staff on the new policy.  The Pharmacy Director confirmed that all Fentanyl patches were removed from ED PYXIS machines and therefore not available to the ED staff.  The ability of nursing staff on any unit to override this medication prior to Pharmacy review was revoked 06/09/2008. Therefore, any request for Fentanyl patches must be reviewed by Pharmacy for appropriateness, based on the criteria in Pharmacy Policy #F5, before the medication is dispensed to the nursing staff for administration.  At the Department of Emergency Medicine meeting, the Critical Care Director provided the ED physicians with additional information regarding the Uniform Controlled Substance Act provisions prohibiting the dispensing, administering, or prescribing of a narcotic for the treatment of addiction outside of those facilities and programs identified in the law.	10/15/07  12/31/07  04/09/08  06/09/08  06/10/08

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A 500	<p>Continued From page 99</p> <p>had not received any opiates or narcotics at the hospital.</p> <p>When asked at 8:20 a.m. on October 3, 2007 if the use of a Duragesic Patch on a patient who had no record of receiving a narcotic at the facility. Pharmacy Staff A reported that the Dilaudid and the Fentanyl had been started after the pharmacy was closed so it would not had been reviewed prior to its use. He further reported the facility had recently started a system (no dated specified) where new orders at RSMC started after the pharmacy was closed were to be faxed to IVMC which had a 24 hour pharmacy. The questioned was then rephrased to if the order was at 9 a.m. when the pharmacy was opened should it have been questioned. Pharmacy Staff A reported that the pharmacy probably would be busy at 9 a.m. and therefore he would not expect it to be reviewed. Pharmacy Staff B who was present during this interview stated that the order would be eventually reviewed but if the pharmacy is busy they would have to prioritize the work load. It was not clear if Pharmacist Staff B thought the use of the Duragesic was questionable.</p> <p>Further review of the record revealed that Patient 705 had receive Oxycodone 10 mg extended release daily prior to her admission. The warning below specifically states that prior to the use of a Duragesic patch a patient should have received oxycodone 30 mg per day for at least a week</p> <p>Due to a number of patient deaths related to the use of transdermal fentanyl the drug product package insert includes the following warning:</p> <p>DURAGESIC® should ONLY be used in patients who are already receiving opioid therapy, who</p>	A 500	<p>The Director of Pharmacy sent memoranda to Nursing departments about contraindications for administering fentanyl transdermal patches, including prohibition on the administration of narcotics to treat an addict outside of those facilities and programs identified in the law. Nursing Managers communicated this information to staff.</p> <p>Monitoring:</p> <p>1. Prior to dispensing, a hospital pharmacist must review all orders for Fentanyl patches according to FDA guidelines stated in Policy F5. The pharmacist must not execute orders not conforming to the criteria and must inform the prescriber of the policy and request alternate orders as appropriate for the patient.</p> <p>2. The Pharmacy Director is responsible for reporting to the P&amp;T Committee the findings of the review of Fentanyl transdermal patch orders. The Committee analyzes the data and determines appropriate action and follow-up as indicated.</p> <p>4. LAMINAR FLOW HOOD</p> <p>The Pharmacy Director ordered a separate laminar flow hood for preparation of non-chemotherapeutic medications.</p> <p>The Pharmacy Director will report to P &amp; T Committee when the 2nd laminar flow hood is installed.</p> <p>5. ASSURING ALL PHARMACY POLICIES ARE APPROVED:</p> <p>The P&amp;T Committee reviewed and approved the Pharmaceutical Waste Policy. Committee on Oct. 24, 2007. The Pharmacy Director is responsible for assuring that all</p>	<p>06/10/08</p> <p>05/12/08 &amp; ongoing</p> <p>May 2008</p> <p>10/24/07 &amp; ongoing</p>



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A 500	<p>Continued From page 101</p> <p>well-meaning but misinformed primary care physicians or surgeons have prescribed the drug for opiate-naive patients under contraindicated circumstances such as acute post-operative pain. Unfortunately, pharmacists have often filled these prescriptions without question, and nurses caring for patients have applied the patches without recognizing the prescribing error. ISMP is deeply troubled by these practices and alarmed by what appears to be a steady stream of reports of adverse events with fentanyl patches-including fatalities-caused by inappropriate prescribing, dispensing, and administration of the drug. The databases to which ISMP has access bear proof of this ongoing safety issue, and numerous case reports have already appeared in previous editions of ISMP newsletters (May 31, 2007; June 29, 2006; May 4, 2006; August 11, 2005; May 20, 2004; September 19, 2001).</p> <p>As noted two years ago in our August 11, 2005 newsletter (New fentanyl warnings: more needed to protect patients), Ortho-McNeil (Janssen), maker of DURAGESIC (fentanyl transdermal), issued a "Dear Health Professional" letter to bring attention to new boxed warnings in the product label related to improper prescribing. Likewise, FDA issued a Public Health Advisory (alert healthcare providers that deaths and overdoses had occurred in patients using both the brand name product Duragesic and the generic product. Despite these warnings, label changes, and publication of prescribing problems in ISMP newsletters and elsewhere, some practitioners still seem unaware of the dangers with this potent narcotic and the proper prescribing guidelines. of the article).</p> <p>Applicable standards of practice as identified by The American Society of Health-System Pharmacist practice guidelines for the delivery of pharmaceutical care require the pharmacy to</p>	A 500	<p>2. Should the pharmacist identify an incomplete order, the pharmacist is responsible for contacting the physician to discuss the issue and the clinical status of the patient, and to obtain a complete titration order</p> <p>3. The Pharmacy Director reports aggregate data at the P&amp;T Committee meeting for analysis, action planning and follow-up as appropriate.</p>	<p>06/10/08 &amp; ongoing</p> <p>06/10/08 &amp; ongoing</p>
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CENTERS FOR MEDICARE & MEDICAID SERVICES

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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>
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A 500	<p>Continued From page 102</p> <p>review orders for medications prior to administration and for real and potential medication problems to be clarified before the drug is used.</p> <p>2. During a review of Patient 703 record in the RSMC on October 2, 2007 beginning at 2 p.m. it was noted that the record contained a pre-printed order sheet entitled "Intra-Spinal Narcotic Form" that included Droperidol (dose to be specified by prescriber) every 3 hours as needed for nausea. The pre-printed order sheet did not restrict the use of the droperidol nor did it require a patient receiving droperidol to be receiving EKG monitoring. When interviewed at 2:15 p.m. on October 2, 2007, Pharmacy Staff A reported that the facility did not restrict the use of droperidol but that it was used sparingly.</p> <p>During a review of Patient 705's closed medical record from RSMC on October 3, 2007 beginning at 7:50 a.m. it was noted that on September 9, 2007 the physician ordered Droperidol 0.625 mg intravenously every 6 hours (on a routine basis). The order did not require the patient to be on a cardiac monitor. Per the interviewed at 2:15 p.m. on October 2, 2007 with Pharmacy Staff A the facility did not a policy, protocol or any restriction that required a patient to be on a cardiac monitor while receiving droperidol. Documentation in the record did show that Patient 705 was coincidentally on a cardiac monitor the entire time she was receiving the droperidol.</p> <p>During the reconciliation of observations made during the medication administration the October 4, 2007 at 9:50 a.m. at IVMC, a preprinted order sheet entitled "Laparoscopic Gastric By Pass Routine Postoperative day one orders was noted in Patient 711 record. This order set included an order for Droperidol 0.625 mg intravenously every 6 hours as needed for nausea. The order set did</p>	A 500	<p>7. PROPOFOL (Diprivan)</p> <p>The Pharmacy Director reviewed the FDA guidelines for Diprivan and confirmed that Southwest Healthcare System uses only Diprivan pre-mixed by the manufacturer in 20 ml, 50ml, and 100ml bottles.</p> <p>The Pharmacy Director confirmed that the six hour limit applies when the Diprivan is removed from the bottle via syringe for administration to patients receiving Diprivan for general anesthesia or for monitored anesthesia care (MAC) sedation, and that the hospital complies with that limit. The medication is prepared just prior to use for an individual patient. The vial is for single patient use, and is discarded after use or in six hours, whichever comes first. This practice is consistent with the FDA approved guidelines.</p> <p>The Pharmacy Director confirmed that according to the approved FDA guidelines, when Diprivan is administered directly from the spiked, premixed bottle, the medication can hang for 12 hours. This parameter applies specifically when patients receive a continuous IV infusion of Diprivan in the ICU for sedation. The bottle received from the manufacturer is directly spiked and connected to the IV infusion tubing. This eliminates the need to withdraw medication via syringe; no mixing of Diprivan by Pharmacy or Nursing staff is required or performed.</p>	<p>03/31/08</p> <p>03/31/08</p> <p>03/31/08</p>

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A 500	Continued From page 103 not require the patient to be on a cardiac monitor. Due to reported deaths and cardiac irregularities the manufacturer of Inapsine (brand name for droperidol) issued the follow letter in December, 2001. Reports of deaths associated with QT prolongation and torsades de pointes in patients treated with doses of INAPSINE (droperidol) above, within and even below the approved range have prompted Akorn to revise sections of the prescribing information, specifically 1) WARNINGS (including a new Box Warning) which call attention to the potential for serious morbidity and mortality, 2) INDICATIONS which reinforces the appropriate patient population for whom this product is intended, and 3) DOSAGE AND ADMINISTRATION which clarifies the available dosing information. There have been a number of reports of patients who have been treated with droperidol and who developed suspected or established torsades de pointes, at times leading to death. There have been additional cases of symptomatic arrhythmia associated with a prolonged QT interval after droperidol administration that have been submitted via ongoing safety surveillance activities. In addition, clinical investigators have reported a dose-related increase in QT prolongation with droperidol and replication of cardiac changes in a patient rechallenged with droperidol. Therefore, Acorn, Inc. has made important changes to the INAPSINE label. The labeling changes will be implemented within the next several weeks. In the meantime, we want you to be aware of this important safety information. Listed below are highlights of important changes to WARNINGS and INDICATIONS. You should consult the full prescribing information accompanying this letter for all of the changes.	A 500	Below is the FDA Warning, June 2007: "FDA ALERT [6/15/2007] - FDA is issuing this alert to inform healthcare professionals about several clusters of patients who have experienced chills, fever, and body aches shortly after receiving propofol for sedation or general anesthesia. FDA has tested multiple units of propofol vials and lots used in patients who have experienced these symptoms and to date, these tests have not identified any vials contaminated with bacteria or endotoxins." FDA recommends that healthcare professionals who administer propofol for sedation or general anesthesia carefully follow the recommendations for handling and use found in the current product labeling.  Below are the current guidelines provided in the FDA approved product labeling specific to Aseptic Technique for ICU Sedation: "Administration should commence promptly and must be completed within 12 hours after the vial has been spiked. The tubing and any unused portions of DIPRIVAN Injectable Emulsion must be discarded after 12 hours."  The Pharmacy Director confirmed that the Propofol policy reviewed at the time of survey was consistent with the FDA product information specific to Aseptic Technique for ICU Sedation. The Pharmacy Director re-verified that this information is current.	06/09/08

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A 500	Continued From page 104 The following BOX WARNING has been added: WARNING Cases of QT prolongation and/or torsades de pointes have been reported in patients receiving INAPSINE at doses at or below recommended doses. Some cases have occurred in patients with no known risk factors for QT prolongation and some cases have been fatal. Due to its potential for serious proarrhythmic effects and death, INAPSINE should be reserved for use in the treatment of patients who fail to show an acceptable response to other adequate treatments, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs (see Warnings, Adverse Reactions, Contraindications, and Precautions). Cases of QT prolongation and serious arrhythmias (e.g., torsades de pointes) have been reported in patients treated with INAPSINE. Based on these reports, all patients should undergo a 12-lead ECG prior to administration of INAPSINE to determine if a prolonged QT interval (i.e., QTc greater than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, INAPSINE should NOT be administered. For patients in whom the potential benefit of INAPSINE treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2-3 hours after completing treatment to monitor for arrhythmias. INAPSINE is contraindicated in patients with known or suspected QT prolongation, including patients with congenital long QT syndrome. The prescribing physician for Patient 703 was interviewed at 3 p.m. on October 2, 2007. He reported that he was aware of the boxed warning and did not use droperidol as a first line agent. He only used the droperidol in low doses and when other agents for nausea have been tried and	A 500	Monitoring: 1. The ICU Charge RN performs concurrent observations of ICU patients receiving IV Sedation with Propofol to ensure that the infusion hang-time does not exceed 12 hours. 2. The ICU Manager reports aggregate data at the Operational PI Committee. The Pharmacy Director also forwards and reports this information to the P&T Committee for action and follow-up as necessary.	06/09/08 & ongoing  06/09/08 & ongoing
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A 500	<p>Continued From page 105</p> <p>found ineffective. He also stated that all of his patients are EKG monitored but he could not answer for the whole facility. Pharmacy Staff A was interviewed at 3:15 p.m. on October 2, 2007. During the interview he stated that the Food and Drug Administrations (FDA) boxed warning was only advisory and that the FDA does not tell physicians how to prescribe. He further reported that that the use of a drug contrary to the manufacturer's and FDA's warnings was the same as using a medication for an off labeled use (an non FDA approved use supported by evidenced based medical literature). Title 21, Code of Federal Regulation, section Section 201.57(e). states " Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning of clinical data. "</p> <p>A black box warning is a Food and Drug Administration (FDA) requirement of a drug manufacturer to draw attention to special problems associated with that drug by prominently displaying that information within a black box in the product labeling. A black box is reserved for those special problems that may lead to death or serious injury. It is the strongest warning that the FDA requires manufacturer ' s to include in their product information.</p> <p>The presence of this high risk medication (Droperidol) on the preprinted order sets without any restrictions for its use or a facility written policy restricting the droperidol's use does not ensure that the drug would be used with accepted standards of practice as defined by the</p>	A 500			

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A 500	<p>Continued From page 106 manufacturer and Food and Drug Administration's warnings and could easily lead to the inappropriate use of the drug</p> <p>3. During a review on October 3, 2007 at 10 a.m. of Patient 706's closed medical record from the emergency room at RSMC on revealed that at 1:06 p.m. on April 24, 2007 the emergency room physician ordered s Duragesic 75 mcg patch for Patient 706. The initial The physician progress written at 11:31 a.m. stated "Withdrawal from heroin; heroin on/off x 1 year, off for 3 days". The physician dictated not regarding the emergency room stated "The patient is in withdrawal from heroin. The patient was given Ativan (anti-anxiety medication), Zofran (anti-nausea medication), Dilaudid (a narcotic medication), and Duragesic Patch to help her for the next 3 days. However, the mother has been instructed to have her follow up at Hemet Hospital." The initial nursing assessment documented at 10:56 a.m. on April 24, 2007 that Patient 706 was "Off Heroin for 3 days, unable to get thru withdraws, R Pupil larger. Pt Reports normal c/o intermittent R sided H/A (head ache) for last week" The assessment also documented that the patient had pain level of 8 on a 10 point scale. Based on state law -Business and Professions Code 4301, the Uniform Controlled Substance Act found in the Health and Safety Code 11153 (a), 11154,11217, and 11217.5 the dispensing, administering or prescribing a controlled substance for the treatment of addiction unless the patient is in a registered drug withdrawal program is prohibited. Patient 706 was ordered, dispensed and administered a control substance (Duragesic Patch) to "help her for the next 3 days".</p>	A 500			

