

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

PRINTED: 03/23/2010
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/19/2010
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 000	<p>INITIAL COMMENTS</p> <p>The following reflects the findings of the Department of Public Health during a FULL MEDICARE VALIDATION survey.</p> <p>Representing the Department: Barbara Mellor, HFES; Sanford Weinstein, Medical Consultant; Raul Reyes, HFEN; Lucy Yang, HFEN; Halbert Rand, HFEN; Barbara Ruger, HFEN; Letitia Creighton, Infection Control Consultant; Kerry Kelly, Nutrition Consultant; Terry Rubin, Pharmacy Consultant; John Christensen, Pharmacy Consultant; Francia Trout, Medical Records Consultant; Gerri Kaplan, Medical Records Consultant.</p> <p>The survey team entered at the Rancho Springs Medical Center (RSMC) campus at 0800 hours on 1/11/10. The inpatient census for both campuses was 213.</p> <p>On 1/12/10 at 1825 hours, the Administrator was notified of Immediate Jeopardy (IJ) to the health and safety of Emergency Department (ED), Cardiac Catherization Laboratory and Radiology patients as a result of housing patients and equipment in emergency egress corridors and in front of emergency pull boxes of the ED on the Rancho Springs Medical Center campus.</p> <p>A written plan of correction for the IJ was received on 1/13/10 at 0800 hours and was not acceptable for monitoring to ensure continued compliance and safety for the patients. A revised written plan of correction for the IJ was received at 1900 hours on 1/14/10 and found to be unacceptable. The IJ had not been abated at the conclusion of the survey at 1700 hours on 1/15/2010. A plan of correction was submitted via e-mail at 2000 hours</p>	A 000		
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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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A 000	<p>Continued From page 1 on 1/15/10; however, the survey team was not available for review.</p> <p>Monitoring visits were conducted at 1710 hours on 1/16/10, at 1600 hours on 1/17/10 and at 0740 hours on 1/18/10. The ED corridors were kept clear of patients and equipment. There was a monitoring system implemented to ensure all emergency egress corridors and equipment were kept clear of obstruction.</p> <p>The hospital's written plan of correction was accepted by the survey team at 1530 hours on 1/19/10 and the Administrator was notified the Immediate Jeopardy was abated. See A700 and the Life Safety Code Survey conducted concurrently. Glossary:</p> <p>ACLS - Advanced Cardiac Life Support AIA - American Institute of Architects AORN - Association of periOperative Registered Nurses BBW - Black Box Warning C - Centigrade CAT/CT - Computerized Axial Tomography scan CDC - Centers for Disease Control and Prevention CEO - Chief Executive Officer CHT - Certified Hyperbaric Technician CLS - Clinical Laboratory Scientist CM - Case Manager CMRN - Case Manager RN CMS - Centers for Medicare and Medicaid Services COW - Computer on Wheels deg - degrees DOP - Director of Pharmacy</p>	A 000		
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A 000	Continued From page 2 ED - Emergency Department EMS - Emergency Medical Services EKG - Electrocardiogram EOC - Environment of Care F - Fahrenheit FeSO4 - Ferrous (Iron) Sulfate FDA - Food and Drug Administration HAACP - Hazard Analysis & Critical Control Point HCW - Health Care Workers Hg - Mercury HVAC - Heating, Ventilation, Air-Conditioning ICU - Intensive Care Unit IV - Intravenous or Intravenously IVMC - Inland Valley Medical Center IVP - Intravenous Push L&D - Labor and Delivery LSC - Life Safety Code LVN - Licensed Vocational Nurse MAR - Medication Administration Record mg - milligram or milligrams MH - Malignant Hyperthermia ml - milliliter or milliliters mm- -millimeters MSE - Medical Screening Examination MVI - Multi-Vitamins NARA - National Archives and Records Administration NFPA - National Fire Protection Association NS - Normal Saline O2 - Oxygen OR - Operating Room PA - Physician Assistant PACU - Post Anesthesia Care Unit PCA - Patient Controlled Analgesia PALS - Pediatric Advanced Life Support P&P - Policy and Procedure PICC - Peripherally Inserted Central Catheter Pyxis - Medication cabinet on the patient care unit QAPI - Quality Assurance and Performance	A 000		

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A 000	Continued From page 3 Improvement RCP - Respiratory Care Practitioners RD - Registered Dietitian RN - Registered Nurse RSMC - Rancho Springs Medical Center SART - Sexual Assault Response Team SPD - Sterile Processing Department TB - Tuberculosis WCC - Wound Care Center	A 000		
A 043	<p>482.12 GOVERNING BODY</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview, a review of selected policies and procedures and a review of professional credentials files and human resource files, the hospital failed to ensure the governing body carried out its full and complete oversight for the hospital as a whole. The cumulative effect of these systemic problems identified during the Life Safety Code (LSC) and Full Health Medicare Validation survey resulted in exhibiting the hospital's inability to ensure the provision of quality health care in a safe environment.</p> <p>Findings:</p> <p>The governing body failed to ensure that the medical staff bylaws and appointments of practitioners to the medical staff had been performed in a manner consistent with the medical staff bylaws of the hospital. See A045,</p>	A 043		

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A 043	<p>Continued From page 4 A341 and A353.</p> <p>The governing body failed to ensure the provision of care in a safe environment. See A144 and A724 #4 .</p> <p>The governing body failed to ensure an effective, data driven QAPI program that addressed high risk, problem prone areas and used the data collected to identify opportunities for improvement. See A263.</p> <p>The governing body failed to ensure the security and patient safety for the newborn nursery area. See A310.</p> <p>The governing body failed to ensure a safe environment was maintained for fire safety for patients in the radiology, cardiac catheterization, and emergency departments and the Wound Care Center. See A710.</p> <p>The governing body failed to ensure the preparation of a complete and accurate medical record. See A274, A450, A457 and A1005.</p> <p>The governing body failed to ensure compliance with the condition of participation for nursing services. See A385.</p> <p>The governing body failed to ensure development and implementation of policies and procedure for infection control. See A747.</p> <p>The governing body failed to ensure safety and compliance with the condition of participation for Emergency Services. See A 1100.</p> <p>The cumulative effect of these systemic problems</p>	A 043		

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A 043	Continued From page 5	A 043		
A 045	<p>resulted in the failure by the hospital to provide quality care in a safe environment.</p> <p>482.12(a)(1) MEDICAL STAFF - APPOINTMENTS</p> <p>[The governing body must] determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and a review of professional credentials files, the governing body failed to ensure which practitioners were eligible for appointment to the medical staff for six of 11 PA (PAs 1, 2, 6, 8, 10 and 11) credential files reviewed which could potentially effect the quality of medical care the patients received.</p> <p>Findings:</p> <p>1. During an on site visit to the hospital and interviews with M56 conducted on 1/14/10 at approximately 1400 hours, the credentials files for 11 physician assistants were reviewed. PA1 applied for medical staff privileges and was appointed to the staff. The privileges for PA1 expired prior to the completion of proctoring for PA1. The medical staff bylaws specify concurrent and retrospective review of medical records and services provided by each PA for 10 cases, prior to appointment to the staff of the hospital.</p> <p>2. PA2 was appointed to the medical staff of the hospital on 3/10/09. A review of the credentials file for PA2 and interviews with M56 revealed that proctoring was completed on the evening of 1/13/10, during the survey process for the hospital. According to interviews with the medical</p>	A 045		

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A 045	<p>Continued From page 6</p> <p>staff representative and a review of the medical staff bylaws of the hospital, "proctoring shall consist of retrospective and concurrent case reviews."</p> <p>3. PA6 was appointed to the medical staff of the hospital on 10/19/09. A review of the credentials file for PA6 and interviews with the medical staff representative revealed that proctoring was completed on the evening of 1/13/10, during the survey process for the hospital.</p> <p>4. PA8 was appointed to the medical staff of the hospital on 4/16/07. A review of the credentials file for PA8 revealed that documentation of proctoring was performed for nine cases on 4/30/08. This did not comply with the medical staff bylaws of the hospital that specify 10 concurrent and retrospective case reviews. When interviewed on 1/14/10 at approximately 1440 hours, PA8 stated that she was unaware of her "responsibility to initiate contact with her proctor when treating a patient."</p> <p>5. The professional credentials file for PA10 revealed that proctoring was performed for 10 cases on the same date. There was no written documentation that the medical records review was consistent with the medical staff bylaws that require concurrent and retrospective case review.</p> <p>6. On 1/11/10 at 1350 hours, an interview was conducted with PA11. PA11 was observed sitting in a room designated as a MSE room. MSE's are patient examinations done to determine if a patient has an emergency medical condition. PA11 stated that she did MSEs for ED patients and ordered tests and treatments.</p> <p>On 1/12/10, a review of the credential file for</p>	A 045		
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A 045	Continued From page 7 PA11 failed to show any written evidence of proctoring. The governing body failed to ensure that appropriate proctoring of each category of practitioner for appointment to the medical staff had been implemented in accordance with the medical staff bylaws of the hospital. See A341 #6 and A353.	A 045		
A 092	482.12(f)(1) EMERGENCY SERVICES If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55. This STANDARD is not met as evidenced by: Based on observation, interview and record review the hospital failed to comply with the requirements of CFR 482.55. By failing to ensure: 1. The provision of a valid back up specialty on call schedule. See A1102. 2. The following was implemented in the ED: a. Not housing patients and equipment in emergency egress corridors and in front of emergency pull stations which subjected the patients to danger from fire. See A710 and A1104 #1. b. A process was in place to accurately document patients' arrival times in the ED. See A1104 #2. c. Patient privacy was provided. See A1104 #3. d. LVN assignments reflected the patients' acuities. See A1104 #4	A 092		

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A 092	Continued From page 8	A 092		
A 115	<p>3. Six of 11 PAs were competent to perform MSEs. See A1112.</p> <p>The cumulative effect of these systemic problems resulted in the failure by the hospital to provide quality care in a safe environment.</p> <p>482.13 PATIENT RIGHTS</p> <p>A hospital must protect and promote each patient's rights.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview and record review, the hospital failed to</p> <p>1. Ensure the patients' right to receive care in a safe setting in the Emergency and Radiology Departments, Cardiac Catheterization Laboratory, and the newborn nursery of the RSMC campus and the Wound Care Center of the IVMC campus.</p> <p>The emergency egress corridor for the ED, Radiology Department and Cardiac Catheterization Laboratory was blocked with patients in gurneys, patient care equipment and visitor chairs 80% of the time per staff interview.</p> <p>The newborn nursery failed o have adequate safeguards in place to prevent infant abduction after removal of a security alarm system approximately one year prior to the survey.</p> <p>There was not maintenance of the fire emergency equipment, smoke wall barriers, and emergency evacuation procedures in the Wound Care Center. See A144, and A710.</p>	A 115		