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A 500	<p>Continued From page 107</p> <p>When interviewed on October 3, 2007 at 11:24 a.m., Pharmacy Staff B agreed that Patient 705 should not have received the Duragesic Patch for the treatment of addiction.</p> <p>4. During the review of the Pharmacy at RSMC on October 2, 2007 at 10:20 a.m., Pharmacy Staff B reported that the facility used the same "Laminar Flow Biological Safety Cabinet" (BSC) (a special cabinet used to prepare injectable cytotoxic medications such as cancer drugs) for the preparation of all intravenous solutions. The same cabinet was used for both hazardous medications (such as cytotoxic medications) and routine intravenous admixtures.</p> <p>Pharmacy Staff B reported don October 5, 2007 at 8 a.m. that the cabinet was decontaminated by swabbing the cabinet with alcohol and allowed to dry for 20 minutes.</p> <p>The National Institute for Occupational Health and Safety of the Centers for Disease Control and Prevention (NIOSH) recommendations state health care workers should ..."Prepare hazardous drugs in an area that is devoted to that purpose alone and is restricted to authorized personnel and Health care employers should ...Provide a work area that is devoted solely to preparing hazardous drugs and is limited to authorized personnel."</p> <p>ASHP "Guidelines on Handling Hazardous Drugs" Decontamination, deactivation, and cleaning. Decontamination be defined as cleaning or deactivating. Deactivating a hazardous substance is preferred, but no single process has been found to deactivate all currently available hazardous drugs. The use of alcohol for disinfecting the BSC or isolator will not deactivate any hazardous drugs and may result in the spread of contamination rather than any actual cleaning.</p> <p>The accepted standards of practice as</p>	A 500		

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A 500	Continued From page 108 established by the recommendations NIOSH and on ASHP statement regarding the decontamination of the cabinet is to prepare hazardous medications to prepared in an are solely designated for that purposes. 5. When interviewed on October 2, 2007 at 11:50 a.m., Pharmacy Staff A and Pharmacy Staff B reported that all policies procedures pertaining to the pharmacy services are reviewed, discussed and approved by the "Pharmacy and Therapeutics Committee". State law (Section 70263 (c)(1), Title 22, California Code of Regulations) requires the committee to develop the written policies and procedures fir the establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. 6. During a review on October 4, 2007 at 2:20 p.m. of Patient 708's record at RSMC an order to administer Levophed gts (drip - an intravenous administration method) (norepinephrine a drug used to increase or maintain blood pressure) to keep SBP (systolic blood pressure) above 90 was noted. When interviewed at 3 p.m. on October 4, 2007, Nursing Staff D reported that the facility did not have a protocol stating an appropriate starting dose, how often to adjust the dose or by how much to adjust the dose. Nursing Staff D did provide a copy of guidelines for the intravenous administration of several medications. These guidelines did provide starting dose ranges and ranges of by how much to adjust the levophed dose. That is the guidelines stated the initial dose was 8 to 12 mcg/min. There were no guidelines on when to use 8 versus 9 etc mcg/min. 7. During a review on October 4, 2007 at 2:20 p.m. of Patient 708's record at RSMC an order to administer propofol was noted. When interviewed at 3 p.m. on October 4, 2007 Nursing Staff D provided a copy of the facility's protocol for	A 500		



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A 505	Continued From page 110 on October 1, 2007 where noted. 3. During a review of medications stored on the anesthesia cart in Operating Room #2 at RSMC at 2:45 p.m. on October 2, 2007 seven (7) vials of undated of Atracurium (a medication used as an adjunct in surgery) and 4 undated vials of succinylcholine (a medication used as an adjunct in surgery) where observed to be stored at room temperature. Both the the Atracurium and the Succinylcholine have a limited stability when stored out side a refrigerator. The facility lacked a sytem to determine how long these drugs have been stored at room temperature and therefore could not ensure the stability or potency of either agent. 4. During a review of medications stored on the anesthesia cart in Operating Room #3 at RSMC at 2:50 p.m. one undated vial of succinylcholine, one undated vial of Zemuron (a drug used as an adjunct in anesthesia) and 7 vials of Atracurium were observed being stored at room temperature. Atracurium, Zemuron and the Succinylcholine have a limited stability when stored out side a refrigerator. The facility lacked a sytem to determine how long these drugs have been stored at room temperature and therefore could not ensure the stability or potency of either agent. 5. During a review of medications stored on the anesthesia cart in labor and delivery room at RSMC at 3:20 p.m. two vials of succinylcholine and 3 vials of Zemuron where observed being stored at room temperature. The facility lacked a sytem to determine how long these drugs have been stored at room temperature and therefore could not ensure the stability or potency of either agent.  6. The Operating Room Suite at RSMC was toured on October 2, 2007, at 2:35 p.m. There	A 505	refrigerated drugs and outdates in the Anesthesia Cart, the Malignant Hyperthermia Cart, ED, and OB areas and reports the results of the monitoring to the P&T Committee.		

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A 505	Continued From page 111 were bags of intravenous (IV) solutions stored on a cart in a small storage area. One bag, labeled "5% Dextrose, 1000 ml," had an expiration date of May 2006.  The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. Neither had an explanation for the expired bag of dextrose.	A 505		
A 507	482.25(b)(5) STOP-ORDERS FOR DRUGS  Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.  This Standard is not met as evidenced by: Based on a review of the facility's policies and procedures and a review of the medical staff rules and regulations drugs and biologicals would not be automatically stopped after the predetermined time established by the medical staff. The written policy conflicted with the time limites established in the medical staff rules and regulations.  Findings:  1. During a review of the facility policy and procedure entitled "Automated Stop Orders" it was determined that the facility written policy conflicted with the time frames established by the	A 507	The P&T Committee reviewed and revised the policy concerning Automatic Stop Orders for Medications was reviewed so that the policy is consistent with Medical Staff Rules and Regulations.  The Pharmacy staff was educated about the change in policy on the same day as the changes were approved.	04/07/08  04/07/08

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A 507	Continued From page 112 medical staff rules and regulations, The policy stated that anti--inflectives of 10 days while the medical staff rules and regulations stated antibiotics had a stop order of 7 days. The policy stated that schedule II drugs had a stop order of 3 days. The medical staff rules and regulations stated "narcotics" had a stop order of 3 days. Narcotics is a vague term that usually refers to oplate medication used to treat pain. Not al narcotic medications are in schedule II and not all schedule II medications are "narcotics". The rules and regulations of the medical staff stated that "all other drugs" had a stop order of 15 days. There was no designation in the policy for "all other drugs".	A 507		
A 528	<b>482.26 RADIOLOGIC SERVICES</b>  The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.  This Condition is not met as evidenced by: Based on observation, interview and record review, the facility failed to provide safe diagnostic radiological services to ED patients after hours, by failing to;  a. Track medical errors and adverse patient events through the PI process, with no mechanism for tracking ED misreads of x-rays (A286) (A529), and;  b. Ensure there was a system in place that	A 528	For corrective action see Tags A284, A286, A529, and A537.	

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A 528	Continued From page 113 supplies used for cardiac and radiological procedures were not outdated and unsafe for use (A284)(A537).  The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the provision of safe radiology services.	A 528		
A 529	482.26(a) SCOPE OF RADIOLOGIC SERVICES  The hospital must maintain, or have available, radiologic services according to the needs of the patients.  This Standard is not met as evidenced by: Based on interview and record review, the facility failed to ensure an integration of services between the Emergency Medicine Department and Imaging Department. The facility failed to perform a quality control assessment of x-ray reading discrepancies between the radiologists and emergency medicine physicians, resulting in a failure to track and trend discrepant x-ray readings between the two departments, and the potential for inappropriate diagnosis and treatment of patients receiving diagnostic x-rays in the ED after hours. The facility also failed to ensure supplies used for cardiac and radiological procedures at RSMC and IVMC were not outdated, and safe for use, resulting in the potential for injury and infection in patients undergoing surgical, cardiac and radiological procedures.  Findings:  The two hospitals used separate Emergency	A 529	Physician representatives from the Departments of Imaging and Emergency and the PI Director reviewed the policy, "Patient Contact after Discharge from the ED" (ED P#16) the decision was made to draft a new policy specific to the Medical Staff concerning variances in x-ray readings between Emergency Physicians and Radiologists. The new policy establishes a process to identify when there is a variance in the interpretation of imaging studies. When such a variance is identified: 1. Appropriate action is taken to alert a physician when a variance is identified that could impact the patient's plan of care. 2. The Medical Staff, as part of their ongoing efforts to improve the quality of care provided, review each variance on a regular basis to identify opportunities for improvement.  On 12/10/2007, the hospital implemented a digital imaging system referred to as "PACS" that provides better capabilities to track the variance.	12/10/07

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A 529	<p>Continued From page 114 Medicine Medical Groups to staff the two ED's.</p> <p>1. The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on October 4, 2007, at 1 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>2. A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the</p>	A 529	<p>Under the new process:</p> <p>1. The ED physician or PA reviews the exam and enters in PACS an internal note of their findings for each exam reviewed. Treatment is initiated as appropriate and the patient/representative is advised of the preliminary findings.</p> <p>2. The radiologist reviews the exam for a final interpretation and result reporting.</p> <p>a. If the Radiologist reading is different than the preliminary ED read, the Radiologist informs the on-duty ED physician about the variance so appropriate clinical action can be taken if necessary.</p> <p>b. The Radiologist documents the variance (where the official interpretation differs from the ED preliminary finding) in the final dictated report, and who was notified.</p> <p>c. The Radiologist copies the case information to the ED – QA Worklist in the PACS system. This worklist serves as the tracking log for potential ED "misreads."</p> <p>3. The on-duty ED physician reviews the patient's chart and takes appropriate clinical action to.</p> <p>a. Contact the patient or their representative to inform them of the final interpretation and any change in their plan of care.</p> <p>b. Document the action taken in the patient's medical record.</p>		

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A 529	<p>Continued From page 115</p> <p>radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>3. The policy governing both facilities titled, "Patient Contact After Discharge From the ED," was reviewed on October 3, 2007. The policy stated the following:</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist to see what the ED physician concluded;</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of the ED physician on duty;</p> <p>d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;</p> <p>e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for 3 reasons:</p> <ol style="list-style-type: none"> <li>1. Documentation in the patient's medical record,</li> <li>2. Serves as a log for performance</li> </ol>	A 529	<p>4. The variance readings are tracked by ED physician and type of exam to address trends and identify areas for improvement or change in practice.</p> <p>5. Variance rates and results of the reviews are reported to ED Committee, OPIC Committee and the Governing Board at part of the QAPI process.</p> <p>The PACS software company was contacted in February to assist in configuring the system to enable the required ED – QA Worklist tab. The PACS software company configured the tabs for the ED-QA Worklist. The function was tested and found to be functioning. The ED physicians and Radiologists were given reminders of the revised process. Additional written reminders were posted in the physician areas in the ED and Imaging departments.</p> <p>Responsible Party: ED and Imaging Department Chairs</p> <p>Monitoring:</p> <ol style="list-style-type: none"> <li>1. The ED Department Chair (or designee) provides oversight to the review of variances to consider trends or clusters of:             <ol style="list-style-type: none"> <li>a. Variance involving the same provider.</li> <li>b. Variances of similar types of exams.</li> </ol> </li> <li>2. The ED physicians review the variances to identify opportunities for improvement. Significant variances will be routed to the ED committee for</li> </ol>	<p>04/01/08</p> <p>Ongoing</p>

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A 529	<p>Continued From page 116 improvement activities, and,</p> <p>3. Can provide feedback to the initial ED physician;</p> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director or designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> <li>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</li> </ol> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>4. During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic</p>	A 529	<p>discussion and action as appropriate.</p> <p>3. Routine variance reporting will be incorporated into the ED Department peer review process for analysis and follow-up action as indicated. At a minimum, this will be done twice annually.</p> <p>4. Variance reviews are incorporated into the provider's reappointment profile.</p>	

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A 529	<p>Continued From page 117 finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).</p> <p>During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or 416 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."</p>	A 529		

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A 529	<p>Continued From page 118</p> <p>5. The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10 a.m. There were multiple wrapped angiocatheters and other equipment, for use in the Special Procedures/Cardiac Cath suite, stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angiocaths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angiocaths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.</p> <p>The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired supplies available for use.</p> <p>6. The Radiology Suite at IVMC was toured on October 4, 2007, at 2 p.m. Examination of the supplies in the room revealed one Vista 8 french endovascular catheter with an expiration date of September 2007, indicating that the period for safe use had ended 4 days prior. Three biliary stents (used to catheterize the gall bladder) were also expired September 2007. The staff was unable to explain why the expired instruments were stored with the supplies for patient use.</p>	A 529		
A 537	<p>482.26(b)(2) PERIODIC EQUIPMENT MAINTENANCE</p> <p>Periodic inspection of equipment must be made and hazards identified must be promptly corrected.</p>	A 537	<p>The Director of Perioperative Services changed the GI tech and SPD Tech job specific competencies to reflect that all enzymatic cleaners must be diluted per manufacture instructions using exact measurements of water and enzymatic</p>	10/31/07

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A 537	Continued From page 119  This Standard is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure angiocatheters, biliary stents, and other supplies for use in invasive procedures were inspected in a manner to prevent the use of expired products in patients, resulting in the potential for infectious complications of these procedures.  Findings:  1. The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10 a.m. There were multiple wrapped angiocatheters and other equipment for use in the Special Procedures/Cardiac Cath suite stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angiocaths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angiocaths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.  The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired instruments available for use.  2. The Radiology Suite at IVMC was toured on	A 537	cleaner. All GI techs, SPD techs and RN GI staff at both facilities have signed the revised job description competency. All GI and SPD personnel were updated on the enzymatic cleaner changes at the October 2007 staff meetings and OR board meetings. The policy on SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies was revised to reflect "all enzymatic cleaners are diluted per manufactures instruction." Random audits are currently done to check the validity of this practice.  All SPD and GI staff at Inland Valley and Rancho Springs Medical Centers were updated on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the revised SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies.  Responsible Party: Director of Perioperative Services or designee is conducting random audits to ensure compliance. Results of the audits are reported to the OPIC Committee to assure that corrective action is sufficient to assure staff comply with requirements.  Director of Imaging / Lead RN Cardiac Cath reviewed and revised the policy and procedure related to sterilization of TEE probes. The Lead RN reviews all inventory for outdates on the first week of each month. In addition, the Imaging Managers conduct bi-weekly random inspections that include a review of	10/31/07  10/27/07  10/27/07
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A 537	Continued From page 120 October 4, 2007, at 2 p.m. Examination of the Special Procedure Room revealed one Vista 8 french endovascular catheter with an expiration date of September 2007, indicating that the period for safe use had ended 4 days prior. Three biliary stents (used to catheterize the gall bladder) also expired September 2007. The staff was unable to explain why the expired instruments were stored with the supplies for patient use.	A 537	expiration dates.  The Imaging Department maintains a log to confirm that the require audits are conducted and the results of checking the expired items. The Director of Imaging reviews the log at least quarterly to confirm that the required inventories and random inspections are occurring and the results of the inventories and reviews. (continued on next page)	Ongoing
A 618	<b>482.28 FOOD AND DIETETIC SERVICES</b>  The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.  This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to provide an organized dietary service, staffed by adequate qualified personnel that met the needs of the patients, by failing to;  a. Ensure food and nutrition services departments	A 618	For corrective action see Tags A274, A619, A622, A628, A630, A631.	

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A 537		A 537	Continued from 121  Responsible Party: Director of Imaging / Lead RN Cardiac Cath  Monitoring: Physical Inventory Inspection log and inventory report from inventory computer system reviewed weekly by Lead RN.  The Cardio Manager revised the TEE cleaning logbook to include a column requiring documentation of Cidex test strip expiration date, which is to be filled in prior to use of the Cidex. Policy and procedure has been revised to reflect this practice. All staff involved in the cleaning of TEE equipment have been educated to this new procedure. The Cardio Manager reviews the log book on a monthly basis to assure compliance with the new procedures. The Cardio Manager added this item as a quality indicator under the PI Program and results of the reviews are reported to the PI Committee.  Responsible Party: Cardio Manager  Monitoring: Checked monthly and added to PI program as a Quality Indicator	Ongoing  04/02/08  Ongoing

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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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 patients. (See Instructions.) Except for nursing homes, the findings stated 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.

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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
A 618	Continued From page 121 were managed effectively, organized effectively, and had policies and procedures that reflected the current state regulations and acceptable standards of practice (A619);  b. Ensure dietary staff were competent and properly trained to store and cool foods appropriately, and check dishwashing equipment for proper chemical concentrations (A622);  c. Ensure meals were served to patients according to the menu and production sheets (A628);  d. Ensure patients were given the opportunity to select alternate foods (A628);  e. Ensure the kitchen had enough steam table wells to accommodate every food item required to comply with the diet orders of the practitioners responsible for their patients (A630), and;  f. Ensure the current diet manual approved by medical staff was followed by the dietary staff(A631).  The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the provision of safe and effective dietary services to the patients in the hospital.	A 618		
		A619	To relieve the Food and Nutrition Services Director (FNSD) from having to provide direct clinical patient care, the hospital hired an additional full-time Registered Dietician (RD). This has allowed for the following coverage at the hospitals:  1. Inland Valley Medical Center (122 beds): a. Monday – Friday: 2 RDs b. Saturday/Sunday: 1-2 RDs based upon volume and patient acuity.  2. Rancho Springs Medical Center (90 beds) a. 1 RD seven days per week b. An additional RD is scheduled on any day based upon volume and patient acuity.  The hospital also hired a per diem RD to provide more flexibility in scheduling. The per diem staff member is available to cover patient care assignments at either facility on an as needed basis. This keeps the Director focused on the Leadership aspects of the department.	FT-RD Hired 10/2007
A 619	482.28(a) ORGANIZATION OF DIETARY SERVICES  The hospital must ensure that specific food and dietetic services organization requirements are met.		To provide additional support in the Lead Diet Clerk role, the FNSD provided the following: 1. One staff member at Inland Valley Medical Center was cross-trained to the Lead Diet Clerk role. 2. The existing back-up Lead Dietary Clerk at Rancho Springs Medical Center was given updated information regarding the current expectations of the role.	Per Diem RD Hired 5/2008  Lead Clerk Training VMC – 8/2008 RSMS – 6/10/2008



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A 619	<p>Continued From page 123 responsible for both campuses, and; 3) leads in each kitchen (hospital). There was no manager for clinical nutrition.</p> <p>The DNFS explained in an interview on October 2, 2007, at 10 a.m., she had clinical responsibilities in one of the hospitals for two weeks because they were short-staffed. She also indicated that some of the cleaning had not been completed due to budget cut-backs.</p> <p>The role and responsibilities of the director of a dietary department had not been fulfilled. The writing and updating of policies and procedures, collaborating with other departments and services, approval of menus, and quality improvement had not been done. Patients were given diets that did not exist in the diet manual. The DNFS's explanation was that there were plans to update the menus.</p> <p>Patients on regular diets were being served LSLF diets because of lack of wells on the steam table. She stated she was not aware that the patients on regular diets were being served the wrong diet. Portion sizes were not consistent for same food between diets. No explanation or rationale was provided.</p> <p>Policies and procedures had not been updated and the Emergency Plan had a significant error whereby it stated, "During an electrical black out, the emergency generator will not supply electric power for the kitchen." Other policies do not reflect current community standards and HACCP principles. Hospital policies still reflect 45 degrees F as the temperature for holding cold foods, current standards recommend 41 degrees F. The last time these policies were reviewed was May, 2003.</p>	A 619	<p>c. In-house patient satisfaction survey d. Timeliness of Nutrition Assessment by the dietitian e. Refrigerators/Freezers temperatures with recording devices on freezers f. Cafeteria food Temperatures g. Tray line Temperatures h. Dish machine Temperatures i. Final Rinse Temperatures on Dish machine j. Sanitizing Solution Concentration in the Pot Sink</p> <p>The Food and Nutrition Service Director and Food Service Manager review the results of these QAPI activities monthly and report the results to the OPIC committee quarterly, which in turn reports to the Governing Body. All QAPI activities and progress are further discussed and tracked during the Department's monthly leadership meetings held monthly on the third Friday of the month.</p> <p>B. Ensure dietary staff are competent and properly trained to store and cool foods appropriately and check dishwashing equipment for proper chemical concentrations.</p> <p>1. Food and Nutrition Service Director researched HACCP and FDA guidelines and initiated recommendations regarding proper shelf storage in freezer.</p>	<p>Ongoing</p> <p>10/07/07</p>

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A		A 619	<p>continued from page 124</p> <p>2. Food and Nutrition Service Director provided education to all FNS staff concerning general freezer storage requirements including proper shelving locations for various types of foods.</p> <p>3. Food and Nutrition Service Director provided educations to all FNS staff regarding proper cooling of foods prior to placement in freezer and recognition of ice crystallization related to foods that were refrozen. Staff also received education on proper reporting if they believe food may have been thawed and refrozen.</p> <p>4. The Food and Nutrition Service Director changed the sanitization products and processes to be consistent between the two campuses and staff were educated concerning the new products and processes.</p> <p>5. Food and Nutrition Service Director provided educations to all FNS staff concerning proper use of all sanitizing products and sanitizing processes were reviewed.</p> <p>Responsible Party: Food and Nutritional Services Director</p> <p>Monitoring: FNS director requires staff to conduct bi-weekly freezer and refrigerator storage inspections. Random observations are conducted and concerns addressed and followed through with individual staff. A litmus test is used to ensure proper chemical concentration for sanitation.</p>	<p>10/27/07</p> <p>01/31/08</p> <p>10/10/08 07</p> <p>10/27/08 07</p> <p>OK TO CHANGE per TLC - Melinda - Brown DWS - Pam Divan, P 6-13-08 1035AM (P)</p> <p>Ongoing</p>
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE		TITLE		(X6) DATE

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A		A 619	<p>continued from page 124a</p> <p>The FNS Director requires that logs be kept to track daily compliance with new process and they are reviewed by FNS leadership staff weekly. As described above, patient satisfaction survey results and test tray information are reported quarterly through OPIC and begin the 2nd quarter of 2008.</p> <p>C. Ensure meals are served to patients according to the menu and production sheets.</p> <p>1. Food and Nutrition Service Director revised production sheets to reflect current portion size.</p> <p>Food and Nutrition Service Director educated FNS Department staff concerning the changes to the production sheets, including how to provide correct portion size</p> <p>2. Food and Nutrition Service Director implemented audits of test trays to monitor quality and temperature of foods.</p> <p>3. Food and Nutrition Service Director ordered and had installed additional steam table wells to ensure patients receive diets according to order from practitioner.</p> <p>Responsible Party: Food and Nutrition Services Director</p>	<p>10/10/07</p> <p>10/10/07</p> <p>04/30/08</p> <p>10/31/07</p>

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A		A 619	<p>continued from page 124b Food and Nutrition Service Director reviews the Cooks' log weekly to monitor food temperatures, quantity, and menu volume. This is an internal measure the department uses to improve its performance. As described above, overall order compliance is monitored as described above and the test tray information is reported through OPIC.</p> <p>D. Ensure patients are given the opportunity to select alternate foods</p> <p>Food and Nutrition Service Director reviewed and revised menus to add additional soup choices to dinner menu for increased variety.</p> <p>Food and Nutrition Service Director re-educated staff as to requirements and process for alternate menu choices.</p> <p>As described above, Food and Nutrition Service Director monitors compliance through test tray surveys and general patient satisfaction survey results. Patient satisfaction survey results are reported quarterly, to begin 2nd quarter of 2008, to OPIC.</p> <p>E. Ensure the kitchen had enough steam table wells to accommodate every food item required to comply with the diet orders of the practitioners responsible for their patients.</p>	<p>Ongoing</p> <p>10/10/07</p> <p>10/20/07</p> <p>Ongoing</p>

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A		A 619	<p>continued from page 124c Food and Nutrition Service Director ordered and had installed additional steam table wells to ensure patients receive diets according to order from practitioner.</p> <p>Food and Nutrition Service Director revised the in-house patient satisfaction surveys to include a query regarding the taste of the food.</p> <p>Food and Nutrition Service Director reviews test tray data to ensure patients are getting the correct diet at the appropriate temperature and the results of patient satisfaction surveys. As described above, Food and Nutrition Service Director reports the results of patient satisfaction survey to OPIC on a quarterly basis.</p> <p>F. Ensure the current diet manual approved by medical staff was followed by the dietary staff.</p> <p>1. Food and Nutrition Service Director met with Speech Therapy staff to discuss revision of diet manual to reflect changes in mechanical soft terminology vs. national dysphagia diet terminology.</p> <p>2. Food and Nutrition Service Director took diet manual P&amp;T for review/approval of revisions to address national dysphagia diet terminology change.</p> <p>3. Food and Nutrition Service Director presented diet manual revisions to OPIC for review/approval.</p>	<p>10/31/07</p> <p>04/07/08</p> <p>04/01/08</p> <p>10/2007</p> <p>10/24/07</p> <p>11/13/07</p>

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A		A 619	<p>continued from page 124d</p> <p>4. OPUS computerized diet management program was modified to reflect updated terminology.</p> <p>5. Food and Nutrition Service Director provided education to staff education related to national dysphagia diet terminology change and diet manual changes.</p> <p>As described above, Food and Nutrition Service Director implemented a diet order accuracy study implemented to validate accuracy of diet orders received and compared to physicians order. Study validated compliance in new process. Another study will be done starting in April 2008 to validate 11/2007 findings. The data from this validation study will be presented at OPIC following the completion of 2nd quarter 2008.</p>	<p>04/07/08</p> <p>04/07/08</p> <p>12/11/07</p>

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A 622	Continued From page 124	A 622		
A 622	482.28(a)(3) COMPETENT DIETARY STAFF  There must be administrative and technical personnel competent in their respective duties.  This Standard is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure dietary staff were competent and properly trained to store and cool foods appropriately, and check dishwashing equipment for proper chemical concentrations at RSMC and IVMC, resulting in the potential for cross contamination and growth of microorganisms in the kitchen, food borne illnesses in their patients, and improper cleaning of dishes and utensils.  Findings:  1. During the initial tour of the kitchen at RSMC on October 2, 2007, at 10:20 a.m., a build-up of ice on the freezer floor, measuring approximately 12 inches by 8 inches, on the northeast corner was observed. Other areas of the floor had solidified chunks of ice. Ice was also observed on the tops of food, and on the boxes stored on the shelves closest to the ceiling.  The following frozen items, stored in the freezer, were observed to have layers of ice crystals on the surface (a common sign of thawing and refreezing): a. Pans of cooked beef casserole and vegetable lasagna had layers of ice on the top;	A 622 A 622	1. Food and Nutrition Service Director researched HACCP and FDA guidelines and initiated recommendations regarding proper shelf storage in freezer. 2. Food and Nutrition Service Director provided education to all FNS staff concerning general freezer storage requirements including proper shelving locations for various types of foods. 3. Food and Nutrition Service Director provided educations to all FNS staff regarding proper cooling of foods prior to placement in freezer and recognition of ice crystallization related to foods that were refrozen. Staff also received education on proper reporting if they believe food may have been thawed and refrozen. 4. The Food and Nutrition Service Director changed the sanitization products and processes to be consistent between the two campuses and staff were educated concerning the new products and processes. 5. Food and Nutrition Service Director provided educations to all FNS staff concerning proper use of all sanitizing products and sanitizing processes were reviewed.  Responsible Party: Food and Nutrition Service Director  Monitoring: FNS director requires staff to conduct bi-weekly freezer and refrigerator storage inspections. Random observations are conducted and concerns addressed and followed	10/07/07  10/27/07  01/31/08  10/10/07  10/27/07  Ongoing

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A 622	<p>Continued From page 125</p> <p>b. A pan containing tilapia had similar ice crystals in the corners, and dried out, freezer burned edges on some of the raw fish pieces;</p> <p>c. A box containing chorizo sausage had ice crystals and chunks of ice inside. The chorizo was frozen as a solid block, not in individual pieces;</p> <p>d. A box of precooked chicken filets had ice crystals inside the box.</p> <p>The DNFS stated she did not know what the signs of thawing and refreezing were. She stated she did not know if the ice crystals found on the food in the freezer were a result of food thawing and refreezing, or if it was from the food being placed directly in the freezer after cooking. The DNFS stated if the food was placed directly in the freezer after cooking, the staff did not go through the proper cooling procedures before storing food in the freezer.</p> <p>Inside the freezer, cooked and ready to eat food items (ice, french toast, and pizza crust) were stored on shelves directly under raw fish and sausage. The FSM stated he was aware of the proper order of storage to prevent cross-contamination in the refrigerator, but the facility had not utilized that same principle in the freezers.</p> <p>2. During an inspection of the outside freezer at RSMC on October 2, 2007, at 11 a.m., a large mass of ice was observed, measuring approximately 40 inches long and 10 inches thick, on the east side of the wall of the freezer. There were icicles on the shelves all around the freezer, formed as a result of dripping water.</p> <p>The DNFS and FSM were present during the observation. Both stated this outside freezer</p>	A 622	<p>through with individual staff. A litmus test is used to ensure proper chemical concentration for sanitation. The FNS Director requires that logs be kept to track daily compliance with new process and they are reviewed by FNS leadership staff weekly. FNS Director reviews these logs at least monthly As described above, patient satisfaction survey results and test tray information are reported quarterly through OPIC and begin the 2nd quarter of 2008.</p>	
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A 622	<p>Continued From page 126</p> <p>worked well, but they had problems with ice build up, which had been reported to plant operations on several occasions. The FSM stated every time the power went out and the freezer inside went off, the staff would move some of the frozen foods to the outside freezer, and the frequent opening and closing of the doors may have resulted in fluctuations in the outside freezer temperature. The FSM stated it was his responsibility to clean the excess ice formed in the freezer. The FSM stated he did not know how long ago the task had been completed.</p> <p>3. At 10:15 a.m., on October 2, 2007, in the kitchen at RSMC, a dietary employee working in the dish room near the pots and pans sink was asked to demonstrate the procedure for testing the concentration of the sanitizer. Using a test strip, he immersed it in the iodine solution for approximately 25 seconds. Not satisfied with the result he observed, he retested with a new strip, immersing in the solution for approximately 15 seconds. The employee tried for the third time. When asked how long he needed to immerse the strip in the solution, he responded, "1 minute". The poster on the wall that demonstrated the procedure to test the sanitizer listed 30 seconds. However, the test strip container listed 5 minutes as the appropriate time for testing.</p> <p>4. On October 4, 2007, at 9:20 a.m., the cook responsible for dish washing duties at IVMC was asked to demonstrate the testing of the chemicals in the sanitizing sink. She proceeded to immerse the strip in the solution for approximately 1 minute. The posted instructions indicated the strip was to be immersed for approximately 5 seconds and the utensils for 1 minute.</p> <p>During an interview with the DNSF on October 4,</p>	A 622		