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A 115	Continued From page 9 2. Ensure the patients' rights to personal privacy in the ED of the RSMC campus. See A143. 3. The hospital failed to ensure adequate systems in place to ensure the temperature and humidity monitors in the OR were calibrated and tested for accuracy on a regular basis. See A 144. The cumulative effect of these systemic problems resulted in the failure by the hospital to provide quality care in a safe environment.	A 115		
A 143	482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY The patient has the right to personal privacy. This STANDARD is not met as evidenced by: Based on observations and interviews, the hospital failed to provide privacy for ED patients at the RSMC campus and patients in the preoperative and PACU area of the IVMC campus which could potentially affect the patients' rights to respect and dignity. Findings: 1. On 1/11/10 at 1400 hours and 1/12/10 at 0950 hours, the hospital's RSMC campus ED was toured and a lack of patient privacy was observed on both days: A double doorway served as an exit from the ED into the hallway of the Radiology Department. The long radiology hallway had ED patients on gurneys lining the entire right side of the hallway. A shorter hallway on the left had two patients in gurneys lining the left side which filled the left side to the exit doors. All eight patients, on both days,	A 143		

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A 143	<p>Continued From page 10</p> <p>had screen between each gurney but no screens or curtains in front of them and all eight patients were visible to people (which included hospital staff and visitors), walking down the hall. On 1/11/10 at 1430 hours, one of the unsampled patient was uncovered and had one hand down the front of his pants.</p> <p>On 4/11/10 at 1430 hours, the surveyor was conducting an interview with Patient 317 in ED Room 3. The room was intended for one patient but there were two patients in the room. A staff members discussion with the other patient was clearly audible at Patient 314's bedside.</p> <p>2. On 1/11/10 a confidential patient interview was conducted. The patient stated he had to leave the ED waiting room due to embarrassment about other people in the waiting area seeing his condition. When the patient was taken to the treatment area he was placed in a bed in the hallway. He stated this lacked privacy but then he was transferred to a regular space in the ED. This also lacked privacy because everyone kept coming in to get supplies out of the room. He stated he was in Room 5.</p> <p>At 1100 hours on 1/11/10 observations of the ED were made. There were patients on gurneys in the hallway. There were privacy curtains between patients but each patient could be viewed by any visitor walking down the hallway. Room 5 of the ED was observed to contain supply carts, casting equipment, and the blanket warmer for the ED patients. A patient was on the gurney in this bay but the privacy curtain had not been pulled to maintain privacy from visitors in the ED.</p> <p>3. On 1/12/10 at 1045 hours, the preoperative</p>	A 143		

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A 143	Continued From page 11 area at IVMC's campus was toured accompanied by M36. One patient, in Bay #5 was observed in a reclining chair receiving a blood transfusion. In Bay #6, another patient was semi-reclining in a gurney receiving an IV infusion. There was no privacy protection device provided between the two patients. M36 stated the preoperative area was used to prepare patients for procedures and outpatient IV infusions.	A 143			
A 144	4. On 1/12/10 at 1140 hours, the PACU at the IVMC campus was toured with M36. No patient's privacy curtain was present between Bays 7 and 8. M36 stated the unit was designed as an eight bay patient recovery unit. Bay 8 currently was used for storage of the OR C-arms, camera tower, and OR patient positioning devices. Patients being recovered in Bay 7 could be exposed to staff members when they were using the C-arms or supplies from Bay 8. 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on observation, interviews and a tour of the hospital, the hospital failed to ensure the provision of care in a safe environment which could potentially effect fire safety in the ED and the OR at RSMC campus and the WCC at the IVMC campus. Also, the hospital did not protect infants from being abducted at the RSMC campus. Findings: 1. Based on observation and staff interview, the	A 144			

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A 144	<p>Continued From page 12</p> <p>hospital failed to ensure that the physical plant, equipment and hospital environment were maintained in such a manner that the safety and well-being of patients was assured. At RSMC, by not maintaining exit access in the emergency department (ED), by penetrations in the smoke barrier wall enclosing the ED suite, and by obstructed access to manual pull stations, the hospital created the potential for lack of safety. This affected 19 patients in the ED and in the Radiology Department corridor outside the ED, visitors, radiology department patients and hospital staff. See A710.</p> <p>On 1/13/10 at the WCC on the IVMC campus, there were penetrations in the walls, insufficiency of firewalls/firedoors, no alarm system in place and no staff training for patient evacuation. This could potentially result in the inability to stop the spread of fire and evacuate patients in the event of a fire resulting in potential harm or death. See A710.</p> <p>2. A tour of the surgical suites at RSMC campus was performed on 1/11/10 at approximately 1300 hours. The temperature and humidity for each surgical suite was provided by a hand held device fixed to the wall of the surgical area. This device, or fluke as it was called by representatives from the operating room and plant maintenance, registered the room temperature and humidity. Hospital employees E141 and M46 stated that these devices had been calibrated at the factory. When asked to produce a log to document that these devices had been re-calibrated or re-tested to ensure accuracy, representatives from the facility were unable to do so. Temperature and humidity control in the operating rooms is essential to decrease the risk of fire in this oxygen</p>	A 144		

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A 144	Continued From page 13 rich environment. 3. The hospital failed to ensure the provision of safety for its pediatric patients when it failed to ensure that the exit areas adjacent to the newborn nursery had appropriate alarms or security measures to protect from infant abduction. See A724.	A 144		
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 those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on observation, interview and record review the hospital failed have an effective QAPI program by failing to ensure: Data used in the ED to measure performance was accurate and reflected actual practice and data collected for healthcare associated infections was used to identify opportunities for improvement and make changes. - See A267. QAPI activities were in place for monitoring	A 263		

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A 263	Continued From page 14 compliance with hospital P&Ps designed to detect and prevent the spread of MRSA. See A267. Data collected for hospital associated infections was used to improve performance. See A267, A276. The executive responsibilities for oversight of QAPI data collection, analysis and use for performance improvement were defined and ongoingly implemented. See A310.	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 interviews and record review, the hospital failed to have a process in place to accurately document patients' arrival times in the ED so data collection for QAPI was accurate, implement and use data collected for use in preventing healthcare associated infections, implement a system to monitor compliance with the hospital's P&Ps for detecting and preventing the spread of MRSA and ensure data collection to monitor the timely administration of antibiotics was congruent with P&Ps. This resulted in the potential for the hospital not to recognize problems and correct processes that could improve patient outcomes.	A 267		

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A 267	<p>Continued From page 15</p> <p>Findings:</p> <p>1. On 1/12/10, review of the most recent quarter performance improvement dashboards for both the RSMC and IVMC showed areas for measurement included ED turn around times, time to provider, and other measures. When the ED logs for the EDs were reviewed, the arrival time was part of the ED log. However, further investigation showed this was not the time the patient actually arrived at the ED for walk-in patients (that is all patients not arriving by EMS ambulance) but the time the patient was triaged.</p> <p>According to M49, interviewed on 1/12/10 at 1530 hours, upon arrival to the ED walk-in patients obtained a form from the admissions clerk titled "ED Demographics." The patients were to fill out this form on arrival to the ED. The top of the form had a section for date and time of arrival. A review of 12 sampled ED patients showed no arrival time for five patients (Patients 16, 294, 295, 296, and 318) and an inaccurate time for one patient (Patient 16). See A1104.</p> <p>On 1/13/10 at 1630 hours, M48 confirmed there was no record that accurately showed total patient time in the EDs.</p> <p>2. On 1/13/10 at 1215 hours an interview was conducted with M14 and E166. During the interview, M14 and E166 was asked about their process for reducing healthcare associated infections. E166 stated that in July 2009, the hospital had developed subcommittees for "Bundles" (a group of actions that together reduce the risk of developing a healthcare associated infection); but, had not done much with the data collected or analyzed from the four bundles</p>	A 267		
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A 267	<p>Continued From page 16 developed.</p> <p>During the same interview, M14, stated that the two hospital campuses planned on implementing the four bundles in 2010.</p> <p>3. On 1/11/10 at 1600 hours, the hospital's 4/09, policy and procedure titled, "MRSA - screening and prevention program" (methicillin resistant staphylococcus aureus). On page two direction was given that the following patients must be tested within 24 hours of admission: Any patient scheduled to undergo an inpatient surgery. Any patient who has been previously discharged from a general acute care hospital within 30 days prior to the current hospital admission. Any patient being transferred from a skilled nursing facility. Any patient admitted to ICU, NICU units (Intensive care unit, neonatal intensive care unit). Any patient who receives inpatient dialysis or outpatient dialysis treatment. Any patient who has a prior history of MRSA infection.</p> <p>On 1/12/10 at 0910 hours, an interview was conducted with E26. E26 was asked to describe the MRSA screening process in accordance with their policy and procedure. E22 stated that neither of the two hospital campuses tracked compliance with their MRSA policy. E22 further stated that the two hospital campuses had no idea what their MRSA policy and procedure compliance was.</p> <p>4. On 1/15/10 at 1140 hours, AS5 stated that the quality review for antibiotic administration was to assure that antibiotics were administered within 6</p>	A 267		

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A 267	Continued From page 17 hours, however, according to the hospitals policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics needed to be administered within two hours of the physician order to prevent or treat an infection. The QAPI program data collection measurement was not in accordance with the standards of care developed by the hospital for the timely administration of antibiotics.	A 267		
A 276	482.21(b)(2)(ii) QAPI IDENTIFY IMPROVEMENT [The hospital must use the data collected to--] (ii) Identify opportunities for improvement and changes that will lead to improvement. This STANDARD is not met as evidenced by: Based on interview, the hospital failed to ensure the data collected for hospital acquired infections was used to identify opportunities for improvement. Findings: On 1/13/10 at 1215 hours an interview was conducted with M14 and E166. During the interview, M14 and E166 was asked about their process for reducing healthcare associated infections. E166 stated that in July 2009, the hospital had developed subcommittees for "Bundles" (a group of actions that together reduce the risk of developing a healthcare associated infection); but, had not done much with the data collected or analyzed from the four bundles developed. During the same interview, M14, stated that the two hospital campuses planned on implementing the four bundles in 2010.	A 276		

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A 310	<p>482.21(e)(1) EXECUTIVE RESPONSIBILITIES</p> <p>That an ongoing program for quality improvement ... is defined, implemented, and maintained.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the executive leadership, medical staff and administrative officials failed to ensure QAPI data collection was defined, measured progress toward meeting the goals of the antibiotic administration P&Ps and was accurate, that it ongoingly implemented processes to make improvements in hospital acquired infections, and maintained surveillance and data evaluation of MRSA admissions and hospital acquired infections.</p> <p>Findings:</p> <p>1. Interview with Patient 16 on 1/11/10 showed he had come to the Emergency Department at approximately 2115 hours on 3/9/10 and was not seen by a nurse to assess his condition until approximately two hours later. Review of documents used to collect QAPI data about arrival to treatment times (ED Demographics forms) showed they were not always filled out and/or the time entered on the form was the time of triage by a nurse not the actual arrival time.</p> <p>On 1/12/10, review of the most recent quarter performance improvement dashboards for both the RSMC and IVMC showed areas for measurement included ED turn around times, time to provider, and other measures.</p> <p>On 1/13/10 at 1630 hours, M48 confirmed there was no record that accurately showed total patient time in the EDs. See A267.</p>	A 310		