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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
A 622	<p>Continued From page 127</p> <p>2007, at 11 a.m., the DNFS stated the cook had been trained the day before. The DNFS stated the cook got confused and mixed up the utensil immersion time with the test strip immersion time.</p> <p>5. During tray line observation at IVMC on October 4, 2007, at 9:15 a.m., hot items were observed served from the steam table, and some items were reheated in the microwave oven as necessary to achieve the required serving temperature. Cold items were served from an unrefrigerated cart with no obvious mechanism or system to keep the items cold. Milk was the only item served from the refrigerator next to tray line.</p> <p>The following were some of the cold food temperatures taken:</p> <p>Yogurt                    54 degrees Fahrenheit Non-dairy creamer    54 degrees Fahrenheit Apple Juice            50 degrees Fahrenheit 2% Milk                38 degrees Fahrenheit (taken directly out of the refrigerator)</p> <p>The temperature for all the cold food items taken except for the cold milk was higher than the recommended holding temperature according to state regulation. A review of the hospital policy titled, "Infection Control Process," showed, "All perishable foods and beverages..... are maintained at 45 degrees F or below."</p> <p>The FDA food code requires that cold foods leave the kitchen at 41 degrees F or below.</p> <p>The dietary employee responsible for placing the cold items on the tray was interviewed at approximately 9:30 am on October 4, 2007. She stated it was not customary for the cold items to be placed on ice during tray line service. In</p>	A 622		

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A 622	Continued From page 128 response to a question on the frequency of temperature taking, she stated temperatures are taken at the beginning of tray line, but not mid way or upon conclusion.	A 622		
A 628	<p><b>482.28(b) MENUS</b></p> <p>Menus must meet the needs of the patients.</p> <p>This Standard is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure meals were served to patients at RSMC according to the menu and production sheets, resulting in patients receiving diets that were not ordered by their physician. The facility also failed to ensure that patients at IVMC were given the opportunity to select alternate foods, resulting in the same foods being served for two consecutive meals every day.</p> <p>Findings:</p> <p>1. A review of the RSMC lunch menu on October 2, 2007, showed patients on regular diets were to receive a choice of cream of chicken soup, bread crackers and white cake with; 1) oriental beef and vegetables on steamed rice, or; 2) oriental chicken salad. Patients on heart healthy, ADA and calorie controlled, and low sodium diets were to receive the LSLF version of these same foods.</p> <p>During tray line observation at RSMC on October 2, 2007, at 11:10 a.m., it was noted all of the patients on regular, heart healthy, ADA, calorie controlled, and low sodium diets were served the same food items. At the conclusion of the tray line service, this observation was shared with the cook and lead FSW. The lead FSW worker stated all of the patients, including those with an</p>	A 628	<p>A. Ensure meals are served to patients according to the menu and production sheets.</p> <p>1. Food and Nutrition Service Director revised production sheets to reflect current portion size.</p> <p>Food and Nutrition Service Director educated FNS Department staff concerning the changes to the production sheets, including how to provide correct portion size.</p> <p>2. Food and Nutrition Service Director implemented audits of test trays to monitor quality and temperature of foods.</p> <p>3. Food and Nutrition Service Director ordered and had installed additional steam table wells to ensure patients receive diets according to order from practitioner.</p> <p>Food and Nutrition Service Director reviews the Cooks' log weekly to monitor food temperatures, quantity, and menu</p>	<p>10/10/07</p> <p>10/10/07</p> <p>04/30/08</p> <p>10/31/07</p> <p>Ongoing</p>



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A 628	<p>Continued From page 130</p> <p>A review of the production sheets for that meal showed, for patients on the LSLF diets, the recommended utensil was a 3 oz ladle (but they were served with a 6 oz ladle during tray line), and patients on regular diets (not prepared) were to be served with the 6 oz ladle.</p> <p>The discrepancies observed in the serving sizes were discussed with the DNFS. The DNFS had no explanation or rationale for the different serving sizes for the same food item between the diets.</p> <p>3. A review of the menu on October 4, 2007, at IVMC showed for lunch and dinner, the same soup was served at both meals every day of the week. For example, on Mondays potato soup was served for both lunch and dinner, Tuesdays, cream of tomato soup, Wednesdays, chicken noodle, etc. The second option was tossed green salad, which was served both meals everyday.</p> <p>During an interview with the DNFS on October 5, 2007, at 10 a.m., the DNFS stated that was what the menu called for, and the hospital had plans to update the menus. She also stated the hospital had an alternate menu that patients could order from. The DNFS did not know how the patients were informed of the alternate menu, how they would access the alternate menu, or how many patients had ever requested an alternate menu.</p>	A 628		
A 629	<p>482.28(b)(1) THERAPEUTIC DIETS</p> <p>Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.</p>	A 629	<p>1. The FNS Director educated all food service and clinical staff regarding the requirement that each patient must receive the diet prescribed by the physician and how to obtain orders when there is a need to change or clarify the diet order.</p>	10/31/07

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A 629	Continued From page 131  This Standard is not met as evidenced by: Based on observation, staff interview and review of the facility's clinical records, RSMC failed to ensure that the therapeutic diet served to 1 of ___ patients (Patient 503) was ordered by a physician.  Finindgs:  Review of Patient 503's clinical record begun at _____ on _____ revealed a that a swallowing evaluation was completed by the speech therapist on September 30, 2007. The speech therapist recommended a mechanical soft diet with thin liquids and no breads. A corresponding note was written by the speech therapist in the physician's progress notes. There was no physician order for implementation of the recommended therapeutic diet.  Review of the _____ begun at _____ on _____ revealed that the patient had been served a mechanical soft diet with thin liquids and no breads since _____.  During an interview begun at _____ on _____ stated _____.  Review of the medical staff rules and regulations begun at _____ on _____ revealed no evidence that the speech therapist had been given privileges to modify a patient's diet.	A 629	2. Food and Nutrition Service Director met with Speech Therapy staff to discuss revision of diet manual to reflect changes in mechanical soft terminology vs. national dysphagia diet terminology. 3. Food and Nutrition Service Director took diet manual P&T for review/approval of revisions to address national dysphagia diet terminology change. 4. Food and Nutrition Service Director presented diet manual revisions to OPIC for review/approval. 5. OPUS computerized diet management program was modified to reflect updated terminology. 6. Food and Nutrition Service Director provided education to staff education related to national dysphagia diet terminology change and diet manual changes. 7. The Rehabilitation Manager educated the Speech Therapist to immediately notify physician when there is a need for a diet order or revised diet order or patients who are assessed as being dysphagic (difficulty swallowing).	10/31/07  10/24/07  11/13/07  04/07/08  04/07/08  10/31/07
A 630	482.28(b)(2) DIETS  Nutritional needs must be met in accordance with recognized dietary practices and in accordance	A 630	The FNS Director ordered and arranged for the installation of more steam table	10/31/07

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A 630	<p>Continued From page 132 with orders of the practitioner or practitioners responsible for the care of the patients.</p> <p>This Standard is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the kitchen at RSMC had enough steam table wells to accommodate every food item required to comply with the diet orders of the practitioners responsible for their patients, resulting in all patients with orders for a regular diet receiving a low sodium, low fat diet.</p> <p>Findings:</p> <p>A review of the RSMC lunch menu on October 2, 2007, showed patients on regular diets were to receive a choice of cream of chicken soup, bread crackers and white cake with; 1) oriental beef and vegetables on steamed rice, or; 2) oriental chicken salad. Patients on heart healthy, ADA and calorie controlled, and low sodium diets were to receive the LSLF version of these same foods.</p> <p>During tray line observation at RSMC on October 2, 2007, at 11:10 a.m., it was noted all of the patients on regular, heart healthy, ADA, calorie controlled, and low sodium diets were served the same food items. At the conclusion of the tray line service, this observation was shared with the cook and lead FSW. The lead FSW worker stated all of the patients, including those with an</p>	A 630	<p>wells to ensure the kitchen had enough steam table wells to accommodate every food item required to comply with the patient's diet orders.</p> <p>The FNS Director revised in-house patient satisfaction surveys to include a query regarding the taste of the food.</p> <p>The FNS Director created and implemented a tray survey to evaluate compliance with diet orders. As described above, the FNS Director reviews test tray data at least monthly to ensure patients are getting the correct diet at the appropriate temperature and reports results of the tray audits and patient satisfaction survey to OPIC quarterly.</p>	<p>04/07/08</p> <p>11/30/07 &amp; ongoing</p>
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A 630	Continued From page 133 order for a regular diet, received the LSLF version of each food item, because the regular entree was not prepared. The lead FSW stated the hospital did not have enough wells on the steam table to accommodate the different types/versions of food that needed to be prepared. The lead FSW and the cook agreed that patients on regular diets received diets not ordered by their physician.	A 630		
A 631	482.28(b)(3) THERAPEUTIC DIET MANUAL  A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.  This Standard is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to ensure the current diet manual, approved by the medical staff in March, 2006, was followed by the dietary staff, resulting in unapproved substitutes being provided to patients receiving soft textured diets at RSMC and IVMC.  Findings:  During tray line observation at the RSMC campus on October 2, 2007, at 11 a.m., one of the menu items prepared and served was a "surgical soft" diet. During preparation of the tray, the cook was observed making substitutions to this diet order. She placed mashed potatoes on the tray, when the menu called for rice.	A 631	1. Food and Nutrition Service Director met with Speech Therapy staff to discuss revision of diet manual to reflect changes in mechanical soft terminology vs. national dysphagia diet terminology. 2. Food and Nutrition Service Director took diet manual P&T for review/approval of revisions to address national dysphagia diet terminology change. 3. Food and Nutrition Service Director presented diet manual revisions to OPIC for review/approval. 4. OPUS computerized diet management program was modified to reflect updated terminology. 5. Food and Nutrition Service Director provided education to staff education related to national dysphagia diet terminology change and diet manual changes. 6. The Rehabilitation Manager educated the Speech Therapist to immediately notify physician when there is a need for a diet order or revised diet order or patients who are assessed as being dysphagic (difficulty swallowing).	10/31/07  10/24/07  11/13/07  04/07/08  04/07/08  10/31/07

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A 631	<p>Continued From page 134</p> <p>During an interview with the cook at RSMC on October 2, 2007, at 12:30 p.m., the cook stated the speech therapist had trained the dietary staff to eliminate rice from the "surgical soft" diet, and substitute it with mashed potatoes.</p> <p>A review of the hospital's diet manual (for RSMC and IVMC), approved by the medical staff in March 2006, indicated a "surgical soft" diet was not included in the diet manual, and was not one of the diets approved by the dietitian and medical staff. The diet manual included a "soft" diet. The soft diet was described in the hospital diet manual as, "consists of foods which are easy to digest, such as whole tender meats, cooked fruits and vegetables." Under the heading, "Foods Allowed," in the category of potato and starches, rice was listed. According to the hospital diet manual, the mechanical soft diet for the management for patients with dysphagia allowed rice.</p> <p>Based on the substitutions made, it was not clear what kind of diet the patient was served. During an interview with the DNFS on October 2 and 3, 2007, the DNFS stated the ST did not agree with the information in the diet manual regarding rice for patients with dysphagia who were on a soft diet. The DNFS stated the ST provided training for the dietary staff on what to include in the diets, and the training included the dysphagia and mechanically altered diets.</p> <p>The hospital diet manual recognized the three levels of NDD textures; NDD 1, NDD 2, and NDD 3. During an interview with the ST, she stated she disagreed with the approved dysphagia diets in the current hospital manual.</p> <p>A review of correspondence between the ST and</p>	A 631	<p>7. It is important to note that the Speech Therapy plan of care includes diet recommendations for patients. A physician's signature on the plan of care for diet changes constitutes an order for such.</p> <p>As described above, Food and Nutrition Service Director implemented a diet order accuracy study implemented to validate accuracy of diet orders received and compared to physicians order. Study validated compliance in new process. Another study will be done starting in April 2008 to validate 11/2007 findings. The data from this validation study will be presented at OPIC following the completion of 2nd quarter 2008.</p> <p>Southwest Healthcare System respectfully disputed the deficiency citation concerning the substitution of mashed potatoes for rice. Rice and mashed potatoes were both permitted under the soft diet requirements. However, the Speech Therapist, who is responsible for evaluating patients with difficulty swallowing, correctly noted that the use mashed potatoes are more easily swallowed than rice for individual with difficulty swallowing. This is important because rice creates a higher risk of aspiration. Therefore, any citations that fault the hospital for substituting mashed potatoes for rice in the surgical soft diet should be removed. See A274, A619, A629.</p>	11/30/07 & ongoing
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A 631	Continued From page 135 the DNFS, dated December 21, 2004, revealed that the NDD was discussed. The current hospital diet manual was approved by the Medical Staff in March 2006, with no changes in the soft diet information. The ST conducted training for the dietary staff in March 2007, and taught them not to use rice for mechanical soft diets, in conflict with the diet manual information.  During an interview with the ST and the DNFS on October 5, 2007, at 11 a.m., the DNFS stated she left the issue of texture modification to the ST. She also stated she and her staff did not provide any education to patients on texture modification. Both stated the issue was never brought to the P&T Committee for resolution. Both the ST and the DNFS agreed the items allowed in the diet manual did not match what was being served in the hospital.	A 631		
A 700	<b>482.41 PHYSICAL ENVIRONMENT</b>  The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.  This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the maintenance of patient safety by failing to:  a. Ensure that 17 of 18 pieces of electrically powered patient care equipment received calibration/electrical safety testing at the intervals determined by the facility. IVMC failed to ensure	A 700	For corrective actions see Tags A284, A724, and A726.	