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A 310	<p>Continued From page 19</p> <p>2. On 1/13/10 at 1215 hours an interview was conducted with M14 and E166. During the interview, M14 and E166 was asked about their process for reducing healthcare associated infections. E166 stated that in July 2009, the hospital had developed subcommittees for "Bundles" (a group of actions that together reduce the risk of developing a healthcare associated infection); but, had not done much with the data collected or analyzed from the four bundles developed.</p> <p>During the same interview, M14, stated that the two hospital campuses planned on implementing the four bundles in 2010. The executive leaership failed to ensure the data collected was acted on to improve the hospital's performance. See A276.</p> <p>3. On 1/15/10 at 1140 hours, AS5 stated that the quality review for antibiotic administration was to assure that antibiotics were administered within 6 hours, however, according to the hospitals policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics needed to be administered within two hours of the physician order to prevent or treat an infection. The QAPI program data collection measurement was not in accordance with the standards of care developed by the hospital for the timely administration of antibiotics. See A500.</p> <p>4. On 1/12/10 at 0910 hours, an interview was conducted with E26. E26 was asked to describe the MRSA screening process in accordance with their policy and procedure. E22 stated that neither of the two hospital campuses tracked compliance with their MRSA policy. E22 further</p>	A 310		
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A 310	Continued From page 20 stated that the two hospital campuses had no idea what their MRSA policy and procedure compliance was. The executive leadership failed to ensure data was collected to monitor this important aspect of care to ensure potential problems were identified and actions taken to improve the hospital's performance. See A267.	A 310		
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 medical care provided to patients by the hospital. This CONDITION is not met as evidenced by: Based on interviews, a tour of the facility during an onsite visit to the hospital conducted on 1/12/10 and a review of selected documents and medical staff bylaws, the medical staff failed to be accountable to the governing body for the quality and appropriateness of care provided to its patients. Findings: The medical staff failed to ensure the preparation and maintenance of a complete and accurate medical record for anesthesia and emergency department medical records. See A449. The medical staff failed to ensure the appropriate credentialing of physician assistants providing direct care in the emergency department. See A341. The cumulative effect of these systemic problems resulted in the failure by the hospital to provide a safe and quality care for patients.	A 338		

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A 341	<p>482.22(a)(2) MEDICAL STAFF CREDENTIALING</p> <p>The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.</p> <p>This STANDARD is not met as evidenced by: Based on interviews and a review of 11 credentials files for physician assistants (PA) providing services in the emergency department of the hospital, the medical staff failed to follow its own mechanism for proctoring six of 11 applicants (PAs 1, 2, 6, 8, 10 and 11). This resulted in a lack of oversight of mid-level practioners delivering treatment and care to patients within the hospital.</p> <p>Findings:</p> <p>During an on site visit to the hospital and interviews with the medical staff representative conducted on 1/14/10 at approximately 1400 hours, the credentials files for 10 physician assistants were reviewed:</p> <p>1. PA1 applied for medical staff privileges and was appointed to the staff. The privileges for PA1 expired prior to the completion of proctoring for PA1. The medical staff bylaws specify concurrent and retrospective review of medical records and services provided by each PA for 10 cases, prior to appointment to the medical staff of the hospital.</p> <p>2. PA2 was appointed to the medical staff of the hospital on 3/10/09. A review of the credentials file for PA2 and interviews with the medical staff representative revealed that proctoring was completed on the evening of 1/13/10, during the survey process for the hospital. According to</p>	A 341		
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A 341	<p>Continued From page 22</p> <p>interviews with the medical staff representative and a review of the medical staff bylaws of the hospital, "proctoring shall consist of retrospective and concurrent case review."</p> <p>3. PA6 was appointed to the medical staff of the hospital on 10/19/09. A review of the credentials file for PA6 and interviews with the medical staff representative revealed that proctoring was completed on the evening of 1/13/10, during the survey process for the hospital.</p> <p>4. PA8 was appointed to the medical staff of the hospital on 4/16/07. A review of the credentials file for PA8 revealed that documentation of proctoring was performed for nine cases on 4/30/08. This did not comply with the medical staff bylaws of the hospital that specify 10 concurrent and retrospective case reviews. When interviewed on 1/14/10 at approximately 1440 hours, PA8 stated that she was unaware of her "responsibility to initiate contact with her proctor when treating a patient."</p> <p>5. The professional credentials file for PA10 revealed that proctoring was performed for 10 cases on the same date. There was no written documentation that the medical records review was consistent with the medical staff bylaws that require concurrent and retrospective case review.</p> <p>6. On 1/11/10 at 1350 hours, an interview was conducted with PA11. PA11 was observed sitting in a room designated as a MSE room. MSE's are patient examinations done to determine if a patient has an emergency medical condition. PA11 stated that she did did MSEs for ED</p>	A 341		
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A 341	Continued From page 23 patients and ordered tests and treatments. On 1/13/10, a review of the credential file for PA11 failed to show any written evidence of proctoring for MSEs.	A 341		
A 353	482.22(c) MEDICAL STAFF BYLAWS The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must: This STANDARD is not met as evidenced by: Based on interviews and a review of 19 professional credentials files of the medical staff, the medical staff failed to enforce its own bylaws. This resulted in a lack of oversight of mid-level practioners delivering treatment and care to patients in the ED. Findings: A review of 19 professional credentials files revealed that the medical staff failed to comply with its own medical staff bylaws for the proctoring of 6 of 19 applicants to the medical staff of the hospital. When reviewed, the professional credentials files for six physician assistants revealed that the proctoring in concurrent and retrospective chart review, had not been completed. See A341.	A 353		
A 385	482.23 NURSING SERVICES 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: Based on observation, interview, and record review, the hospital failed to ensure the organized	A 385		

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A 385	<p>Continued From page 24</p> <p>delivery of nursing services by failing to:</p> <ol style="list-style-type: none"> 1. Assess and/or re-evaluate patients regarding pain and their response to intervention on an ongoing basis per hospital policy. See A395 #1 and #4. 2. Implement policies and procedures for two of two patients sampled for fall prevention. See A395 #2 and #3. 3. Intervene for a patient with with low blood pressure. See A395 #6. 4. Develop and keep current nursing care plans. See A396. 5. Show documentation of how the ED LVN assignments were related to patient acuity. See A397. 6. Carry out physician orders to administer two medications to lower blood pressure. See A404 #1. 7. Administer Dilaudid according to written policies and procedures. See A404 #2. 8. Carry out the 24 hour check of a patient's MAR for accuracy. See A404 #3. 9. Check a patient's blood pressure prior to administration of a medication that lowered blood pressure. See A404 #3. 10. Administer the first dose of intravenous antibiotics to patients within two hours of the order according to the hospital's P&P. See A405. 	A 385		

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A 385	Continued From page 25	A 385		
A 395	<p>The cumulative effect of these systemic problems resulted in the failure by the hospital to provide quality care in a safe environment.</p> <p>482.23(b)(3) RN SUPERVISION OF NURSING CARE</p> <p>A registered nurse must supervise and evaluate the nursing care for each patient.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the hospital failed to assess and/or re-evaluate four of 86 sampled patients (Patients 2, 16, 66 and 169) regarding pain and their response to intervention on an ongoing basis per hospital policy and a hypertensive (high blood pressure) patient with low blood pressure (Patient 66). The hospital failed to ensure policies and procedures were implemented for two of two patients sampled for fall prevention (Patients 32 and 320). The failures resulted in ineffective relief and management of acute pain and possible patients' injuries secondary to fall and low blood pressure. Additionally, one RN was unable to correctly use a cardiac defibrillator/pacemaker which could potentially result in a delayed response in an emergency.</p> <p>Findings:</p> <p>1. At 1015 hours on 1/11/10 Patient 16 was interviewed. He was observed to have a nasogastric tube for drainage of stomach contents. Patient 16 stated he was waiting to have emergency surgery on his abdomen. The patient and family stated he had come to the ED at approximately 2115 hours on 1/9/10 with severe abdominal pain. The patient stated it had taken two hours before he saw a nurse in the ED</p>	A 395		

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A 395	<p>Continued From page 26</p> <p>to evaluate the severity of his condition. During the long wait in the ED before seeing a nurse, the patient had to step outside because he was embarrassed to be seen doubled over in pain. When he did see a nurse, the family member stated the patient stated his pain was 13 on a scale of 1 to 10 with 10 being the worst pain. Review of the patient's record on 1/13/10 revealed the "ER Demographics" form did not document a time that the patient arrived at the ED. There was a hand written note on this form that said the patient was called at 2240 hours and there was no answer. The ED record revealed a nurse first saw Patient 16 at 2308 hours and he complained of a "10" pain. Interview with Patient 16 at 1600 hours on 1/12/10 revealed the surgeon had found an intestinal blockage approximately the size of a small cantaloupe.</p> <p>2. On 1/12/10 at 1505 hours the door to Patient 32's room was observed closed. There was a sticker on the room number of the door identifying the patient was a high risk for falls. D1 stated the patient's door could be closed if the patient requested. Review of the policy and procedure titled Patient Fall Prevention Program identified that the patient identified to be at risk for falls would have a yellow arm band and door sign applied during the admission process. At 1600 hours on 1/12/10 Patient 32 was interviewed. She was observed not to have a yellow arm band on. She stated she was dizzy sometimes and therefore was at risk of falling. She stated she had been in the hospital for one week and had never had a yellow arm band.</p> <p>3. At 1540 hours on 1/12/10 Patient 320 was observed ambulating in the hallway with the assistance of staff. He was using a walker and</p>	A 395		

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A 395	<p>Continued From page 27</p> <p>had a gait belt around his waist. He was observed to enter a room that had a sign identifying him at a risk for falls. Review of the Patient 320's medical record revealed an admission date of 1/11/10. As of 1550 hours on 1/12/10 there was no documented evidence of nursing education given to the patient about how to prevent falls while in the hospital. After talking with the patient's RN, this was confirmed by D1 who stated the RN had not done the patient education as described in the Patient Fall Prevention Program policy and procedure.</p> <p>4. On 1/15/10 at 1300 hours, review of the hospital's P&P on Pain Management (revised on 2/09) stated, "Monitor efficacy of pain treatment and patient satisfaction. Any adverse reaction or uncontrolled pain should be reported to the physician as quickly as possible. Pain interventions that are deemed ineffective will be addressed and alternative measures will be taken and documented on the Interdisciplinary Plan of Care."</p> <p>In the pain management P&P entitled "Special Considerations," it was stated on #7 that, "Patients who are in a special procedure, or in another department who need narcotic pain medication must be monitored for 30 minutes post narcotic administration by an RN. Monitoring includes assessment for pain control, and repeat vital signs to include O2 saturation."</p> <p>At RSMC medical-surgical floor, east side, on 1/14/10 at 0930 hours, the medication pass to three patients was observed with M54. E18 told Patient 2 that the patient's medications had not been delivered by the pharmacy. Patient 2 nodded in acknowledgement but with painful</p>	A 395		
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A 395	<p>Continued From page 28</p> <p>facial grimaces. E18 was ready to leave Patient 2's bedside without assessing the patient's pain until M54 indicated to turn off the lights because it looked like the patient was having pain. Only then did E18 ask Patient 2 about pain. Patient 2 complained of abdominal pain which was rated at 8/10, with 10 as the most painful on a scale of 1-10.</p> <p>E18 verified the physician's order for Dilaudid 2 mg to be given intravenously as necessary for pain. The pain medication was administered by pushing Dilaudid 2mg intravenously into the patient's IV access within 40 seconds, based on the second hand of the patient's wall clock. The patient's facial grimaces were noted to relax. E18 left the patient's room and charted the medication in the MAR as given.</p> <p>Per review of the nursing care plan for Patient #2 on 1/14/10 at 1000 hours, regarding the nursing problem of alteration in comfort (pain), the goal was to achieve a pain level of 2/10.</p> <p>Review of the nurses' notes and MAR on 1/15/10 at 1030 hours revealed that, on 1/14/10, Patient 2 continued to receive Dilaudid 2 mg intravenously every two hours from 1000 hours to 2045 hours. The abdominal pain was continuously rated by the patient as 8/10 pain level at 1000 and 1200 hours subsiding to only 6/10, an hour after the Dilaudid was pushed intravenously. The pain rating went up twice to pain level of 9/10 at 1400 hours and 1600 hours, however, record review failed to reveal any evidence that the physician was informed for other alternative pain relieving measures. Further record review revealed that the pain level and medication response was not consistently re-assessed/re-evaluated after</p>	A 395		

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A 395	<p>Continued From page 29</p> <p>narcotic administration per the written plan of nursing care. There was no evidence that repeat vital signs were taken 30 minutes after medication administration per hospital policy and/or whether the patient was monitored for respiratory depression per MAR instruction.</p> <p>On 1/15/10 at 1300 hours, M54 and M55 acknowledged that the physician was not informed the pain medication was not working as stated in the hospital policy. Both stated that the 30-minute vital signs were being monitored only in special procedures and not on a medical-surgical floor despite the patient receiving narcotic pain medication.</p> <p>5. Review of the RSMC "Structure Standards-Med/Surg/Tele" showed that vital signs are to be taken every four hours and could be monitored more frequently if necessary.</p> <p>On 1/11/10 at 0915 hours, Patient 66's medical record was reviewed. The patient was admitted to the RSMC campus Telemetry Unit on 1/9/10. The patient had multiple diagnoses including a history of hypertension (high blood pressure). The initial B/P reading was taken at 0130 hours and was recorded as 82/45 (below normal) with the patient complaining of weakness. There was no documentation the physician was notified of the low blood pressure. The next blood pressure was not taken until 0400 and was 107/55. When the low B/P reading was reviewed with M50, an RN, she stated she would have taken another blood pressure sooner - within 15 minutes. Further review of Patient 66's medical record showed the patient had another episode of low blood pressure in the 80s on 1/10/10 and the rapid response team was called.</p>	A 395		

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A 395	Continued From page 30	A 395		
A 396	<p>482.23(b)(4) NURSING CARE PLAN</p> <p>The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the nursing staff failed to develop and keep current nursing care plans on one of three patients (Patient 2) observed for medication pass. This failure contributed to ineffective pain management.</p> <p>Findings:</p> <p>On 1/15/10 at 1300 hours at RSMC, review of the hospital policy on Pain Management (revised on 2/09) stated that, "Monitor efficacy of pain treatment and patient satisfaction. Any adverse reaction or uncontrolled pain should be reported to the physician as quickly as possible. Pain interventions that are deemed ineffective will be addressed and alternative measures will be taken and documented on the Interdisciplinary Plan of Care."</p> <p>On 1/14/10 at 0930 hours, medication pass for three patients by E18 was observed with M54. Patient 2 received Dilaudid 2 mg intravenously pushed (IVP) in 40 seconds for abdominal pain</p>	A 396		

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A 396	Continued From page 31 rated at 8/10, with 10 as the most painful on a scale of 1-10. The pain level was reduced to 6/10 after 1000 hours. Per review of the nursing care plan on alteration of comfort (pain) dated 1/12/10, the goal was to achieve a pain level of 2/10. On 1/15/10 at 1000 hours, review of the patient care flow sheet and MAR dated 1/14/10 revealed that Patient 2 continuously received Dilaudid 2 mg intravenously every two hours from 0800 till 2045 hours. The lowest pain level documented in response to the pain medication was 6/10, however, the care plan was not revised to note the efficacy of the pain intervention and to suggest other pain relief alternative measures. In addition, the written intervention in the plan of care to reassess the patient's response to pain medication 30 minutes after the pain medication was administered was not evident. The patient's vital signs continued to be taken routinely every 4 hours without monitoring respiratory depression per MAR instruction. On 1/15/10 at 1300 hours, M54 and M55 acknowledged that the physician was not informed for alternative pain measures. Both made no comment regarding updating the care plan to keep it's interventions current on an ongoing basis.	A 396		
A 397	482.23(b)(5) PATIENT CARE ASSIGMENTS 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. This STANDARD is not met as evidenced by: Based on interview and record review, the	A 397		

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A 397	Continued From page 32 hospital failed to have show documentation of how the ED LVN's assignments were related to patient acuity. This had the potential for LVN's to be assigned to patients who require a higher level of care which could effect the quality of the patient care. Findings: Review of the hospital's ED policy Structure Standards: Emergency Department (revised 10/09), showed assignments would consider patient needs and in another section of the Standards, LVNs receive direction from the Staff Nurse, Charge Nurse and other nurse managers. Additionally, the Structure Standards showed that patient assignments would consider patient needs, staff credentialing and certifications. On 1/11/10 at 1355, M49 stated RSMC's ED had three LVNs on staff. At 1500 hours, on 1/11/10 M49 was asked about the ED patient acuity system. According to M49, the ED used a five level triage system that ranged from Level One as the most acutely ill and Level 5 as the least acute patient. On 1/12/10, review of the Five Level Triage P & P failed to show how the acuity would be used for assignments by staff licensure/qualifications. Further review of the ED policy Structure Standards: Emergency Department failed to show any specific direction of how LVN assignments would be made.	A 397			
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	A 404			

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A 404	<p>Continued From page 33</p> <p>practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the hospital failed to carry out physician orders to administer two antihypertensive medications (medications to lower blood pressure) to Patient 304 who had a history of high blood pressure and congestive heart failure. The failure could result in patient injury. In addition, one of three patients (Patient 2), observed for medication pass, received Dilaudid 2 mg intravenously pushed (IVP) within 40 seconds instead of the written standards of practice of administering Dilaudid 2 mg IVP at a rate of over 2-3 minutes. The failure could result in respiratory depression and low blood pressure. The hospital also failed to carry out the 24 hour check of Patient 256's MAR for accuracy of a Ramipril order by failing to note the lack of a hold parameter on the 1/13/10 MAR as ordered by the physician. As a result, the nurse did not check or even consider the patient's blood pressure before administering the Ramipril to Patient 256 on 1/14/10. Potentially, Patient 256 could have received this blood pressure medication when her systolic blood pressure, as determined by the physician, was too low for her to receive this medication.</p> <p>Findings:</p> <p>1. At RSMC, on 1/13/10 at 1629 hours, review of Patient 304's medical record revealed an order to administer Lasix and Aldactone (blood pressure medications) today at 1230 hours. The dose of Lasix was 40 milligrams by intravenous route (in</p>	A 404		

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A 404	<p>Continued From page 34</p> <p>the vein) and Aldactone 12.5 milligrams by mouth. During an interview with E58 who stated she decided to hold these two medications because Patient 304's blood pressure was 98/61 mmHg. (The mmHg is millimeters of mercury-the units used to measure blood pressure). When asked if there was a physician order to hold these medications based on blood pressure parameters, E58 stated there wasn't. She stated she holds blood pressure medications if the systolic blood pressure (top number) is below 100 mmHg and may hold the medications if the systolic blood pressure is between 100 - 110 mmHg. E58 held two blood pressure medications and made this decision on her own and not in accordance with the orders of the physician or hospital policies.</p> <p>2. On 1/14/10 at 0930 hours, E18 was observed for medication pass to three patients on the medical-surgical floor, east side.</p> <p>Patient 2 complained of abdominal pain rated at 8/10, 10 being the most painful on a scale of 1-10. E18 verified the physician's order for Dilaudid 2 mg to be given intravenously as necessary for pain.</p> <p>The pain medication was administered by pushing Dilaudid 2mg intravenously to the patient's IV access within 40 seconds, based on the second hand of the patient's wall clock. The patient's facial grimace was noted to relax. E18 left the patient's room and charted the medication in the MAR as given.</p> <p>On 1/14/10 at 1300 hours, the Risk Manager provided the requested hospital's Guidelines of Intravenous Medications. It revealed that</p>	A 404		

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A 404	<p>Continued From page 35</p> <p>Hydromorphone (Dilaudid) 1-4 mg (undiluted) could be given in Critical Care Units, PACU, Medical-Surgical Telemetry Unit, and at Women's Center. However, Dilaudid should be intravenously pushed at a rate of over 2-3 minutes.</p> <p>Further record review of the MAR and nursing care plan revealed instructions to monitor for respiratory depression and reassess response to pain medication after 30 minutes. However, neither one was evident except the vital signs routinely taken every four hours.</p> <p>3. On 1/14/10 at 0913 hours at the IVMC, E105 passed medications including a Ramipril 5 mg tablet (used to treat high blood pressure) to Patient 256. A review of Patient 256's medical record at 0946 hours on 1/14/10 indicated a physician had written an order on 1/12/10 to hold the Ramipril for systolic (top number) blood pressure less than 110 mmHg. E105 had not measured Patient 256's blood pressure before she administered the Ramipril. During an interview of E105 at this time, she stated she was not aware Ramipril was to be held for a systolic blood pressure of less than 110 mm of Hg. She did point out that this information did not appear on Patient 256's MAR (used by nurses to accurately medicate their patients and to document the date and time a dose of medication was administered) and that the Patient 256's systolic blood pressure had been measured at 168 mm of Hg that morning at 0830 hours but she stated she did not take that information into account when medicating the patient.</p> <p>A review of the 1/14/10 MAR at 0955 hours indicated that the hold parameters were not</p>	A 404		
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A 404	<p>Continued From page 36</p> <p>printed on the Ramipril entry on this document, which nursing staff depend on to accurately medicate their patients. During an interview of M32 on 1/14/10 at 1019 hours, he stated that the MARs were printed on the nursing units at 2300 hours daily using data from the pharmacy computerized patient medication profiles. He stated that the pharmacist who entered the order should have entered the hold parameters which would then have printed out on the MAR. He stated that if nurses detected an error on an MAR, they were to correct the error by hand on the MAR and fax a copy of the corrected MAR to the pharmacy so that the pharmacy staff could correct the error in the computerized patient medication profile.</p> <p>On 1/14/10 at 1029 hours during an interview of M30, he stated that there was a 12 hour and a 24 hour check of the accuracy of the MARs by nursing staff. He stated that the 24 hour check would have been done after midnight by the night shift (after midnight on 1/13/10 for this order). He stated the nurse should have hand written in the correction on the 1/13/10 MAR. He stated the nurse missed the error in the pharmacy order entry.</p>	A 404		
A 405	<p>482.23(c)(1) ADMINISTRATION OF DRUGS</p> <p>All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the</p>	A 405		