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A 700	Continued From page 136 that 1 of 1 hydrocollators in the physical therapy department was adequately maintained (A724);	A 700		
A 724	b. Ensure proper temperature controls in two of two food storage freezers at RSMC, resulting in the potential for growth of microorganisms and food borne illness in patients and visitors. The facility also failed to ensure the proper storage of ready to eat food items at RSMC, resulting in the potential for juices from raw fish and sausage dripping on the ready to eat food items, cross contamination, and food borne illness in patients and visitors (A726).  The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the provision of a safe patient care environment.  482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE  Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.	A 724	The Director of Safety & Environment had a Biomed inventory completed, all equipment verified, and appropriate maintenance performed.  The Director of Safety & Environment contacted the vendor for the anesthesia machine and the preventive maintenance was completed.  The Director of Safety & Environment had preventive maintenance schedules aligned and put on an automatic schedule to be generated monthly for review and performance of preventive maintenance as it comes due.	12/31/07  10/25/07  12/31/07
	This Standard is not met as evidenced by: Based on observation, staff interview and review of facility's policies and procedures, IVMC failed to ensure that 17 of 18 pieces of electrically powered patient care equipment received calibration/electrical safety testing at the intervals determined by the facility. IVMC failed to ensure that 1 of 1 hydrocollators in the physical therapy			

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
A 724	Continued From page 137 department was adequately maintained.  Findings:  a) During a tour of the rehabilitation services area begun at 8:32 am. on October 4, 2007 one cold pac freezer, one paraffin bath (a heat treatment), one splint pan, five hi-lo plinth (an adjustable treatment table), four ultrasound machines (a treatment modality), one balance test plate, one hydrocollator (a water bath for storing hot packs) and one treadmill were observed affixed with calibration/electrical safety stickers indicating the equipment was due for service in December 2006. One ultrasound machine was not affixed with a sticker. One cold pac freezer was affixed with a sticker indicating that it was due for service in June 2007. The director of physical therapy, who accompanied the surveyor, acknowledged that the equipment had not received calibration/electrical safety testing at the intervals indicated on the service stickers.  Review of the facility's policies and procedures begun at 4:13 pm..... on October 4, 2007 revealed a policy titled "Equipment Management Program". The policy stated that all equipment used in the facility would be tested by the clinical engineering department and included in a regularly scheduled preventive maintenance program.  b) During a tour of the rehabilitation services area begun at 8:32 am. on October 4, 2007 one hydrocollator was observed in the physical therapy area. The inside of the tank and lid were observed to be rusty.  During an interview begun at 8:35 am. on October 4, 2007 the director of physical therapy	A 724	The Rehabilitation Manager had the hydrocollator completely cleaned and deoxidized, and had a new rack and lid hinge installed.  The Rehabilitation Manager developed and implemented a new and more thorough policy and procedure regarding the maintenance of the hydrocollator.  The Rehabilitation Manager is responsible for monitoring the hydrocollator daily and documenting in a tracking logbook.  New endoscope cabinets arrived and were installed at both campuses.  All endoscopes were immediately placed in the new scope cabinets. The endoscopes are hung in the scope cabinets in a vertical position; the new cabinets protect the scopes from contamination and the tips hanging freely in the well-ventilated cabinet to protect the scopes from contamination. The endoscopes are stored in accordance with the Southwest Healthcare policy and procedure (SUR #E5 Endoscopes Flexible use, Care and Processing of) in accordance with AORN recommended practices for Cleaning and Processing Endoscopes and Endoscope Accessories.  Perioperative Services Director reviewed and revised the policy on SUR #E5 Endoscopes Flexible use, Care and Processing.	04/07/08  04/07/08  04/07/08  10/31/07  10/31/07  10/31/07

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A 724	<p>Continued From page 138</p> <p>stated that the hydrocollator had been cleaned on September 28, 2007. The director stated that the routine cleaning of the unit was not intended to remove corrosion and rust. The director acknowledged that the rust inside the hydrocollator tank could pose an infection control risk.</p> <p>Review of the facility's policies and procedures begun at 4:13 pm..... on October 4, 2007 revealed a policy titled "Cleaning Hydrocollator". The policy stated that the unit would be cleaned monthly "or more often if needed." The policy did not address maintaining the tank free of corrosion and rust.</p> <p>3. The OR Suite at RSMC was toured on October 2, 2007, at 2:35 p.m. OR 2 was not in use, and was inspected. The anesthesia machine contained a PM sticker indicating the machine was due for PM July of 2007, two months prior to the survey.</p> <p>a. The Clinical Lead (interviewed at the same time) for the OR was unable to explain the policy for preventive maintenance of the anesthesia machines.</p> <p>b. A representative from the hospital's biomedical department was interviewed on October 5, 2007, at 11 a.m. He was unable to explain the expired PM sticker on the anesthesia machine, or to provide evidence for the performance of the PM.</p> <p>4. During a tour of the SPD area on October 2, 2007, at 3:20 p.m., a cart was observed with a towel on top. Clean endoscopes were observed curled up in the towel. The clinical lead for Surgical Services stated the old cabinet for hanging the endoscopes had to be discarded,</p>	A 724	<p>Perioperative Services Director updated all Sterile Processing Department and GI staff on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the policy.</p> <p>The Sterile Processing Department personnel are responsible for checking all test strip containers for outdates on a weekly basis. Random audits are currently done to check the validity of this practice.</p>	10/31/07  Ongoing

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A 724	Continued From page 139 and they were awaiting approval of the capital budget to purchase a new one. In the meantime, the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.	A 724			
A 726	<b>482.41(c)(4) VENTILATION, LIGHT, TEMPERATURE CONTROLS</b>  There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.  This Standard is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure proper temperature controls in two of two food storage freezers at RSMC, resulting in the potential for growth of microorganisms and food borne illness in patients and visitors. The facility also failed to ensure the proper storage of ready to eat food items at RSMC, resulting in the potential for juices from raw fish and sausage dripping on the ready to eat food items, cross contamination, and food borne illness in patients and visitors.  Findings:  1. During the initial tour of the kitchen on October 2, 2007, at 10:20 a.m., a build-up of ice on the freezer floor, measuring approximately 12 inches by 8 inches, on the northeast corner was observed. Other areas of the floor had solidified	A 726	<b>IMMEDIATE (TEMPORARY) CORRECTIVE ACTIONS:</b>  As documented in the citation, the Hospital took the following actions immediately on 10/03/07 to ensure safe practices for food handling. The Chief Operating Officer was responsible for being sure all actions were accomplished.  1. Freezers were locked on the day of notice to prevent inadvertent access to contents.  2. All foods currently in the freezers at Rancho Springs were discarded.  3. No food products were stored in the freezers at Rancho Springs until such time that the organization was assured that the freezers were fully functional. This included any or all of the following: > Full evaluation and repair by an appropriate service, > Evaluation of the option of securing a rental freezer that meets established	10/03/07	

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A 726	<p>Continued From page 140</p> <p>chunks of ice. Ice was also observed on the tops of food, and on the boxes stored on the shelves closest to the ceiling.</p> <p>The following frozen items, stored in the freezer, were observed to have layers of ice crystals on the surface (a common sign of thawing and refreezing);</p> <p>a. Pans of cooked beef casserole and vegetable lasagna had layers of ice on the top;</p> <p>b. A pan containing tilapia had similar ice crystals in the corners, and dried out, freezer burned edges on some of the raw fish pieces;</p> <p>c. A box containing chorizo sausage had ice crystals and chunks of ice inside. The chorizo was frozen as a solid block, not in individual pieces;</p> <p>d. A box of precooked chicken filets had ice crystals inside the box.</p> <p>The DNFS stated she did not know what the signs of thawing and refreezing were. She stated she did not know if the ice crystals found on the food in the freezer were a result of food thawing and refreezing, or if it was from the food being placed directly in the freezer after cooking. The DNFS stated if the food was placed directly in the freezer after cooking, the staff did not go through the proper cooling procedures before storing food in the freezer.</p> <p>During an interview with the DNFS and the DPO on October 2, 2007, at 4:45 p.m., the DPO stated the hospital suffered several power outages this summer and, on one occasion, up to seven power interruptions in one day. He stated dietary staff called to inform his department each time there was an outage.</p> <p>Inside the freezer, cooked and ready to eat food</p>	A 726	<p>requirements,</p> <p>&gt; Replacement of the existing freezer if necessary.</p> <p>4. In preparing meals at Rancho Springs, all perishable products taken from the Rancho Springs inventory were fresh, non-frozen.</p> <p>5. To ensure the availability of the appropriate products to meet the dietary needs of patients, if frozen foods were required, they were brought to the Rancho Springs campus from the Inland Valley campus just prior to preparation, or purchased for same day delivery.</p> <p>6. Unused portions were properly wrapped or packaged and refrigerated. No unused portions were frozen until the freezers were confirmed to be fully functional.</p> <p>Patient menus for 10/03/07 were reviewed and adjusted by 7pm on 10/02/07.</p> <p>There are patient refrigerators that contain frozen products. To be thorough in addressing this issue, the contents of those freezers were discarded. (Items can include Healthy Choice frozen meals, ice cream cups, and popsicles.)</p> <p>SUBSEQUENT ACTIONS:</p> <p>Freezer Temperature Monitoring</p>	10/02/07  10/02/07



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A 726	<p>Continued From page 142</p> <p>every time the power went out and the freezer inside went off, the staff would move some of the frozen foods to the outside freezer, and the frequent opening and closing of the doors may have resulted in fluctuations in the outside freezer temperature. The FSM stated it was his responsibility to clean the excess ice formed in the freezer. The FSM stated he did not know how long ago the task had been completed.</p> <p>3. The refrigerator and freezer temperature logs for the month of September, 2007 were reviewed on October 2, 2007. The temperatures were checked every 12 hours, and the log showed no temperatures out of range. The DNFS agreed this meant that the temperatures were in range at the times they were checked, but it did not represent any fluctuations in temperatures that may have occurred during the power outages when the inside freezer was off, and the outside freezer was being opened and closed frequently. There was no documentation of the power outages on the log, and no evidence that the freezer temperatures were monitored during the power outages.</p> <p>4. During the team meeting on October 2, 2007, at 4:15 p.m., the team reviewed the above findings, and determined that the deficient practice met the criteria for Immediate Jeopardy. The CFO was notified of the Immediate Jeopardy on October 2, 2007, at 6:05 p.m.</p> <p>On October 3, 2007, at 8 a.m., an acceptable plan of correction was received by the facility, which consisted of;</p> <p>a. Locking the inside and outside freezers to prevent inadvertent access;</p>	A 726	<p>to move products to an alternate location during a prolonged outage before a critical temperature is reached.</p> <p>As part of the organization's emergency preparedness plan during power outages, the Hospital is in contact with the utility company to determine the estimated "down time" and when the utility company anticipates that power will be restored.</p> <p>The Director of Nutrition and Food Service (DNFS) determined that, should there be any prolonged time frame when the freezer temperature is above freezing, the organization will follow the USDA Guidelines of the Food Safety and Inspection Service under the direction of the DNFS and/or the MFS:</p> <ol style="list-style-type: none"> <li>1. "When the power goes back on, if the refrigerator is still 40°F and the freezer is 0°F or below, the food is safe."</li> <li>2. "If food is partly frozen, still has ice crystals, or is as cold as if it were in a refrigerator (40°F), it is safe to refreeze or use."</li> <li>3. "Discard any foods that have been contaminated by raw meat juices. Dispose of soft or melted ice cream for quality's sake."</li> </ol> <p>Condensation Causing Excessive Ice Build-up</p> <p>Administration had a freezer repair service inspect the freezers, and the freezer repair services determined that the freezers were functioning and running at design set points.</p>	<p>12/11/07 &amp; ongoing</p> <p>12/11/07 &amp; ongoing</p> <p>10/03/07</p>



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A		A 726	<p>continued from page 144 In addition to the biweekly monitoring by the FSM, The Director of Plant Operations (DPO) incorporated general freezer inspection rounds into the Building Maintenance Program. Rounds are to be done at least quarterly.</p> <p>Adequacy of Freezer Power Supply</p> <p>The DPO reviewed building plans and confirmed that the inside walk-in freezer in the Dietary Department at Rancho Springs is on emergency power.</p> <p>The DPO was able to test and verify the power supply and monitoring procedures when the Hospital was on generator power. The freezer continued to be operational and appropriate temperatures were maintained during the 2-hour test.</p> <p>Food Storage</p> <p>The DFNS and MFS conducted staff education to review and reinforce the procedure for storing food and products in the refrigerators and freezers. Education emphasized that raw meat/fish or other potentially hazardous products must be stored on the bottom shelves, and that staff members must be aware of and follow the proper storage requirements each time food is placed in the refrigerator or freezer.</p>	<p>10/08/07 &amp; ongoing</p> <p>11/14/07</p> <p>11/14/07</p> <p>10/10/07</p>

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A		A 726	<p>continued from page 144a Dietary supervisory staff members inspect the refrigerators and freezers on a biweekly basis to confirm that food is stored properly and that no raw meat/fish products or potentially hazardous uncooked foods are stored above ready-to-serve items. Should there be any such findings, they are responsible for immediately having the problem corrected and addressing it with the staff involved. Compliance with safe food handling is incorporated in to each staff member's evaluation.</p> <p>The DFNS researched the aspect of food storage in freezers. She confirmed that the Hospital's current policy for proper cooling before storing food in the freezer was consistent with safe food handling practices according to HACCP.</p> <p>The DFNS/designee provided education to the staff on the signs of thawed and refrozen food. The policy for proper cooling before storing food in the freezer was reviewed and reinforced.</p> <p>Dietary supervisory staff members are responsible for monitoring compliance with this aspect of safe food handling by direct observation. In addition, as part of each employee's evaluation, compliance with the HACCP guidelines is assessed.</p>	<p>10/10/07 &amp; ongoing</p> <p>02/01/08</p> <p>02/01/08</p> <p>02/01/08 &amp; ongoing</p>

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A		A 726	<p>continued from page 144b</p> <p>The Hospital nevertheless disagrees that this citation identifies a situation that constituted an Immediate Jeopardy as defined by state or federal rules. California Code §1280.1(c) defines "immediate jeopardy" as "a situation in which a licensee's non compliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient." The Medicare definition is similar: immediate jeopardy is a "situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." The citation does not indicate that any harm was caused or was likely to be caused to any patient.</p> <p>First, because the inside walk-in freezer is on emergency power, power outages do not (and did not) affect its functioning. Therefore, power outages did not cause any of the food in the inside freezer to thaw and refreeze. Staff was misinformed about this issue.</p> <p>Second, the Hospital confirmed through inspection by a freezer repair company that the freezers were functioning and running at design set points. Therefore, the concern in the citation that the freezers were not functioning properly was misplaced.</p>	

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A		A 726	<p>continued from page 144c</p> <p>Third, there was no other evidence that the storage of food did cause or was likely to cause harm to a patient.</p> <p>For these reasons, the Hospital disagrees that an immediate jeopardy ever existed with the freezers and refrigerators and requests that this citation be removed.</p>	

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A 747	<p>Continued From page 144</p> <p>This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure the maintenance of an effective infection control program by failing to;</p> <ul style="list-style-type: none"> <li>a. Ensure IC surveillance at the RSMC campus (A749);</li> <li>b. Ensure clean tables in the OR (A749);</li> <li>c. Ensure proper cleaning of surgical instruments (A749);</li> <li>d. Ensure current, up to date policies for cleaning instruments (A749);</li> <li>e. Ensure proper storage of endoscopes (A749);</li> <li>f. Ensure intravenous fluids and supplies stored in areas ready for patient use were not outdated (A749);</li> <li>g. Ensure policies for decontamination of surgical instruments were followed (A284), and;</li> <li>h. Ensure there was a system in place that supplies used for cardiac and radiological procedures were not outdated and unsafe for use (A284)(A537).</li> </ul> <p>The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the provision of a safe and sanitary patient care</p>	A 747	For corrective action see Tags A284, A537, A749.	



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A 749	<p>Continued From page 146 radiological procedures.</p> <p>Findings:</p> <p>The IC plan (for both RSMC and IVMC) was reviewed on October 2, 2007. According to the plan, the IC program was comprehensively designed to serve all programs, departments and services of both facilities, with a focus on surveillance, control and prevention of infection. The plan indicated the IC department would perform routine rounds in the clinical departments.</p> <p>A review of the IC risk assessment for 2007 was done on October 2, 2007. The statistics were combined for both facilities. The action plan for reducing the risks in both facilities included;</p> <ul style="list-style-type: none"> <li>a. Monitoring staff on all units for hand washing;</li> <li>b. Direct observation of RT and nursing staff in the ICU's;</li> <li>c. Daily review of isolation logs with staff at both facilities;</li> <li>d. Direct observation of staff performing bronchoscopy at each facility;</li> <li>e. Direct observation of the OR, preoperative, SPD and PACU areas at both facilities, and;</li> <li>f. Direct observation of EVS terminal cleaning at least monthly at both facilities.</li> </ul> <p>1. The IC staff (consisting of the CNO and the ICC), was interviewed on October 5, 2007, at 1:12 p.m. During the interview, the ICC stated she made daily rounds, attended construction</p>	A 749	<p>The IC Practitioners are responsible for rounding twice a week within both IVMC and RSMC. All findings are documented and conveyed to departmental Directors for resolution/follow-up.</p> <p>The Director of Infection Control is responsible for noting targeted surveillance with Quality Improvement Activities and presenting results quarterly at the Infection Control Committee meetings. Information is also disseminated among the affected units for optimal Infection Prevention/Reduction activities.</p> <p>The Circulating RN is responsible for assessing the integrity of the mattresses on the OR tables while preparing each OR for the next case. If the mattress has a tear or irreparable soiling, the Circulating RN is responsible for having the mattress replaced immediately.</p> <p>The Lead RN is responsible for checking the integrity of mattresses on OR tables on the first week of each month.</p> <p>The Director of Perioperative Services changed the GI tech and SPD Tech job specific competencies to reflect that all enzymatic cleaners must be diluted per manufacture instructions using exact measurements of water and enzymatic cleaner. All GI techs, SPD techs and RN GI staff at both facilities have signed the revised job description competency.</p>	<p>Ongoing</p> <p>Ongoing</p> <p>10/31/07</p> <p>04/21/08 &amp; ongoing</p> <p>10/31/07</p>	

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A 749	Continued From page 147 rounds and meetings, and called for corrective action when needed at IVMC, but not at RSMC. The ICC stated the IC activities at RSMC consisted of review of culture results. The CNO stated they used to have two IC employees, but one left the facility several months ago, and they had not replaced that position. The CNO stated there was no way one person could do complete surveillance at both campuses, so the IC Coordinator was doing, "only the essentials," at RSMC.  2. The OR suite at RSMC was toured on October 2, 2007, at 2:35 p.m. The sheets on the operating room table in OR 2 were pulled back to reveal a two inch tear on the mattress, partially covered by tape. The inside foam was exposed, visible, and available to soak up any liquid substance that it came in contact with including blood and body fluids.  3. The SPD at RSMC was toured on October 2, 2007, at 3:20 p.m. Tech 1 was observed washing instruments, and was interviewed about the procedure she followed. The tech stated the washing sink held about six quarts of water, and when she mixed the solution for decontamination of surgical instruments in this sink, she added, "a few squirts," of Ultrazyme cleaner to the water. The tech stated there was no measured amount of solution added to the water, sometimes she added more, and sometimes she added less. A review of the manufacturer's recommendations on the Ultrazyme bottle indicated one ounce (one pump) of cleaner should be added to each gallon of water.  The tech was not aware of the need to accurately measure the amount of enzymatic cleaner to be added to a known amount of water. She stated	A 749	The Director of Perioperative Services/designee updated GI and SPD personnel on the enzymatic cleaner changes at the October 2007 staff meetings and OR board meetings.  The Director of Perioperative Services reviewed and revised the policy on SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies to reflect "all enzymatic cleaners are diluted per manufactures instruction."  All SPD and GI staff at IVMC and RSMC were updated on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the revised SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies.  The Director of Perioperative Services/designee conducts random audits to check the validity of this practice. Results are reported to the OPIC Committee.  The Director of Imaging / Lead RN Cardiac Cath reviewed and revised the policy and procedure related to sterilization of TEE probes.  The Cardio Manager revised the TEE cleaning logbook to include a column requiring documentation of the Cidex test strip expiration date, which is to be filled in prior to use of the Cidex.	10/31/07  10/31/07  10/31/07  10/31/07 & ongoing  10/27/07  04/02/08

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A 749	<p>Continued From page 148</p> <p>she could not recall being educated about this, or having her competency checked at her last skills day or evaluation.</p> <p>The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. They both stated that the mixing of the cleaner was not part of the annual competency evaluation for the SPD technicians.</p> <p>4. The Endoscopy Lab (used for scoping procedures of the stomach and colon) at IVMC was toured on October 4, 2007 at 3:30 p.m. The Endo technician was questioned regarding the cleaning of the endoscopes. The first step involves soaking the scopes and cleaning them with an enzymatic cleaning solution. The cleaner present in the cleaning area was V. Mueller Dual Enzy-Clean and the instructions were 1-2 pumps (ounces) per gallon of water. The technician described that he would fill the sink with water and add about 10 pumps of solution to the sink water. He did not know how he was taught the mixing procedure. He did not recall having this part of his job checked with his annual competencies.</p> <p>5. During the tour of the SPD, the side opposite the instrument pre wash area was identified as the area for washing TEE probes (used to do a cardiac ultrasound from inside the esophagus). The SPD tech stated the cardiology techs were responsible for cleaning these instruments. The tech stated Cidex was used as the enzymatic cleaner for this procedure. The tech identified a bottle of test strips used to verify the concentration of the cleaner after mixing. The date on the bottle of test strips indicated they had expired.</p>	A 749	<p>The Cardio Manager reviewed and revised the policy and procedure to reflect documentation of the Cidex test strip expiration date.</p> <p>The Cardio Manager/designee education all staff involved in the cleaning of TEE equipment on this new procedure.</p> <p>The Cardio Manager reviews the log book on a monthly basis to assure compliance with the new procedures. The Cardio Manager added this item as a quality indicator under the PI Program and results of the reviews are reported to the PI Committee.</p> <p>New endoscope cabinets arrived and were installed at both campuses.</p> <p>All endoscopes were immediately placed in the new scope cabinets. The endoscopes are hung in the scope cabinets in a vertical position; the new cabinets protect the scopes from contamination and the tips hanging freely in the well-ventilated cabinet to protect the scopes from contamination. The endoscopes are stored in accordance with the Southwest Healthcare policy and procedure (SUR #E5 Endoscopes Flexible use, Care and Processing of) in accordance with AORN recommended practices for Cleaning and Processing Endoscopes and Endoscope Accessories.</p>	<p>04/02/08</p> <p>04/02/08</p> <p>04/02/08 &amp; ongoing</p> <p>10/31/07</p> <p>10/31/07</p>	

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A 749	Continued From page 149 The hospital policy on cleaning TEE probes was reviewed on October 2, 2007. The policy indicated the probes should be cleaned with one to two ounces of enzymatic cleaner per gallon of water. However, the bottle of Cidex specified one ounce of cleaner per gallon of water. The tech stated the old cleaner was mixed with one to two ounces of solution per gallon of water, and the policy was outdated.  6. In the same area, a cart was placed with a towel on top. The clean endoscopes were observed curled up on the towel. The clinical lead for Surgical Services stated the old cabinet for hanging the endoscopes had to be discarded, and they were awaiting approval of the capital budget to purchase a new one. In the meantime, the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.  7. The Operating Room Suite at RSMC was toured on October 2, 2007, at 2:35 p.m. There were bags of intravenous (IV) solutions stored on a cart in a small storage area. One bag, labeled "5% Dextrose, 1000 ml," had an expiration date of May 2006.  The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. Neither had an explanation for the expired bag of dextrose.  8. The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10	A 749	Perioperative Services Director reviewed and revised the policy on SUR #E5 Endoscopes Flexible use, Care and Processing.  Perioperative Services Director updated all Sterile Processing Department and GI staff on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the policy.  The Sterile Processing Department personnel are responsible for checking all test strip containers for outdates on a weekly basis. Random audits are currently done to check the validity of this practice.  The Lead RN reviews all inventory for outdated equipment and supplies on the first week of each month.  In addition, the Imaging Managers conduct bi-weekly random inspections that include a review of expiration dates.  The Imaging Department maintains a log to confirm that the require audits are conducted and the results of checking the expired items. The Director of Imaging reviews the log at least quarterly to confirm that the required inventories and random inspections are occurring and the results of the inventories and reviews.	10/31/07  10/31/07.  Ongoing  10/31/07 & ongoing  10/31/07 & ongoing  Ongoing

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A 749	Continued From page 150 a.m. There were multiple wrapped angiocatheters and other equipment, for use in the Special Procedures/Cardiac Cath suite, stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angiocaths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angiocaths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.  The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired supplies available for use.  9. The Radiology Suite at IVMC was toured on October 4, 2007 at 2 p.m. The Special Procedure Room was inspected. One Vista 8 French endovascular catheter was found with an expiration date of September 2007, indicating that the period for safe use had ended 4 days prior. Three biliary stents (used to catheterize the gall bladder) were also expired September 2007. The staff was unable to explain why the expired instruments were stored with the supplies for patient use.	A 749		
A 940	482.51 SURGICAL SERVICES  If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.	A 940	Please see response to A951.	

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A 940	Continued From page 151  This Condition is not met as evidenced by: Based on a review of the emergency supplies for the treatment of malignant hyperthermia (a rare life-threatening condition that is triggered by exposure to drugs used for general anesthesia, such as volatile anesthetics or the depolarizing muscle relaxant succinylcholine), staff interviews and a review of the facility' policy and procedure for the treatment of malignant hyperthermia, the surgical services were not consistent with the acceptable standards of practice for the treatment of malignant hyperthermia as established by the Malignant Hyperthermia Association of the United States (MHAUS).  The cumulative effects of this systemic problem resulted in the hospital's inability to ensure the provision of surgical services in a safe and effective manner  Findings.  1. See A 951 regarding the failure of the facility to maintain the minimal amount of dantrolene (an a drug used to treat malignant hyperthermia).	A 940		
A 951	482.51(b) OPERATING ROOM POLICIES  Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.  This Standard is not met as evidenced by:	A 951	J resolution:  The Hospital undertook the following steps to resolve the immediate jeopardy identified by surveyors: • The Hospital had a total of 48 vials of Dantrolene between its two campuses (IV-18 vials and RS-30 vials) • As IVMC is the designated trauma center, it was important to maintain full	10/04/07

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A 951	<p>Continued From page 152</p> <p>Based on a review of the emergency supplies for the treatment of malignant hyperthermia (a rare life-threatening condition that is triggered by exposure to drugs used for general anesthesia, such as volatile anesthetics or the depolarizing muscle relaxant succinylcholine), staff interviews and a review of the facility policy and procedure for the treatment of malignant hyperthermia the surgical services were not consistent with the facility's resources and the policy for the treatment of malignant hyperthermia was not consistent the standards of medical practice and patient care established by the Malignant Hyperthermia Association of the United States (MHAUS).</p> <p>Neither the RSMC or the IVMC had the minimum amount of dantrolene (a drug used to treat this rare but life threatening adverse reaction to some medications used in surgery) recommended by MHAUS. The facility policy entitled "MALIGNANT HYPERTHERMIA" contradicted itself on the amount of dantrolene to be immediately available and was not consistent with the recommendations of MHAUS.</p> <p>The failure of the facility to have minimum amount of dantrolene recommended MHAUS to treat this life threatening condition placed all patients who received drugs known to cause malignant hyperthermia (MH) at risk for serious harm including death. This failure resulted in the hospital's inability to ensure the provision of quality health care in a safe and effective manner. At 6:10 p.m. on October 4, 2007 the survey team met with the facility's to declare an immediate jeopardy. The facility developed an immediate action plan that included consolidated the available dantrolene supplies at the IVMC, contacting other hospitals in the area to obtain</p>	A 951	<p>surgical capacity at the facility</p> <ul style="list-style-type: none"> <li>The Pharmacy Director was contacted and transported 18 vials of Dantrolene from RSMC to IVMC to bring up the total number of vials to the required level of 36 vials</li> <li>Pending the arrival of the additional vials of Dantrolene to make up the full inventory of 36 vials for both sites, the surgical cases at RSMC that required the use of triggering drugs were held</li> <li>To make up the required full inventory of 36 vials of Dantrolene for each site, the Hospital obtained an additional 24 vials from two nearby facilities</li> <li>The Hospital contacted the vendor that supplies Dantrolene to SWHCS to provide written verification of the Dantrolene order that was placed on 10/03/07</li> <li>Once all vials had been delivered, they were dispersed so that there were 36 dantrolene vials at each campus</li> </ul> <p>The Plan of Correction was accepted and the IJ was lifted when the additional vials of Dantrolene arrived, which was on 10/4/07 @ 1935.</p> <p>On an ongoing basis, the Director of Pharmacy maintains 36 vials of Dantrolene at each facility (36 vials at VMC and 36 vials at RSMC). Any use of the Dantrolene triggers replenishment from Pharmacy stock and re-order of Pharmacy stock from the manufacturer.</p>	10/04/07  10/04/07 & ongoing

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A 951	Continued From page 153 additional dantrolene and suspending surgeries at RSMC until sufficient dantrolene is obtained that both campuses could have the recommended minimum amount. At 7:35 p.m. on October 4, 2007 the facility had transferred the RSMC dantrolene supply to IVMC. The facility had identified and made arrangements to transfer an additional 36 vials of dantrolene from two local hospitals. The facility had held or suspended surgeries using drugs known to trigger MH at the RSMC until the additional 36 vials of Dantrolene had been obtained. Based on the facility obtaining he recommended amount at IVMC and holding surgeries at RSMC the immediate jeopardy was abated at 7:35 p.m. on October 4, 2007.  Findings:  1. During a review of the RSMC malignant emergency drug supply on October 2, 2007 beginning at 2:15 p.m. it was noted that the malignant hyperthermia cart contained 18 vials of dantrolene. When interviewed at 2:15 p.m. on October 2, 2007 Pharmacy Staff A and Pharmacy Staff B reported that the pharmacy had an additional 12 vials of the dantrolene. If needed, additional supplies were available from the IVMC campus. Pharmacy staff B reported the other campus was approximately 15 minutes away.  When interviewed on October 4, 2007 at 2 p.m., Pharmacy Staff C reported that the IVMC currently had 18 vials of Dantrolene. Recently (staff was unsure of the actual date) 18 vials of dantrolene had expired and more vials were on order from the manufacturer. Pharmacy Staff C reported the additional dantrolene would not be available for about a week.	A 951	On a monthly basis, the Director of Pharmacy/designee checks pharmaceuticals for upcoming expiration. Any Dantrolene that will expire within the next 3 months following the check is automatically re-ordered.  The Perioperative Services Director reviewed and revised the Malignant Hyperthermia policy and procedure to conform to the current Malignant Hyperthermia Association of the United States (MHAUS) and the American Perioperative Nurses (AORN) guidelines.  The Perioperative Services Director presented the policy and procedure to the Surgery and Anesthesia Committees respectively for approval. The policy was also approved by the CNO, and by clinical and ancillary departments throughout Southwest Healthcare System (SWHCS). The policy reflects the various settings in which Malignant Hyperthermia can occur in a hospital setting.  The Perioperative Services Director updated staffs at IVMC and RSMC on the major policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the revised MH policy and procedure.  An annual competency for all SWHCS clinical RN's and Perioperative staff was created to reflect the current MHAUS guidelines.	10/04/07 & Ongoing  01/31/08  01/31/08  04/05/08