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A 405	<p>Continued From page 37</p> <p>hospital failed to administer the first dose of intravenous antibiotics to three of three patients on both campuses within two hours of the order (Patients 1, 257, and 304). According to the hospitals policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics need to be administered within two hours of the physician order to prevent or treat an infection." Not administering the medication within this two hour time slot and leaving the infection untreated, may lead to an elevated fever and spread of the infection.</p> <p>Findings:</p> <p>At RSMC on 1/14/10 at 1140 hours, during an interview, E157 stated the time to initiate intravenous antibiotics when a bed was available in the ED was one to two hours but usually one hour. At 1145, during an interview E16 stated that sometimes the emergency department was crowded and could take as long as four hours to initiate intravenous antibiotics but usually it only takes one to two hours and often one hour.</p> <p>1. At RSMC, on 1/14/10 at 1524 hours, review of Patient 1's medical record revealed that he was admitted to the hospital with a severe ankle wound. Fortaz 1 gram (antibiotic medication) was ordered intravenously every 8 hours on 1/8/10 at 1540 hours. The dose was not given until 0600 hours on 1/9/10 (over 14 hours after the medication was ordered). E59, who was unable to find any earlier dose of Fortaz documented in the chart as administered replied, "I can't explain it."</p> <p>2. At IVMC, on 1/15 /10 at 1530 hours, review of Patient 257's clinical record revealed he was</p>	A 405		
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A 405	Continued From page 38 admitted to the hospital with the diagnosis of pneumonia. Rocephin 1 gram (antibiotic medication) was ordered intravenously one time on 1/2/10 at 0950 hours. Review of the Pyxis withdrawal report shows the medication was removed at 1004 hours but was never documented as administered. E161 stated the medication should have been given after the blood cultures were drawn. 3. At RSMC, on 1/15/10 at 0900 hours, review of Patient 304's medical record revealed he was admitted on 1/11/10 with shortness of breath and an exacerbation of congestive heart failure. Levaquin 500 milligrams (antibiotic medication) was ordered intravenously every 24 hours on 1/11/10 at 1050 hours. The dose was not given until 2130 hours on 1/11/10 (over 10 ½ hours after the medication was ordered). M49 was asked if she could explain why the dose was not administered even though it was located on the nursing unit in their Pyxis Medstation which makes the medication readily available. M49 stated the patient was transferred from the ED to the Medical-Surgical floor at 1600 hours. She had no explanation as to why the medication as not given until 2130 hours.	A 405			
A 409	482.23(c)(3) BLOOD TRANSFUSIONS AND IV MEDICATIONS Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.	A 409			

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A 409	<p>Continued From page 39</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to administer the first dose of intravenous antibiotics to three of three patients on both campuses (Patients 1, 257, and 304) within two hours of the order. According to the hospital's policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics need to be administered within 2 hours of the physician order to prevent or treat an infection. By not administering the medication within this 2 hour time slot and leaving the infection untreated, may lead to an elevated fever and spread of the infection. Additionally, at IVMC, the hospital failed to follow its own P&P regarding labeling intravenous medications. This had the potential for the prolong utilization of intravenous medications beyond their effectiveness and continuing the practice of not labeling intravenous medications that could expand hospital wide.</p> <p>Findings:</p> <p>1. At RSMC on 1/14/10 at 1140 hours, during an interview, E157 stated the time to initiate intravenous antibiotics when a bed was available in the ED (Emergency Department) is 1 - 2 hours but usually 1 hour. At 1145, during an interview E156 stated that sometimes the emergency department was crowded and could take as long as four hours to initiate intravenous antibiotics but usually it only takes 1 - 2 hours and often 1 hour.</p> <p>a. At RSMC, on 1/14/10 at 1524 hours, review of Patient 1's medical record revealed that he was admitted to the hospital with a severe ankle wound. Fortaz 1 gram (antibiotic medication) was ordered intravenously every 8 hours on 1/8/10 at</p>	A 409		

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A 409	<p>Continued From page 40</p> <p>1540 hours. The dose was not given until 0600 hours on 1/9/10 (over 14 hours after the medication was ordered). E59, who was unable to find any earlier dose of Fortaz documented in the chart as administered replied, "I can't explain it."</p> <p>b. At IVMC, on 1/15 /10 at 1530 hours, review of Patient 257's clinical record revealed he was admitted to the hospital with the diagnosis of pneumonia. Rocephin 1 gram (antibiotic medication) was ordered intravenously one time on 1/2/10 at 0950 hours. Review of the Pyxis withdrawal report shows the medication was removed at 1004 hours but was never documented as administered. E15 stated the medication should have been given after the blood cultures were drawn.</p> <p>c. At RSMC, on 1/15/10 at 0900 hours, review of Patient 304's medical record revealed he was admitted on 1/11/10 with shortness of breath and an exacerbation of congestive heart failure. Levoquin 500 milligrams (antibiotic medication) was ordered intravenously every 24 hours on 1/11/10 at 1050 hours. The dose was not given until 2130 hours on 1/11/10 (over 10 ½ hours after the medication was ordered). M49 was asked if she could explain why the dose was not administered even though it was located on the nursing unit in their Pyxis Medstation (medication cabinet that stores medications that are frequently needed on the nursing unit) which makes the medication readily available. M49 stated the patient was transferred from the Emergency Department to the Medical-Surgical floor at 1600 hours. She had no explanation as to why the medication as not given until 2130 hours.</p> <p>2. Review of the hospital P&P for the IVMC and</p>	A 409		

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A 409	<p>Continued From page 41</p> <p>RSMC campuses entitled IV Certification and Administration For Licensed Nurses, revision date 11/07, showed that all peripheral IVs would be labeled with the date and initials of the nurse initiating the IV. Further review of the policy also showed that all IV solutions would be changed every 48 hours, if they did not contain additives. IV solutions containing additives would be changed every 24 hours, if prepared by appropriate hospital staff. Manufactured pre-mixed IV solutions would be changed equal to or less than every 48 hours.</p> <p>On 1/12/10 at 1000 hours, during a tour of the 2 West medical/surgical unit at the IVMC campus with M29, it was found that IV medication bags in rooms 251, 253, 259, and 252 did not have labels to show the date, time, and signature to show when the IV medication bags were hung. When M29 was asked why some IV medication bags were labeled with date, time, and signature and others were not, she was not able to answer and deferred the question to E32. E32 stated that IV bags were usually labeled when hung.</p> <p>On 1/12/10 at 1100 hours, during a tour of the 2 Central medical/surgical unit at the IVMC campus with E30, IV bags were found unlabeled in rooms 235 and 221.</p> <p>On 1/12/10 at 1200 hours, during a tour of the 2 East medical/surgical unit at the IVMC campus with M30, IV bags in rooms 205, 206, 207, and 208 were not labeled. When M30 was asked about the unlabeled IV bags, he stated that he was not sure what the usual practice was and believed the nurses usually documented in the MAR the time and date of when IV medications were hung. M30 added that he would find out</p>	A 409		

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A 409	Continued From page 42 what the practice was.	A 409		
A 438	<p>482.24(b) FORM AND RETENTION OF RECORDS</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on medical record review and staff interview, the hospital failed to ensure that medical records were accurately written due to blank spaces being left in transcribed reports, and that all entries were authenticated in nine of 19 records reviewed (Patients 33, 272, 273, 275, 276, 277, 278, 279, and 283.) This led to the potential for clinical information to be missing for care of the patients and the inability to determine the authenticity of a physician's order.</p> <p>Findings:</p> <p>On 1/13/10 and 1/14/10, open and closed record review revealed the following deficiencies.</p> <p>1. Transcribed history and physical examination, code blue note, operative and discharge summary reports contained spaces within the content of the report (to indicate the transcriptionist could not understand information</p>	A 438		

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A 438	Continued From page 43 that was dictated). Subsequent interview on 1/14/10 beginning at 0930 with M4 revealed that physicians are requested to fill in the spaces before signing the report. These records were considered "complete," even though information was missing (Patients 272, 273, 275, 276, and 278). 2. Admission Data Base forms lacked a space for signature by the nurse who documented on the form. Per interview on 1/14/10 beginning at 0930 hours with M4, this form had been recently revised; however, the signature line had not been included (Patients 33, 273, 277, and 279). 3. The Emergency Department Physician Record contained a space to document the time the patient was seen. This information was not completed in the records of Patients 272, 273, 277, 279, 283 and 276. In addition, there was no date documented on the form in the records of Patients 272 and 277. These omissions were verified by M4 on 1/14/10 beginning at 0930 hours.	A 438		
A 449	482.24(c) CONTENT OF RECORD The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. This STANDARD is not met as evidenced by: Based on a review of six open and closed anesthesia records, the hospital failed to provide accurate documentation to describe the response of each patient to medications and interventions being provided for two of six patient anesthesia	A 449		

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A 449	<p>Continued From page 44</p> <p>records reviewed (Patients 253 and 277). The hospital also failed to ensure that four of 12 emergency department records reviewed (Patients 306, 314, 315 and 316) provided accurate documentation to describe the response of each patient to medications and interventions being provided. These findings led to inaccurate medical records and could potentially affect continuity of care for the patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. During a tour of the operating room areas of IVMC conducted on 1/12/10, the anesthesia record for Patient 253 was reviewed. This demonstrated that the post-anesthesia record for Patient 253 had been pre-filled out, signed and dated prior to the time that the procedure and anesthesia had been completed for Patient 253. 2. Patient 277 came to the hospital for a surgical procedure that was performed on 12/25/09. The record for Patient 277 revealed that the post-operative anesthesia evaluation had been signed and filled out prior to the completion of the operative procedure by the attending anesthesiologist. 3. Patient 314 came to the ED at RSMC on 1/11/10. A review of the closed medical record for Patient 314 revealed no documentation of the disposition or condition of Patient 314 at the time of discharge from the ED. The "ED Physician record" contained entry boxes at the bottom of the form that read "Disposition": "Home, 24 hr obs (observation), Admit, Transfer, Expired." These boxes were unchecked. Below this, a series of entries read: "Condition: Good, Stable, Guarded, Critical." Each of these boxes was left unchecked. 	A 449		
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A 449	<p>Continued From page 45</p> <p>The hospital failed to ensure that the medical record was complete and reflected the disposition and status for Patient 314 at the time of discharge.</p> <p>4. Patient 315 came to the ED on 1/11/10. A review of the closed medical record for Patient 315 revealed no documentation of the disposition or condition of Patient 315 at the time of discharge from the ED. The "ED Physician record" contained entry boxes at the bottom of the form that read "Disposition: Home, 24 hr obs (observation), Admit, Transfer, Expired." These boxes were unchecked. Below this, a series of entries read: "Condition:" Good, Stable, Guarded, Critical." Each of these boxes was left unchecked. The hospital failed to ensure that the medical record was complete and reflected the disposition and status for Patient 315 at the time of discharge.</p> <p>5. Patient 316 came to the ED on 1/12/10. A review of the closed medical record for Patient 316 revealed no documentation of the disposition or condition of Patient 316 at the time of discharge from the emergency department. The "ED Physician record" contained entry boxes at the bottom of the form that read "Disposition: Home, 24 obs (observation), Admit, Transfer, Expired." These boxes were unchecked. Below this, a series of entries read: "Condition:" Good, Stable, Guarded, Critical." Each of these boxes was left unchecked. The hospital failed to ensure that the medical record was complete and reflected the disposition and status for Patient 316 at the time of discharge.</p> <p>6. Patient 306 came to the ED on 1/13/10. A review of the closed medical record for Patient</p>	A 449		