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A 951	<p>Continued From page 154</p> <p>The standards of medical practice and patient care as defined by the recommendations of MHAUS a minimum of 36 vials of Dantrolene should be available within 5 minutes of the initial diagnosis of MH. In response to a question regarding the need to store 36 vials of dantrolene MHAUS responded "a stock of 36 vials is recommended. The patient experiencing an MH episode must be stabilized before being transported. Stabilization of an MH episode may take 30 minutes or more with multiple doses of dantrolene because, in some cases, MH progresses with explosive rapidity. The full 36 vials of dantrolene is inexpensive insurance against patient injury and a malpractice claim, which the facility will lose. The full 36 vials of dantrolene should be available within five minutes of the diagnosis of MH."</p> <p>2. The facility policy "Malignant Hyperthermia" states that is is based on the recommendations of MHAUS. The policy conflicts with the MHAUS recommendations in that states that the MH emergency supply will contain 18 vials of dantrolene instead of the 36 recommended vials. Further the written procedure for this policy contradicts the policy in that it states the supply will have 20 vials of dantrolene (10 vials at each campus).</p> <p>2. During a review of the MH cart on the IVMC campus on October 4, 2007, at 5:10 p.m., with the Director of Surgical Services and the PACU Clinical Lead, the MH medication tray was observed to contain 18 vials of dantrolene.</p> <p>During an interview with the PACU Clinical Lead, on October 4, 2007, at 5:20 p.m., she stated that 36 vials of dantrolene were needed to treat MH, and the PACU staff had been directed to obtain</p>	A 951	<p>The contents of the Malignant Hyperthermia cart were also revised to reflect the current recommendations. Each MH cart at IVMC and RSMC is stocked with 36 vials of Dantrolene Sodium. The MH cart is checked weekly to ensure that no medication contained within the MH cart is expired.</p> <p>The Director of Perioperative Services changed the GI tech and SPD Tech job specific competencies to reflect that all enzymatic cleaners must be diluted per manufacture instructions using exact measurements of water and enzymatic cleaner. All GI techs, SPD techs and RN GI staff at both facilities have signed the revised job description competency.</p> <p>The Director of Perioperative Services/designee updated GI and SPD personnel on the enzymatic cleaner changes at the October 2007 staff meetings and OR board meetings.</p> <p>The Director of Perioperative Services reviewed and revised the policy on SUR #C7 Centralize Service; Cleaning and Sterilizing Equipment and Supplies to reflect "all enzymatic cleaners are diluted per manufactures instruction."</p> <p>All SPD and GI staff at IVMC and RSMC were updated on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the revised SUR #C7</p>	<p>01/31/08</p> <p>10/31/07</p> <p>10/31/07</p> <p>10/31/07</p> <p>10/31/07</p>

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A 951	<p>Continued From page 155</p> <p>the additional vials of dantrolene from the RSMC campus in the event a patient developed MH. The Clinical Lead stated that this was not a good practice, she had protested to the pharmacy, and no action had been taken. The Clinical Lead stated that this plan had been in place since she began her employment with the facility one year prior. The Clinical Lead stated that the time it would take to obtain the additional medication from the RSMC campus would be dependent on traffic, road and weather conditions and whether the pharmacy was open or closed at RSMC.</p> <p>The team met and discussed the above findings on October 4, 2007, at 5:25 p.m., and determined that the deficient practice met the criteria for Immediate Jeopardy. The CFO and CNO were notified of the Immediate Jeopardy on October 4, 2007, at 5:35 p.m.</p> <p>On October 4, 2007, at 6:05 p.m., an acceptable plan of correction was received from the facility, which consisted of;</p> <p>a. Acquiring 18 vials of dantrolene from the RSMC campus, and taking it to the IVMC campus, which was a trauma center;</p> <p>b. Putting a hold on all surgeries at the RSMC campus that required the use of anesthesia triggering agents known to cause MH (all surgeries were completed for the day); and,</p> <p>c. Borrowing 18 vials of dantrolene from each of two local hospitals, to equal a total of 72 vials (36 at each campus).</p> <p>The Director of QAPI was notified that the Immediate Jeopardy was abated on October 4,</p>	A 951	<p>Centralize Service; Cleaning and Sterilizing Equipment and Supplies.</p> <p>The Director of Perioperative Services/designee conducts random audits to check the validity of this practice. Results are reported to the OPIC Committee.</p> <p>The Director of Imaging / Lead RN Cardiac Cath reviewed and revised the policy and procedure related to sterilization of TEE probes.</p> <p>The Cardio Manager revised the TEE cleaning logbook to include a column requiring documentation of the Cidex test strip expiration date, which is to be filled in prior to use of the Cidex.</p> <p>The Cardio Manager reviewed and revised the policy and procedure to reflect documentation of the Cidex test strip expiration date.</p> <p>The Cardio Manager/designee education all staff involved in the cleaning of TEE equipment on this new procedure.</p> <p>The Cardio Manager reviews the log book on a monthly basis to assure compliance with the new procedures. The Cardio Manager added this item as a quality indicator under the PI Program and results of the reviews are reported to the PI Committee.</p>	<p>10/31/07 &amp; ongoing</p> <p>10/27/07</p> <p>04/02/08</p> <p>04/02/08</p> <p>04/02/08</p> <p>04/02/08 &amp; ongoing</p>

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A 951	Continued From page 156 2007, upon the facility's receipt of 36 vials of dantrolene from the 2 local hospitals, giving them a complete complement of dantrolene at each facility. 3. The SPD at RSMC was toured on October 2, 2007, at 3:20 p.m. Tech 1 was observed washing instruments, and was interviewed about the procedure she followed. The tech stated the washing sink held about six quarts of water, and when she mixed the solution for decontamination of surgical instruments in this sink, she added, "a few squirts," of Ultrazyme cleaner to the water. The tech stated there was no measured amount of solution added to the water, sometimes she added more, and sometimes she added less. A review of the manufacturer's recommendations on the Ultrazyme bottle indicated one ounce (one pump) of cleaner should be added to each gallon of water.  The tech was not aware of the need to accurately measure the amount of enzymatic cleaner to be added to a known amount of water. She stated she could not recall being educated about this, or having her competency checked at her last skills day or evaluation.  The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. They both stated that the mixing of the cleaner was not part of the annual competency evaluation for the SPD technicians.  4. The Endoscopy Lab (used for scoping procedures of the stomach and colon) at IVMC was toured on October 4, 2007 at 3:30 p.m. The Endo technician was questioned regarding the cleaning of the endoscopes. The first step involves soaking the scopes and cleaning them with an enzymatic cleaning solution. The cleaner	A 951	New endoscope cabinets arrived and were installed at both campuses.  All endoscopes were immediately placed in the new scope cabinets. The endoscopes are hung in the scope cabinets in a vertical position; the new cabinets protect the scopes from contamination and the tips hanging freely in the well-ventilated cabinet to protect the scopes from contamination. The endoscopes are stored in accordance with the Southwest Healthcare policy and procedure (SUR #E5 Endoscopes Flexible use, Care and Processing of) in accordance with AORN recommended practices for Cleaning and Processing Endoscopes and Endoscope Accessories.  Perioperative Services Director reviewed and revised the policy on SUR #E5 Endoscopes Flexible use, Care and Processing.  Perioperative Services Director updated all Sterile Processing Department and GI staff on the policy and procedure revision with an acknowledgement form signed to indicate they had read and understood the content of the policy.  The Sterile Processing Department personnel are responsible for checking all test strip containers for outdates on a weekly basis. Random audits are currently done to check the validity of this practice.	10/31/07  10/31/07  10/31/07  10/31/07  Ongoing

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A 951	<p>Continued From page 157</p> <p>present in the cleaning area was V. Mueller Dual Enzy-Clean and the instructions were 1-2 pumps (ounces) per gallon of water. The technician described that he would fill the sink with water and add about 10 pumps of solution to the sink water. He did not know how he was taught the mixing procedure. He did not recall having this part of his job checked with his annual competencies.</p> <p>5. During the tour of the SPD, opposite the side of the instrument pre wash area was identified as the area for washing TEE probes (used to do a cardiac ultrasound from inside the esophagus). The SPD tech stated the cardiology techs were responsible for cleaning these instruments. The tech stated Cidex was used as the enzymatic cleaner for this procedure. The tech identified a bottle of test strips used to verify the concentration of the cleaner after mixing. The date on the bottle of test strips indicated they had expired.</p> <p>The hospital policy on cleaning TEE probes was reviewed on October 2, 2007. The policy indicated the probes should be cleaned with one to two ounces of enzymatic cleaner per gallon of water. However, the bottle of Cidex specified one ounce of cleaner per gallon of water. The tech stated the old cleaner was mixed with one to two ounces of solution per gallon of water, and the policy was outdated.</p> <p>6. In the same area, a cart was placed with a towel on top. The clean endoscopes were observed curled up on the towel. The clinical lead for Surgical Services stated the old cabinet for hanging the endoscopes had to be discarded, and they were awaiting approval of the capital budget to purchase a new one. In the meantime,</p>	A 951	<p>The Lead RN reviews all inventory for outdated equipment and supplies on the first week of each month.</p> <p>In addition, the Imaging Managers conduct bi-weekly random inspections that include a review of expiration dates.</p> <p>The Imaging Department maintains a log to confirm that the require audits are conducted and the results of checking the expired items. The Director of Imaging reviews the log at least quarterly to confirm that the required inventories and random inspections are occurring and the results of the inventories and reviews.</p>	<p>10/31/07 &amp; ongoing</p> <p>10/31/07 &amp; ongoing</p> <p>Ongoing</p>

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A 951	<p>Continued From page 158</p> <p>the scopes were stored in this manner. The clinical lead agreed that endoscopes should be stored in an upright hanging position to ensure that moisture from condensation does not collect in the chambers, forming a place for microbes to grow. She stated, we have to wait for a new cabinet, there is no other place to put them.</p> <p>7. The Operating Room Suite at RSMC was toured on October 2, 2007, at 2:35 p.m. There were bags of intravenous (IV) solutions stored on a cart in a small storage area. One bag, labeled "5% Dextrose, 1000 ml," had an expiration date of May 2006.</p> <p>The Clinical Lead for Surgical Services and Charge Nurse 5 were interviewed during the tour. Neither had an explanation for the expired bag of dextrose.</p> <p>8. The CT unit and the Radiology Special Procedures/Cardiac Catheterization suite at RSMC were toured on October 3, 2007, at 10:00 a.m. There were multiple wrapped angi catheters and other equipment, for use in the Special Procedures/Cardiac Cath suite, stored in the CT room and the special procedures room. Examination of the supplies in the CT room revealed three Cordis 6 french angi caths that had expired three months prior to survey. Examination of the supplies in the Special Procedures room revealed six Cook 5 french angi caths, four expired 8 months prior to the survey, and the other two expired 5 months prior to the survey.</p> <p>The Lead Clinical Nurse for the Special Procedures/Cardiac Catheterization room was present during the tour, and could not explain the presence of expired supplies available for use.</p>	A 951		

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A 951	Continued From page 159  90. The Radiology Suite at IVMC was toured on October 4, 2007 at 2p.m. The Special Procedure Room was inspected. One Vista 8 French endovascular catheter was found with an expiration date of September 2007, indicating that the period for safe use had ended 4 days prior. Three biliary stents (used to catheterize the gall bladder) were also expired September 2007.  The staff was unable to explain why the expired instruments were stored with the supplies for patient use.	A 951		
A1004	482.52(b)(3) INPATIENT POST-ANESTHESIA EVALUATION  With respect to inpatients, a post-anesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia as specified in paragraph (a) of this section within 48 hours after surgery.  This Standard is not met as evidenced by: Based on record review, the facility failed to ensure that the post-anesthesia follow-up report contained adequate documentation of cardiopulmonary status and level of consciousness, resulting in the potential for unrecognized post operative complications.  Findings:  The closed medical records for three surgical patients treated at RSMC were reviewed on October 4, 2007, at 9 a.m.	A1004	The Chair of Anesthesia met with the PI Director to review the Department of Anesthesia's Rules and Regulations, which list the anesthesiologist's primary duties including the post-anesthetic evaluation and treatment, and documentation of the post-anesthetic visit. In addition, they reviewed the CMS Interpretive Guidelines for documentation of the post-anesthesia evaluation.  The Chair of Anesthesia and PI Director revised the Anesthesia Evaluation form (SW124) to enhance the area used to document the post-anesthesia evaluation to expressly include cardiopulmonary status and level of consciousness, anesthesia complications, and other comments, observations and follow-up care. On 12/6/2007 the revised form was approved by the Department of Anesthesia.	10/25/07  12/06/07

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A1004	Continued From page 160 1. The medical record for Patient 101 contained a form labeled, "Preoperative Anesthesia Evaluation." The Post-operative Anesthesia Evaluation written by the anesthesiologist consisted of four lines of text that stated, "No apparent complications." The note did not address the cardiopulmonary status, level of consciousness, follow-up care and/or observations or complications. 2. The medical record for Patient 102 contained a form labeled, "Physician Record of Sedation." This form contained areas for Pre-Sedation Evaluation and Post-Procedure Evaluation. The form was blank. The pre-sedation evaluation was documented in the History and Physical. However, no post-sedation evaluation was documented. 3. The medical record for Patient 103 contained a form labeled, "Preoperative Anesthesia Evaluation." The Post-operative Anesthesia Evaluation written by the anesthesiologist consisted of four lines of text that stated, "NR, 2400". The note did not document the cardiopulmonary status, level of consciousness, follow-up care and/or observations or complications.	A1004	The revised form was available for ordering on 2/21/2008 and implemented with the instructions that prior versions of the Anesthesia Evaluation be destroyed and the new version implemented.  The Health Information Management (HIM) Department is responsible for analyzing each patient's chart for the completeness of the medical record. If the post-anesthesia assessment is not complete, the record is flagged for the anesthesiologist.  Should a physician have records that are not completed within the required time frame, the physician is placed on suspension until the delinquent records are completed. Medical records suspensions are one of the elements evaluated during the physician's reappointment process.	03/01/08  Ongoing  Ongoing
A1103	<b>482.55(a)(2) INTEGRATION OF EMERGENCY SERVICES</b>  The services must be integrated with other departments of the hospital.  This Standard is not met as evidenced by: Based on interview and record review, the facility failed to ensure an integration of services between the Emergency Medicine Department	A1103	Physician representatives from the Departments of Imaging and Emergency and the PI Director reviewed the policy, "Patient Contact after Discharge from the ED" (ED P#16) the decision was made to draft a new policy specific to the Medical Staff concerning variances in x-ray readings between Emergency Physicians and Radiologists. The new	

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A1103	<p>Continued From page 161</p> <p>and Imaging Department. The facility failed to perform a quality control assessment of x-ray reading discrepancies between the radiologists and emergency medicine physicians, resulting in a failure to track and trend discrepant x-ray readings between the two departments, and the potential for inappropriate diagnosis and treatment of patients receiving diagnostic x-rays in the ED after hours.</p> <p>Findings:</p> <p>The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.</p> <p>1. The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the</p>	A1103	<p>policy establishes a process to identify when there is a variance in the interpretation of imaging studies. When such a variance is identified:</p> <ol style="list-style-type: none"> <li>1. Appropriate action is taken to alert a physician when a variance is identified that could impact the patient's plan of care.</li> <li>2. The Medical Staff, as part of their ongoing efforts to improve the quality of care provided, review each variance on a regular basis to identify opportunities for improvement.</li> </ol> <p>On 12/10/2007, the hospital implemented a digital imaging system referred to as "PACS" that provides better capabilities to track the variance. Under the new process:</p> <ol style="list-style-type: none"> <li>1. The ED physician or PA reviews the exam and enters in PACS an internal note of their findings for each exam reviewed. Treatment is initiated as appropriate and the patient/representative is advised of the preliminary findings.</li> <li>2. The radiologist reviews the exam for a final interpretation and result reporting.             <ol style="list-style-type: none"> <li>a. If the Radiologist reading is different than the preliminary ED read, the Radiologist informs the on-duty ED physician about the variance so appropriate clinical action can be taken if necessary.</li> <li>b. The Radiologist documents the variance (where the official interpretation differs from the ED preliminary finding) in the final dictated report, and who was</li> </ol> </li> </ol>	12/10/07
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A1103	<p>Continued From page 162</p> <p>ED at RSMC was interviewed by phone on October 4, 2007, at 1 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>2. A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends the rereads to the ED. The PA is scheduled to come in one hour before being scheduled to see patients, and the PA reviews all of the x-ray rereads, determines if the course of treatment should be changed, contacts the patient, and documents these actions in the record. The ED physician stated the process was documented in each patient's chart, but not in any form for use in the QAPI process.</p> <p>3. The policy governing both facilities titled, "Patient Contact After Discharge From the ED," was reviewed on October 3, 2007. The policy stated the following;</p> <p>a. The ED physician would note a preliminary reading on films taken when the radiologist was off duty;</p> <p>b. The ED physician's preliminary reading would be kept with the films, available for the radiologist to see what the ED physician concluded;</p> <p>c. After the radiologist reviewed the film and rendered a final report, clinically significant discrepancies would be brought to the attention of</p>	A1103	<p>notified.</p> <p>c. The Radiologist copies the case information to the ED – QA Worklist in the PACS system. This worklist serves as the tracking log for potential ED "misreads."</p> <p>3. The on-duty ED physician reviews the patient's chart and takes appropriate clinical action to.</p> <p>a. Contact the patient or their representative to inform them of the final interpretation and any change in their plan of care.</p> <p>b. Document the action taken in the patient's medical record.</p> <p>4. The variance readings are tracked by ED physician and type of exam to address trends and identify areas for improvement or change in practice.</p> <p>5. Variance rates and results of the reviews are reported to ED Committee, OPIC Committee and the Governing Board at part of the QAPI process.</p> <p>The PACS software company was contacted in February to assist in configuring the system to enable the required ED – QA Worklist tab. The PACS software company configured the tabs for the ED-QA Worklist. The function was tested and found to be functioning. The ED physicians and Radiologists were given reminders of the revised process. Additional written reminders were posted in the physician areas in the ED and Imaging departments.</p>
			04/01/08

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NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
A1103	<p>Continued From page 163 the ED physician on duty;</p> <p>d. For films with a positive diagnostic finding that did not have an ED preliminary reading noted, they would also be brought to the attention of the ED physician on duty;</p> <p>e. The physician would complete the, "Patient Contact After Discharge from the ED," form, for 3 reasons:</p> <ol style="list-style-type: none"> <li>1. Documentation in the patient's medical record,</li> <li>2. Serves as a log for performance improvement activities, and,</li> <li>3. Can provide feedback to the initial ED physician;</li> </ol> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director or designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> <li>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</li> </ol> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p>	A1103	<p>Person Responsible: ED and Imaging Department Chairs</p> <p>Monitoring:</p> <ol style="list-style-type: none"> <li>1. The ED Department Chair (or designee) provides oversight to the review of variances to consider trends or clusters of: <ol style="list-style-type: none"> <li>a. Variance involving the same provider.</li> <li>b. Variances of similar types of exams.</li> </ol> </li> <li>2. The ED physicians review the variances to identify opportunities for improvement. Significant variances will be routed to the ED committee for discussion and action as appropriate.</li> <li>3. Routine variance reporting will be incorporated into the ED Department peer review process for analysis and follow-up action as indicated. At a minimum, this will be done twice annually.</li> <li>4. Variance reviews are incorporated into the provider's reappointment profile.</li> </ol>	Ongoing

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A1103	<p>Continued From page 164</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>4. During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p> <p>b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.</p> <p>d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).</p> <p>During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they,</p>	A1103		

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A1103	Continued From page 165 "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or 414 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."	A1103			
A1104	<b>482.55(a)(3) EMERGENCY SERVICES POLICIES</b>  The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.  This Standard is not met as evidenced by: Based on interview and record review, the medical staff of the two hospitals failed to ensure implementation of a policy and procedure for follow up on x-ray reading discrepancies between the radiologists and emergency medicine physicians. There was no recording of data to track and trend which physicians had more variances, or if there were other trends such as variances in reading a particular type of x-ray, resulting in potential for inappropriate diagnosis and treatment of patients receiving diagnostic x-rays in the ED after hours.  Findings:  The two hospitals used separate Emergency Medicine Medical Groups to staff the two ED's.	A1104	Physician representatives from the Departments of Imaging and Emergency and the PI Director reviewed the policy, "Patient Contact after Discharge from the ED" (ED P#16) the decision was made to draft a new policy specific to the Medical Staff concerning variances in x-ray readings between Emergency Physicians and Radiologists. The new policy establishes a process to identify when there is a variance in the interpretation of imaging studies. When such a variance is identified: 1. Appropriate action is taken to alert a physician when a variance is identified that could impact the patient's plan of care. 2. The Medical Staff, as part of their ongoing efforts to improve the quality of care provided, review each variance on a regular basis to identify opportunities for improvement.		

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A1104	<p>Continued From page 166</p> <p>1. The Emergency Department for RSMC was toured on October 3, 2007, at 9 a.m. During the tour, the ED Director was questioned regarding the follow up of x-rays read after hours when a radiologist was not available. The Director stated all diagnostic x-rays were read by the ED physician after hours, and the radiologist would read them the next morning and contact the ED physician if there was a discrepancy. The Director stated the ED physician would then be responsible for following up with the patient. She stated there was no tracking system to ensure that each discrepancy was followed up. She stated there was no tracking of the readings for QAPI purposes to look for trends. She stated there was a quarterly meeting in which some of the cases were reviewed, but could not provide documentation of QAPI activities at that meeting.</p> <p>Radiologist 1 was interviewed during the tour. He was asked about the QAPI process for ED x-ray rereads. He stated that there was no formal process.</p> <p>A physician from the Medical Group covering the ED at RSMC was interviewed by phone on October 4, 2007, at 1:00 p.m. He stated that there was a system in place for patient follow up when there was a discrepancy in the reading of an x-ray, but it was an informal process. He stated that there was no organized QAPI process for x-ray rereads, but he knew his staff was having no problems in this area.</p> <p>2. A physician from the Medical Group covering the ED at IVMC was interviewed in person on October 4, 2007, at 11:55 a.m. He explained at IVMC there is a formal process whereby the radiologist contacts the ED physician, or sends</p>	A1104	<p>On 12/10/2007, the hospital implemented a digital imaging system referred to as "PACS" that provides better capabilities to track the variance. Under the new process:</p> <p>1. The ED physician or PA reviews the exam and enters in PACS an internal note of their findings for each exam reviewed. Treatment is initiated as appropriate and the patient/representative is advised of the preliminary findings.</p> <p>2. The radiologist reviews the exam for a final interpretation and result reporting.</p> <p>a. If the Radiologist reading is different than the preliminary ED read, the Radiologist informs the on-duty ED physician about the variance so appropriate clinical action can be taken if necessary.</p> <p>b. The Radiologist documents the variance (where the official interpretation differs from the ED preliminary finding) in the final dictated report, and who was notified.</p> <p>c. The Radiologist copies the case information to the ED – QA Worklist in the PACS system. This worklist serves as the tracking log for potential ED "misreads."</p> <p>3. The on-duty ED physician reviews the patient's chart and takes appropriate clinical action to.</p> <p>a. Contact the patient or their representative to inform them of the final interpretation and any change in their plan of care.</p> <p>b. Document the action taken in the patient's medical record.</p>	12/10/07



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A1104	<p>Continued From page 168</p> <p>3. Can provide feedback to the initial ED physician;</p> <p>f. The physician would document the attempts made to contact the patient, and if unable to make contact, would initiate a letter, then:</p> <ol style="list-style-type: none"> <li>1. The physician would give the letter to the ED Director of designee,</li> <li>2. A copy of the letter would be attached to the patient's medical record,</li> <li>3. The original letter would be mailed certified, return receipt, and,</li> <li>4. When the ED Director received the return receipt, it would be attached to the patient's medical record.</li> </ol> <p>During an interview with the ER Director on October 3, 2007, at 1:10 p.m., the Director stated a form was used by the physicians at IVMC, but a dictation and a stamp were used at RSMC. The Director stated she does not receive letters from physicians at either campus. She stated she thought the physicians mailed the letters themselves. The Director stated, "Obviously, we need to change our policy."</p> <p>During an interview with the Director of PI on October 3, 2007, at 1:17 p.m., the Director stated she did not receive any forms from either campus regarding x-rays in the ED.</p> <p>4. During a review of records in the radiology room on October 3, 2007, at 3:10 p.m., the following was noted;</p> <p>a. Patient 411 was seen in the ER on October 2, 2007, and had an ankle x-ray. The ED physician did not document a preliminary reading, and the radiologist documented a positive diagnostic finding (orricle vs. fracture).</p>	A1104	<p>3. Routine variance reporting will be incorporated into the ED Department peer review process for analysis and follow-up action as indicated. At a minimum, this will be done twice annually.</p> <p>4. Variance reviews are incorporated into the provider's reappointment profile.</p>		

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A1104	Continued From page 169  b. Patient 412 was seen in the ER on October 2, 2007, and had x-rays of an elbow, an ankle and a wrist. The ED physician did not document a preliminary finding. The radiologist had a negative finding.  c. Patient 413 was seen in the ER on October 2, 2007, and had an x-ray done. The ED physician did not document a preliminary finding. The radiologist had a negative finding.  d. Patient 414 was seen in the ER on October 2, 2007, and had a chest x-ray done. The ED physician did not document a preliminary finding, and the radiologist documented a positive diagnostic finding (bilateral infiltrate vs. atelectasis).  During an interview with the radiologist who reviewed these x-rays on October 3, 2007, at 3:18 p.m., he stated if the positive finding was obvious, and there was no preliminary finding documented by the ED physician, they (radiologists) worked on the assumption that the ED physician read the x-ray correctly, so they, "Didn't bother the ED physician." The radiologist stated if the positive finding was subtle, and there was no preliminary finding documented by the ED physician, they (radiologists) would tell the ED physician who was on duty. The radiologist stated he did not notify the ED physician on duty about Patient 411 or 416 because the findings were obvious, and he assumed the ED physician treated the patients correctly. The radiologist stated they told the ED physicians all the time to write their preliminary finding, "but they get so busy, it isn't their priority."	A1104		
A1123	482.56 REHABILITATION SERVICES	A1123		

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A1123	<p>Continued From page 170</p> <p>If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.</p> <p>This Condition is not met as evidenced by: Based on observation, interview, and record review the facility failed to ensure that rehabilitation services were adequately organized and managed to ensure the health and safety of patients, by failing to:</p> <p>a. Ensure outpatient rehabilitation services were provided in accordance with State licensing requirements (A0022);</p> <p>b. Ensure the rehabilitation services engaged in quality assurance and performance improvement activities during the nine months preceding the survey (A0267);</p> <p>c. Ensure all components of the clinical records for patients receiving outpatient therapy services were readily accessible (A0438);</p> <p>d. Ensure the treating therapist authenticated all entries in the clinical for patients receiving outpatient PT (A0453)</p> <p>e. Ensure therapeutic diets served to were ordered by the practitioner responsible for their care (A0629);</p> <p>f. Ensure electrical patient care equipment received electrical safety/calibration testing at appropriate intervals (A0724);</p>	A1123	For corrective action see Tags A020, A022, A267, A438, A453, A629, A724, and A1132.	
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A1123	Continued From page 171 g Ensure therapy services were provided under the order of the practitioner responsible for the patients (A1132), and;  g. Ensure OT services were provided in accordance with physician's orders (A1132)  The cumulative effect of these systemic problems resulted in the failure of the facility to ensure the provision of safe rehabilitation services.	A1123		
A1132	<b>482.56(b) WRITTEN PLAN OF REHABILITATION TREATMENT</b>  Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.  This Standard is not met as evidenced by: Based on staff interview and review of the facilities' clinical records, policies and procedures and medical staff rules and regulations, RSMC failed to ensure that occupational therapy services provided to 1 of ___ inpatients (Patients 202) were provided in accordance with physician orders. IVMC failed to ensure that physical therapy services provided to 1 of ___ inpatients (Patients 504) were provided in accordance with physician orders.  Findings:  a) Review of Patient 202's clinical record begun at 9:06 am. on October 3, 2007, revealed a	A1132	The Rehabilitation Manager reviewed and revised policy to address current process for evaluation and treatments of inpatients and to require a physician's signature on all treatment plans prior to providing ongoing physical therapy or occupational therapy.  The Rehabilitation Manager educated staff on the plan of care process, emphasizing the requirement for a physician signature approving the plan of care prior to physical therapy or occupational therapy.  The Rehabilitation Manager re-educated physicians (Department of Surgery and Department of Medicine) on the importance of signing the plan of care for physical or occupational therapy in a timely manner. Additional individual physician re-education was conducted on an as needed basis. Physician Office Managers were also educated.	10/17/07  11/14/07  01/03/08 & ongoing as indicated

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A1132	<p>Continued From page 172</p> <p>physician order for an occupational therapy evaluation dated September 23, 2007. The clinical record contained an occupational therapy evaluation and plan of care dated September 23, 2007. The plan of care was not signed by the physician. There was no evidence of an order for ongoing occupational therapy treatments. Review of the occupational therapy documentation revealed that Patient 202 received occupational therapy treatments on September 25, 27, 28 and 29, 2007.</p> <p>During an interview begun at 9:29 am. on October 3, 2007, the director of physical therapy stated that the facility did not have a policy regarding the provision of therapy after completion of an evaluation. The director stated that it was the facility practice to place the therapy plans of care in the physician's progress notes for the physician to review and sign. The director stated that ongoing therapy was routinely provided after an evaluation whether or not a physician order was received. The director acknowledged that the occupational therapy plan of care had not been approved by the physician.</p> <p>Review of the facility's policies and procedures begun at 10:23 am. on October 3, 2007 revealed a policy titled "Physician's Orders." The policy stated, "All diagnostic and therapeutic activities involving the patient will be ordered by a physician member of the Medical Staff".</p> <p>b) During an interview begun at 9:29 am. on October 3, 2007, the director of physical therapy stated that the facility did not have a policy regarding the provision of therapy after completion of an evaluation. The director stated that it was the facility practice to place the therapy plans of care in the physician's progress notes for</p>	A1132	Open and closed chart review. These audits are reviewed monthly by the Rehabilitation Manager and added to PI program as a Quality Indicator which is reported quarterly. Recent reviews reveal the following: December, 2007 audits demonstrate 93% compliance (27 charts), 92% in January (39 charts), 100% in February (31 charts), 100% in March (47 charts).	12/07 & ongoing	

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FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050701</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/05/2007</b>
NAME OF PROVIDER OR SUPPLIER <b>SOUTHWEST HEALTHCARE SYSTEM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
A1132	<p>Continued From page 173</p> <p>the physician to review and sign. The director stated that ongoing therapy was routinely provided after an evaluation whether or not a physician order was received. The director acknowledged that the occupational therapy plan of care had not been approved by the physician.</p> <p>Review of the facility's policies and procedures begun at 10:23 am. on October 3, 2007 revealed a policy titled "Physician's Orders." The policy stated, "All diagnostic and therapeutic activities involving the patient will be ordered by a physician member of the Medical Staff".</p> <p>Review of Patient 504's clinical record begun at 9:29 am. on October 4, 2007 revealed a physician order for a physical therapy consult dated September 30, 2007. The clinical record contained a physical therapy evaluation and plan of care dated September 30, 2007. The plan of care was not signed by the physician. There was no evidence of an order for ongoing occupational therapy treatments. Review of the physical therapy documentation revealed that Patient 504 received physical therapy treatments twice daily on September 30, 2007 and October 1 and 3, 2007.</p>	A1132		