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A 449	Continued From page 46 306 revealed no documentation of the disposition or condition of Patient 306 at the time of discharge from the ED. The "ED Physician record" contained entry boxes at the bottom of the form that read "Disposition": "Home, 24 obs (observation), Admit, Transfer, Expired." These boxes were unchecked. Below this, a series of entries read: "Condition:" Good, Stable, Guarded, Critical." Each of these boxes was left unchecked. The hospital failed to ensure that the medical record was complete and reflected the disposition and status for Patient 306 at the time of discharge.	A 449		
A 450	482.24(c)(1) MEDICAL RECORD SERVICES All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. This STANDARD is not met as evidenced by: Based on closed record review and staff interview, the hospital failed to ensure that all medical record entries were complete, dated, timed and authenticated within 12 of 21 charts reviewed (Patients 33, 272, 273, 275, 276, 277, 278, 279, 283, 286, 319, and 51). This failure resulted in incomplete/inaccurate medical records for health team member usage and could potentially effect the continuity of care for the patient. Findings: On 1/13/10 and 1/14/10, open and closed medical record review revealed the following deficiencies:	A 450		

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A 450	<p>Continued From page 47</p> <ol style="list-style-type: none"> 1. Transcribed history and physical examination, code blue note, operative and discharge summary reports contained spaces within the content of the report (to indicate the transcriptionist could not understand information that was dictated). Subsequent interview on 1/14/10 beginning at 0930 hours with M4, revealed that physicians were requested to fill in the spaces before signing the report. These records were considered "complete" even though information was missing (Patients 272, 273, 275, 276, and 278). 2. Admission Data Base forms lacked a space for signature by the nurse who documented on the form. Per interview on 1/14/10 beginning at 0930 with M4, this form had been recently revised; however, the signature line had not been included (Patients 33, 273, 277, 279). 3. The Emergency Department Physician Record contained a space to document the time the patient was seen. This information was not completed in the records of Patients 272, 273, 277, 279, 283, and 286. In addition, there was no date documented on the form in the records of Patients 272 and 277. These omissions were verified by Administrative Staff M4 on 1/14/10 beginning at 0930. 4. Review of IVMC and RSMC's P&P entitled Physician's Orders, revision date 4/09, showed that physicians' orders for medications were to be dated, timed, and authenticated by the ordering physician, and that orders would be noted with the date, time, signature and title by the appropriate RN/LVN. <ol style="list-style-type: none"> a. On 1/11/10 at 1000 hours, review of Patient 	A 450		
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A 450	Continued From page 48 319's medical record showed a physician's order, dated 1/7/10, with no physician's signature and was not noted by the RN/LVN taking care of the patient with a date, time, and printed name. The order did not show the practitioner who initiated the order nor who among the staff RN/LVNs noted the order. b. On 1/11/10 at 1000 hours, review of Patient 51's medical record showed a designated place for noting telephoned orders, and for physician signatures. Five sets of physicians' orders, dated 1/5/10, showed the physician had signed in the place for telephone orders. Two of the five sets of physicians' orders were not noted by a RN/LVN.	A 450		
A 457	482.24(c)(1)(iii) VERBAL ORDERS AUTHENTICATED BASED ON LAW All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours. This STANDARD is not met as evidenced by: Based on medical record and document review, the hospital failed to ensure that all verbal/telephone orders were authenticated within 48 hours in three of 21 records reviewed (Patients 1, 51 and 319) This failure had the potential to result in orders not being accurately carried out, if misunderstood. Findings: The policy Admin #061/Nur #P3, last revised 4/09, was reviewed on 1/13/10. Section 10 stated: "Verbal/Telephone orders for medications and/or blood products are to be authenticated	A 457		

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A 457	Continued From page 49 within 48 hours by the physician giving the order or the physician covering for the ordering physician." Per interview with M4 on the morning of 1/14/10, it was explained that the hospital's practice was to require that all types of verbal/telephone orders be authenticated within 48 hours, not just those for medications and/or blood products, as stated in the policy. This was not implemented as follows: 1. On 1/11/10 at 1000 hours, review of Patient 51's medical records showed no physician's signature for telephone orders dated 1/4/10 and 1/6/10. The physician orders were not authenticated within 48 hours. 2. On 1/11/10 at 1000 hours, review of Patient 1's, medical record showed no physician's signature for a telephone order dated 1/7/10. The physician orders were not authenticated within 48 hours. 3. On 1/11/09 at 1000 hours, review of Patient 319's medical record showed no physician's signature for four pages of telephone orders, dated 1/5/10, and two sets of telephone orders, dated 1/7/10. The physician orders were not authenticated within 48 hours.	A 457		
A 467	482.24(c)(2)(vi) CONTENT OF RECORD - OTHER INFORMATION [All records must document the following, as appropriate:] All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.	A 467		

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A 467	<p>Continued From page 50</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and document review, the hospital failed to ensure recommendations made regarding patient assessments were acknowledged by the physician for two of eight patients sampled for nutritional review (Patients 233 and 134) which resulted in nutritional recommendations not being implemented with the potential for delayed wound healing for Patient 233 and continued nutritional decline for Patient 134.</p> <p>Findings:</p> <p>1. Patient 233 was admitted 11/19/09 with sepsis (systemic infection), tube feeding, respiratory failure, Diabetes Mellitus, and a Stage 2 pressure ulcer.</p> <p>On 1/13/10 at 1445 hours the patient's medical record was reviewed. The nutrition follow-up dated 11/26/09 was reviewed. The assessment identified Patient 233 at high nutrition risk with depressed albumin at 2.3 mg/dl (11/22), and a Stage 2 peri-rectal (near the rectum) pressure ulcer. The registered dietitian (RD) recommended MVI (multivitamin), vitamin C, Zinc, and FeS04 (iron sulfate supplement).</p> <p>The nutrition follow-up notes dated 12/4/09, 12/8/09, 12/11/09, and 12/15/09 continued to identify Patient 233 at high nutrition risk and recommended MVI, Vitamin C, Zinc, and FeSo4 to help with wound healing. Review of physician progress notes showed no acknowledgement of the 11/26/09, 12/4/09, 12/8/09, or 12/11/09 RD recommendations for MVI, Vitamin C, Zinc, and FeSo4 for wound healing.</p>	A 467		
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A 467	<p>Continued From page 51</p> <p>The nutrition follow-ups dated 12/24/09 and 12/29/09, stated high nutrition risk and history of depleted visceral protein and no new albumin laboratory results. The RD recommended an order for prealbumin (used to assess nutrition status).</p> <p>The nutrition follow-up dated 1/9/10 identified Patient 233 with high nutrition risk and depressed albumin of 2.0 mg/dl (severe visceral protein depletion). The RD recommendation was to order prealbumin. Review of the physician progress reports showed no acknowledgement for the RD recommendations on 12/24/09, 12/29/09, and 1/9/10 for prealbumin.</p> <p>An interview on 1/13/10 at 1300 hours with E23 and E24 stated there was no system for the physician to acknowledge the RD recommendations. In an additional interview on 1/13/10 at 1300 hours E28, a staff RD, stated "we just keep writing recommendation and sometimes talk to the physician," but there was no system for the physician to acknowledge the RD's recommendations.</p> <p>2. Patient 134 was admitted 12/2/09 with abdominal pain and severe nausea. The patient's medical record was reviewed 1/13/10 at 1100 hours. A nutritional follow-up, dated 1/1/10, stated high nutritional risk secondary to moderate depletion of visceral protein with the albumin 2.7 mg/dl. Patient 134's meal intake was poor at less than 25 percent. The RD recommended Megace (appetite stimulus medication) to increase appetite. The nutritional follow-up dated 1/4/10 stated Patient 134 was at high nutritional risk and recommended Megace.</p>	A 467		
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A 467	Continued From page 52 During an interview on 1/13/10 at 1115 hours, E25 stated the nursing staff was not aware of the RD's recommendations and there was no system for the physician to acknowledge the RD's recommendations. Review of the nursing notes and the physician progress noted with staff E25 showed there was no documentation by the physician for the RD recommendations for Megace made on 1/1/10 and 1/4/10.	A 467		
A 490	482.25 PHARMACEUTICAL SERVICES 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. This CONDITION is not met as evidenced by: Based on observation, interview, and medical record, document, and policy and procedure review, the hospital failed to ensure that pharmaceutical services carried out its full and complete oversight that met the needs of the patients in the hospital. Findings: 1. Pharmaceutical services failed to develop and implement a policy and procedure to ensure the safe use of fentanyl patches that would ensure minimal risk of clinically significant hypoventilation (a state where a reduced amount of air enters the lungs) with concomitant risk of death as stipulated by the hospital policy and procedure regarding medications with Black Box Warnings. See A500,	A 490		

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A 490	Continued From page 53 #7. 2. Pharmaceutical services failed to ensure pharmacists who regulate medications by approved hospital protocols were competent in all protocols and not just some. See A500, #1. 3. Pharmaceutical services failed to ensure that first doses of antibiotics were administered within 2 hours of the order according the their policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse" to prevent the spread of infection. See A500, #6. 4. Pharmaceutical services failed to ensure that their approved "Insulin Drip Protocol" was clear from ambiguities and didn't require interpretation by the nursing staff, and failed to ensure correct doses of insulin were charted as administered. See A500, #5. 5. Pharmaceutical services failed to ensure that drugs administered to patients in the hospital were ordered by a physician and the order was documented in the patient's medical record. See A500, #3. 6. Pharmaceutical services failed to ensure that intravenous chemotherapeutic medications (used to treat cancer and have significant side effects) were compounded in a cabinet designed for that purpose, failed to ensure that the deactivating agent to decontaminate the cabinet was used in sufficient quantities, and pharmacy staff was evaluated for competency to compound medications and decontaminate the cabinet. See A500, #8-11.	A 490		

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A 490	<p>Continued From page 54</p> <p>7. Pharmaceutical services failed to ensure that medications stored in the emergency medication crash carts were stored in sufficient quantities as stipulated by the hospital's policy and procedure. See A500, #19.</p> <p>8. Pharmaceutical services failed to ensure that expired medications, wound dressings, intravenous normal saline solution, outdated scrub sponges, and unusable medications in the intubation trays and IV solutions in the surgery warmers and mislabeled Dilaudid were not available for patient use. The hospital failed to follow it's policy and procedure regarding labeling intravenous medications to determine the expiration date. See A505 #1-12.</p> <p>9. Pharmaceutical services failed to ensure that pharmacists checked the Rapid Intubation Drug Box before the box was delivered to the floor for patient use. See A500 #2.</p> <p>10. Pharmaceutical services failed to ensure routine maintenance was performed on the main pharmacy's medication refrigerators according to the hospital's policy and procedure. See A0500 #4.</p> <p>11. Pharmaceutical services failed to ensure that two of two MH (Malignant Hyperthermia) carts, one each at the RSMC and IVMC campuses, were stocked according the standards of practice and the hospital's treatment guidelines for MH. See A500, #12.</p> <p>12. Pharmaceutical services failed to ensure that the policy and procedure regarding MH carts had a current content list which matched the contents for two of two MH carts, one each at RSMC and</p>	A 490		

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A 490	<p>Continued From page 55 IVMC. See A500, #13.</p> <p>13. Pharmaceutical services failed to ensure that written policies and procedures were developed that established the contents of Adult and Pediatric Crash Carts. See A500, #14.</p> <p>14. Pharmaceutical services failed to develop written policies and procedures establishing the contents for and the procedures for use of Intubation Kits maintained on the RSMC and IVMC campuses. See A500, #15.</p> <p>15. Pharmaceutical services failed to ensure that the solutions in the RSMC Surgery Department Warmer, were stored at a temperature stipulated by the hospital policy and procedure and failed to ensure that four of five of these solutions were stored at temperatures recommended by the manufacturer. See A500, #16.</p> <p>16. Pharmaceutical services failed to ensure that solutions in the warmers in the RSMS and IVMC Surgery Departments were inspected by pharmacists as required by state regulation. See A500, #17.</p> <p>17. Pharmaceutical services failed to ensure that opened foil packages of Xopenex were dated once opened as per the pharmacy standard of practice so that the more rapid expiration date of the product that went into effect once the foil pouch was opened could be tracked. See A500, #18.</p> <p>The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe environment.</p>	A 490		

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A 500	<p>482.25(b) DELIVERY OF DRUGS</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, medical record, document review, and policy and procedure review, the hospital:</p> <ul style="list-style-type: none"> * Failed to ensure four of four staff pharmacists (E55, E111, E113 and E114) that regulate medications based on approved hospital medication protocols were competent in all six protocols which require expertise in medication dosing, laboratory ordering, and monitoring for medication adverse events. * Failed to ensure that a pharmacist checked all medications in the Rapid Intubation Drug Box before the box(es) were delivered to the floor for patient use. Two of three boxes were missing documentation that this was done. * Failed to ensure that medications were ordered by a physician before they they were administered to Patient 304. * Failed to ensure that routine maintenance of two of two medication refrigerators located in the main pharmacy were performed according to the hospital's approved policy and procedure. The failure could lead to inaccurate temperature ranges which could compromise drug stability and sterility. * Failed to ensure that the hospital approved Insulin Drip Protocol was clear of ambiguities and didn't require interpretation and clarification by two of two nurses (E56 and E57), and the protocol was followed and the correct dose of insulin was administered to Patient 70. 	A 500			

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A 500	<p>Continued From page 57</p> <ul style="list-style-type: none"> * Failed to administer the first dose of intravenous antibiotics to 3 of 3 patients (Patients 1, 257, and 304) within two hours of the order. According to the hospital's policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics need to be administered within 2 hours of the physician order to prevent or treat an infection. Not administering the medication within this 2 hour time slot and leaving the infection untreated, may lead to an elevated fever and spread of the infection. * Failed to develop and implement a policy and procedure to ensure the use of fentanyl patches that would ensure minimal risk of clinically significant hypoventilation with concomitant risk of death as stipulated by the hospital policy and procedure regarding medications with black box warnings. * Failed to ensure that IV chemotherapeutic medications (used to treat cancer and which have significant side effects including mutagenic side effects) were compounded in a cabinet designed for that purpose when in fact such a cabinet had been purchased; failed to ensure that a process was developed to decontaminate and inactivate all chemotherapeutic agents compounded in this cabinet before it was used to compound regular IV solutions (Rituximab was not inactivated by the decontaminating agent used by the hospital); failed to ensure that the deactivating agent was used in sufficient quantity to decontaminate the cabinet, and failed to develop pharmacist driven policies and procedures that mirrored the current working conditions in the pharmacy, that pharmacy staff was evaluated annually as per the policy and procedure, and that competencies had been developed to evaluate the ability of the pharmacy technicians to compound 	A 500		

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A 500	<p>Continued From page 58</p> <p>chemotherapeutic agents and decontaminate the cabinet.</p> <ul style="list-style-type: none"> * Failed to ensure that two of two MH Carts, one each at the RSMC and IVMC Campuses, were stocked according the standards of practice and the hospital's treatment guidelines for MH. * Failed to ensure that the policy and procedure regarding MH Carts had a current content list which matched the contents of two of two MH Carts, one each at RSMC and IVMC. * Failed to ensure that written policies and procedures were developed that established the contents of Adult and Pediatric Crash Carts. * Failed to develop written policies and procedures establishing the contents for and the procedures for use of Intubation Kits maintained on the RSMC and IVMC Campuses. * Failed to ensure that five of five solutions inspected in the RSMC Surgery Department Warmer were stored at a temperature stipulated by the hospital policy and procedure and failed to ensure that four of five of these same solutions were stored at recommended temperatures as documented by the manufacturer. * Failed to ensure that solutions in the warmers in the RSMS and IVMC Surgery Departments were inspected by pharmacists as required by state regulation. * Failed to ensure that opened foil packages of Xopenex were dated once opened as per the pharmacy standard of practice so that the more rapid expiration date of the product that went into effect once the foil pouch was opened could be tracked. * Failed to ensure epinephrine was available on an emergency cart. <p>These failures could potentially result in medication errors, unusable medications being</p>	A 500		
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A 500	<p>Continued From page 59</p> <p>used, delay in treatment and poor patient outcomes.</p> <p>Findings:</p> <p>1. At RSMC, on 1/11/10 at 1124 hours, the DOP stated, "Pharmacists provide clinical services including aminoglycosides, vancomycin (antibiotic medications), total parenteral nutrition (provides a patient with all the fluid and essential nutrients they need when they are unable to feed themselves by mouth), heparin and coumadin (blood thinning medications to prevent blood clots), and renal dosing (dosing medications when kidney function changes)." These services were provided by the pharmacists following protocols that were approved by hospital committees. According to the protocols for these medications, the pharmacist, "Using clinical experience will assist the medical staff in the safe and effective use of aminoglycosides and vancomycin." The protocols approve the pharmacist to order doses, order appropriate laboratory tests, and order blood levels tests of the medications and adjust doses based on these levels.</p> <p>The American College of Clinical Pharmacy (ACCP), a well known national standard of practice states clinical pharmacists, "Must have a defined list of competencies against which they can measure performance. Describe abilities necessary to practice as a clinical pharmacist and to perform a self-assessment and thereby determine what areas need to be strengthened. Changes and advances in medicine will require periodic reevaluation and modification of therapeutic knowledge areas."</p>	A 500		
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A 500	<p>Continued From page 60</p> <p>On 1/11/10 at 1131 hours, review of E55's competency chart revealed no specific competencies for aminoglycosides and vancomycin. Successful competencies in these areas would qualify the pharmacists as being adequately trained and qualified to perform these services. On 1/11/10 at 1140 hours, according to M44, "There were no pharmacist competencies for aminoglycosides and vancomycin but there were competencies for the other clinical services provided."</p> <p>On 1/14/10 at 1220 hours, review of competencies for E111, 113 and 114 revealed missing competencies for aminoglycosides and vancomycin. There were other competencies in these employee charts; however, none contained questions pertaining to aminoglycosides or vancomycin.</p> <p>2. At IVMC, on 1/12/10, review of the, "Emergency Department Rapid Intubation Kit Order Sheet" revealed that some kits were checked and initialed by a pharmacist before dispensing to the ED and others were not (two kits were not). On 1/12/10 at 1142, during an interview M32 stated all kits should be checked, dated and initialed by a pharmacist according to hospital policy.</p> <p>3. At RSMC, on 1/13/10 at 1629 hours, review of Patient 304's medical record revealed an order written for Protonix 40 milligrams (medication to treat stomach pain) on 1/12/10. Protonix was discontinued and changed to Prilosec 40 milligrams without a physician's order. Prilosec was administered on 1/13/10 and charted on the Medication Administration Record (MAR) as administered at 1215 hours. When M32 was</p>	A 500		

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A 500	<p>Continued From page 61</p> <p>asked if he could locate an order in the chart for Prilosec, he stated he couldn't. The hospital approved an "Automatic Therapeutic Substitution" protocol which was last revised in 8/03. This protocol allowed for the automatic substitution of Prilosec for Protonix but not Protonix for Prilosec. According to the protocol there would be an order in the chart making this change. There was no order per protocol or by Patient 304's physician to execute this change.</p> <p>4. At RSMC, on 1/14/10 at 1415 hours, M30 stated that the refrigerators in the hospital that contain vaccines and other medications were not routinely maintained. "All we do is a visual inspection. There was nothing written by us. This is located in the Plant Operations policy and procedure."</p> <p>On 1/14/10 at 1435 hours, M46 stated that he had not needed to inspect medication refrigerators because he had not been called. Routine maintenance was performed visually and he had no documentation when this was last done.</p> <p>On review of the policy and procedure entitled, "Routine Maintenance of POM Equipment" last revised in 11/09, on page 6 under Maintenance of Refrigeration Units, "All patient refrigeration units shall be given a preventive maintenance check at least annually using the following guidelines,"</p> <ol style="list-style-type: none"> a. Clean condenser coils and compressor area. b. Check for loose screws and nut. c. Check operation of condenser and evaporator fans for noise or other signs of malfunction. d. Check evaporator drain for proper drainage. e. All discrepancies shall be entered on work orders. 	A 500		

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A 500	<p>Continued From page 62</p> <p>5. a. At RSMC, on 1/12/10 at 1000 hours, review of Patient 70's medical record revealed an order for insulin intravenous infusion per hospital approved protocol. On 1/11/10 at 0700 hours, the insulin infusion was increased from algorithm 2 to algorithm 3. According to the "ICU-PCU DKA Insulin Drip Protocol," there is an order that states, "Move up to the next higher algorithm if the BS (blood sugar) does not decrease by 60 mg/dl (milligrams/deciliter) x 2 hours." When asked how to interpret this statement, E56 stated she would have to clarify the statement with a physician because it was incomplete and didn't provide a clear understanding of what to do. When asked the same question, E57 stated she would move up to the next algorithm which was a higher dose. When E57 was asked if the blood sugar was in goal range but did not decrease 60 mg/dl after 2 hours would she increase to the next algorithm which would put the patient in jeopardy of experiencing a low blood sugar reaction? Her reply was no and she stated, "This statement was unclear and I would need to clarify the order." According to the two nurses interviewed, clarification was needed to accurately interpret, and evaluate orders of this protocol.</p> <p>The "ICU-PCU DKA Insulin Drip Protocol was approved by the Pharmacy and Therapeutics Committee in 5/2007. This protocol had been in use for over 2 ½ years and E56 and 57 were unable to interpret part of the protocol that if instituted as directed, could lead to severe hypoglycemic (very low blood sugars) effects including seizure, coma, and death.</p> <p>b. At RSMC, on 1/12/10 at 1023 hours, review of Patient 70's medical record revealed a dose of</p>	A 500		

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A 500	<p>Continued From page 63</p> <p>insulin administered on 1/12/10 at 0300 hours. This dose was based on the protocol entitled, "ICU-PCU DKA Insulin Drip Protocol" which called for blood sugar levels to be drawn hourly. The dose of insulin at 0300 hours was charted as 5 units administered however no blood sugar was documented as being drawn at that time. Without a documented blood sugar at 0300 hours, the dose of 5 units of insulin did not follow the protocol as ordered. The blood sugar at 0400 hours, increased from 148 mg/dl at 0200 hours to 170 mg/dl at 0400 hours which was above the desired goal.</p> <p>6. At RSMC on 1/14/10 at 1140 hours, during an interview, M49 stated the time to initiate intravenous antibiotics when a bed was available in the ED (Emergency Department) was one to two hours but usually one hour. At 1145 hours during an interview, E156 stated that sometimes the ED was crowded and it could take as long as four hours to initiate intravenous antibiotics, but usually it only takes one to two hours, and often one hour.</p> <p>a. At RSMC, on 1/14/10 at 1524 hours, review of Patient 1's medical record revealed that he was admitted to the hospital with a severe ankle wound. Fortaz 1 gram (antibiotic medication) was ordered intravenously every 8 hours on 1/8/10 at 1540 hours. The dose was not given until 0600 hours on 1/9/10 (over 14 hours after the medication was ordered). M59, who was unable to find any earlier dose of Fortaz documented in the chart as administered replied, "I can't explain it."</p> <p>b. At RSMC, on 1/15/10 at 0900 hours, review of Patient 304's medical record revealed he was</p>	A 500		
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A 500	<p>Continued From page 64</p> <p>admitted on 1/11/10 with shortness of breath and an exacerbation of congestive heart failure. Levaquin 500 milligrams (antibiotic medication) was ordered intravenously every 24 hours on 1/11/10 at 1050 hours. The dose was not given until 2130 hours on 1/11/10 (over 10 ½ hours after the medication was ordered). M49 was asked if she could explain why the dose of antibiotic was not administered even though it was readily available on the nursing unit in their Pyxis Medstation (medication cabinet that stores medications that are frequently needed on the nursing unit). M49 stated the patient was transferred from the ED to the Medical-Surgical floor at 1600 hours. She had no explanation as to why the medication was not given until 2130 hours.</p> <p>c. At RSMC at 1530 hours, review of Patient 257's medical record revealed he was admitted to the hospital with the diagnosis of pneumonia. Rocephin 1 gram (antibiotic medication) was ordered intravenously one time on 1/2/10 at 0950 hours. Review of the Pyxis withdrawal report showed the medication was removed at 1004 hours but was never documented as administered. E15 stated the medication should have been given after blood cultures were drawn.</p> <p>On 1/15/10 at 1140 hours, AS5 stated that the quality review for antibiotic administration was to assure that antibiotics were administered within 6 hours, however, according to the hospitals policy and procedure entitled, "Intravenous Therapy: Medications given intravenously by a Registered Nurse," antibiotics needed to be administered within two hours of the physician order to prevent or treat an infection.</p> <p>7. On 1/14/10 at 1221 hours, a review of Patient</p>	A 500		

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A 500	<p>Continued From page 65</p> <p>257's closed medical record indicated that she was admitted to the IVMC on 12/14/09 at 0630 hours with intractable neck and left arm pain and underwent surgery.</p> <p>On 12/16/09 at 0930 hours, a physician ordered a 12.5 mcg/hr fentanyl patch for Patient 257 and the MAR (medication administration record) documented that the patch was applied to the patient at 1200 hours on the same day.</p> <p>Fentanyl patch, also known as fentanyl transdermal system, contains fentanyl, a potent synthetic opiate medication used to treat pain. This medication has a black box warning (BBW) which is the most serious warning required by the Food and Drug Administration to be placed in the product labeling (package insert) for a medication. Boxed warnings document potential problems that can lead to serious injury or death. The boxed warning for the fentanyl patch documents that it has an associated risk of fatal overdose due to respiratory depression. It is indicated for the management of persistent moderate to severe chronic pain that requires continuous around-the-clock opioid (narcotic pain relievers derived from or having the pain relieving action of opium) administration for an extended period of time and that cannot be managed by other pain medications, and that use of the patch is contraindicated in the treatment of postoperative pain. The boxed warning also documents that it should only be used in patients who are opioid-tolerant which is defined in the boxed warning as those patients who have taken at least 60 mg of oral morphine, 30 mg of oral oxycodone, or 8 mg of oral hydromorphone (opiate medications used to treat pain) or an equal dose of another opiate medication daily for</p>	A 500		

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A 500	<p>Continued From page 66</p> <p>a week or longer, and that use of this patch to treat patients who are not opioid-tolerant is contraindicated because serious or life-threatening respiratory depression can occur.</p> <p>There was no documented evidence that Patient 257 received (during her hospital stay) enough narcotics to be considered opiate tolerant and to indicate appropriate use of the fentanyl patch. Additionally, there was no documented evidence that Patient 257 received any narcotics before her admission to the hospital. Review of the "INPATIENT HOME MEDICATION LIST" (a list of the patient's home medications) for Patient 257 revealed that she did not take opioid based pain relieving medications at home.</p> <p>Despite the boxed warning, Patient 257 received fentanyl patch to control post surgical pain. The patient who had not received around the clock opioid pain relieving medications at doses specified in the product labeling for at least a week.</p> <p>On 1/14/10 at 1417 hours, during an interview of M32, he stated that the pharmacists were alerted by the pharmacy computer system that fentanyl patches had a BBW and gave them a brief description of the BBW issues. He said that the pharmacist was supposed to determine if a patient was opioid tolerant before dispensing the medication. Discussions with the physician were supposed to be documented in the pharmacy computer system. He produced a copy of a pharmacist note for Patient 257's computerized medication profile that read: "ordered by pain management, dose equivalent."</p> <p>On 1/14/10 at 1456 hours during an interview of</p>	A 500		

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A 500	<p>Continued From page 67</p> <p>E109, he identified the medication profile note for Patient 257 as his. He stated that "ordered by pain management," meant that a pain specialist ordered the fentanyl patch. He stated that "dose equivalent" meant he had calculated the dose equivalence for a day. He stated that he used a chart (entitled Fentanyl patch dosing based on current narcotic analgesic therapy) that was posted on the wall to determine that Patient 257 had received enough morphine over a 24 hour period to receive at least a 25 mcg/hr fentanyl patch. During the interview, E109 did not say that a pharmacist would need to determine regular use of morphine at stipulated doses over a seven day period to meet the product labeling requirements for use of this patch and he did not mention that use of this patch to treat post-operative pain was a contraindication to the use of this medication.</p> <p>On 1/15/10 at 1108 hours a review of the policy and procedure entitled Fentanyl Transdermal Patches, Orders for, indicated the following:</p> <ul style="list-style-type: none"> · "Orders for Transdermal Fentanyl Patches (TPF) will be reviewed by a pharmacist for appropriate patient selection and dose. Orders not conforming to the guidelines herein shall be referred back to the prescriber." · "...this product not suitable for post-operative pain management." <p>The policy was not clear that one would have to take the stipulated daily doses for seven days to be considered opiate tolerant, and did not mention the contraindications to the use of this medication for post-operative pain. The policy provided no guidance to pharmacy staff as to</p>	A 500		
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A 500	<p>Continued From page 68</p> <p>what they should do if there was pharmacist/physician disagreement as to whether the use of this medication was contraindicated in a given patient.</p> <p>On 1/15/10 at 1148 hours during an interview of M32, he stated that fentanyl patches were not indicated for the management of post-operative pain or for use non-opioid tolerant patients. He stated that the phrase "Orders for Transdermal Fentanyl Patches (TPF) will be reviewed by a pharmacist for appropriate patient selection and dose" found in the hospital fentanyl patch policy meant that the pharmacist was to check to see if the patient was opiate tolerant. He stated that this policy made no mention of the seven day requirement used to determine opioid tolerance (as stipulated in the product labeling). He stated that E106 did not have proper guidance from this policy.</p> <p>8. On 1/11/10 at 0915 hours, during an interview of M10, he stated that there was only one cabinet in the pharmacy at RSMC and it was used to compound IV chemotherapeutic medications and standard IVs. He stated they had a chemotherapeutic order about once a week and after the chemotherapeutic medication had been compounded it was cleaned out. He stated they used an American Society of Health System Pharmacists recommended product to clean out this cabinet. During a visit to the pharmacy at 1059 hours on 1/11/10, the cabinet proved to be a closed cabinet with an antechamber into which IV medications and solutions could be placed and the outer door closed. Then the operator could stick his arms into a sleeve and glove assembly, which was built into the front wall of the cabinet, and remove the products from the antechamber,</p>	A 500		

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A 500	<p>Continued From page 69</p> <p>via an inner door, into the main body of the cabinet where the compounding took place.</p> <p>On 1/13/10 at 1633 hours a review of the manual that came with the cabinet indicated the model number of the cabinet was: Microsphere 6X2 and that it was manufactured by IsoTech Design.</p> <p>On 1/14/10 at 0738 hours during a telephone interview of DSM1 from IsoTech, he stated that the Microsphere cabinet was not designed for compounding IV chemotherapeutic medications and a hospital should not use it for that purpose. He stated that the company is very clear about this when they sell it to an end user. He said it was designed to compound sterile products. He stated that they made a cabinet called Chemosphere that was intended to be used for compounding IV chemotherapeutic products. He stated that the Microsphere cabinet was a positive pressure cabinet while the Chemosphere cabinet was a negative pressure cabinet.</p> <p>On 1/14/10 at 1655 hours review of an undated letter to M10 documented that IsoTech Design had "congratulated" M10 on his purchase of a Chemosphere cabinet. This letter was produced by M44 at 1655 hours on 1/14/10.</p> <p>9. On 1/11/10 at 0915 hours, during an interview of M10, he stated that there was only one cabinet in the pharmacy at RSMC and it was used to compound IV chemotherapeutic medications and standard IVs. He stated they used an American Society of Health System Pharmacists recommended product to clean out this cabinet. At 1058 hour on this date, inspection of the pharmacy indicated they had a product called Surface Safe that staff stated was used to clean</p>	A 500		