

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001099	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/29/2012
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NAME OF PROVIDER OR SUPPLIER MUNCIE CATARACT & LASER EYE CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3300 W PURDUE AVE MUNCIE, IN 47304
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S0000	The visit was for a licensure survey. Facility Number: 2658 Survey Date: 2-27-12 to 2-29-12 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor	S0000	We would like to note our disagreement with the comment placed at the conclusion of several tags "staff member A1 or A2 confirmed that a process for policy was lacking." The processes may have been inadequate in the surveyor's opinion but they were certainly in place for example tags 1152 and 1164.	
S0148	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c) (4) (c) The governing body shall do the following: (4) Require that the chief executive officer designate in writing an administrative officer to serve during his or her absence. Based on document review and interview, the chief executive failed to assure a responsible person to serve in their absence. Findings: 1. The policy/procedure Person in Authority During Absence of Facility Administrator (approved 10-11) failed to indicate who would be in charge when the chief executive officer was unavailable.	S0148	1. A plan was put in place to designate a responsible person to be in charge in the absence of the chief executive and the Administrator. An asterisk will be placed by the Charge Nurse that is to be in charge that particular day.2. This improved client safety to ensure someone would be in charge at all times.3. Policy/Procedure changed to reflect a designated person, an asterisk was added to the weekly schedule to signify who is to be charge nurse and the Organizational Chart was changed also to reflect the addition of a charge nurse. An	03/21/2012

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	2. During an interview on 02-27-12 at 1430 hours, staff A2 confirmed that the policy statement failed to indicate the chain of command when the Administrator was unavailable.		in-service will be done to educate staff on addition. See attached.4. Administrator will be in charge of designating, in writing, the weekly charge nurse.		

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S0156	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on review of the employee handbook, employee file review, and staff interview, the facility failed to follow the handbook, in relation to employee performance reviews, for 1 RN (registered nurse) administrator (P6).</p> <p>Findings: 1. at 2:35 PM on 2/29/12, review of the employee handbook indicated: a. in section 3.21, it reads: "Section IV: Performance Review/Progressive Discipline A. Personnel Status/Performance Review: Every employee has an employment status. The status includes...Every employee will receive a performance review...after the first ninety(90) days of employment and</p>	S0156	<p>1. Performance review uncovered and put in employee file.2. Employee performance review allows for growth in job and increased patient satisfaction.3. All employee files reviewed yearly and master list of employee file contents initiated to help complete compliance.4. Administrator will review employee files yearly.</p>	03/29/2012			

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	<p>at his/her anniversary each year thereafter..."</p> <p>2. at 12:10 PM on 2/27/12, review of employee files indicated that staff member P6's last performance evaluation was dated 9/10</p> <p>3. at 2:45 PM on 2/29/12, interview with staff member NB indicated the most recent employee performance review for staff member P6 was 9/10 and was due to be have been done on September of 2011</p>				

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S0162	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (G)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel, who provide direct patient care.</p> <p>Based on employee file review, and staff interview, the facility failed to ensure the completion of CPR (cardiopulmonary resuscitation) certification for 1 of 1 LPN (licensed practical nurse) employee file reviewed (P2).</p> <p>Findings:</p> <p>1. at 12:10 PM on 2/27/12, review of employee files indicated that staff member P2, a LPN hired 11/11, had documentation of CPR that expired 10/11</p> <p>2. at 3:05 PM on 2/27/12, interview with staff member NA indicated a current CPR certification for staff member P2 would be searched for as this is required</p> <p>3. at 2:45 PM on 2/29/12, interview with staff member NB indicated CPR is required for this position and current</p>	S0162	<p>1. The facility obtained copy of current CPR certification for LPN and put in employee file. 2. Ensures patient safety by having all staff current in CPR skills.3. A master list of what is included in employee files was made to make review of yearly employee files easier and ensure completeness. See attached.4. Administrator will be responsible for reviewing employee files yearly.</p>	03/14/2012			

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	CPR certification documentation for staff member P2 would be searched for 4. No current CPR was found, prior to the exit, for staff member P2				

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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the center failed to maintain a written quality assurance (QA) plan to ensure services were evaluated for 12 contracted services provided at the facility.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Assurance Plan (approved 12-10) failed to indicate a provision for evaluating contracted services (biomedical engineering, clinical laboratory/pathology, fire protection, furnace/humidifier, generator, housekeeping, laundry, medical gasses, medical records and pharmacy consulting, pest control, and security alarm services) provided at the center and failed to describe a process for performing, documenting, and reporting the ongoing evaluation.</p> <p>2. Review of the Contract Services Quality Statement documents failed to</p>	S0310	<p>1. Added Evaluation Services to our Activities under the Quality Assurance Process Improvement. Created a log that will be reviewed quarterly that has measurable criteria to evaluate the quality of the services.2. By quarterly reviewing measurable criteria of our contracted services we ensure patient, visitor and employee safety and promotes high standard of care.3. Reviewed Quality Assurance Process Improvement and added Evaluation Services. Reviewed contracted services and created a log to evaluate measurable criteria of the quality for all services including those in the noted citation.4. Administrator will perform quarterly monitoring of contracted services and report to the governing body.</p>	03/29/2012			

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	<p>indicate standards for evaluating each service.</p> <p>3. During an interview on 2-29-12 at 1030 hours, staff A2 confirmed that the QA plan lacked a provision for evaluating contracted services and confirmed that the current QA standards applied to the contracted services failed to objectively evaluate each service. Staff A2 confirmed that the process failed to ensure the ongoing review of each service by the committee.</p>			

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S0332	<p>410 IAC 15-2.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(1)</p> <p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the center: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained.</p>			

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	<p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to</p>			

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	<p>the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p> <p>(D) The following care management events:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration.</p> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug=drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <p>(AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is</p>			

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	<p>progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the center.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or (BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the center.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on the grounds of the center.</p> <p>(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</p>			

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	<p>Based on document review and interview, the center policy/procedure Reportable Surgical Events lacked a process for identifying the reportable events identified by State law 410 IAC 15-2.4-2.2 Reportable Events and failed to ensure that a reportable event was identified.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Reportable Surgical Events (approved 10-11) indicated the following: " A process for determining the occurrence of the following reportable events within the center. " The policy/procedure statement failed to indicate how the facility would determine an occurrence. 2. The policy/procedure Incident Reports (approved 10-11) failed to ensure that the incident reports were reviewed against the list of events reportable to the department. 3. The 9-29-11 Medical Staff/Quality Assurance Committee minutes indicated the following: " The second [incident report] was an argon PRP [pan retinal 	S0332	<ol style="list-style-type: none"> 1. A new policy was developed and implemented to identify a process for reportable events. 2. This process improves patient care and ensures compliance with regulatory bodies. (State, Federal) 3. After gathering data, the policy was developed and staff was educated on 3/21/2012. 4. Administrator and medical director will monitor any reportable events and will be listed in the facilities annual review. Board reviewed policy. 5. The Committee reviewed Incident Report #2 and investigated the report and found that the consent covered the procedure performed and there was no violation of policy or harm to patient. The Board resolved not to report based on the state's list of reportable events but will continue to review future risk reports. Board recommended that proper safety mechanisms be followed: pre-op checklist, informed consent represents the procedure ordered. The committee meeting minutes will reflect this discussion as well as future discussions on risk reports. 	03/29/2012	

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	<p>procedure] laser was performed instead of a focal grid [argon laser procedure]. "</p> <p>The minutes failed to indicate a discussion of the identified event and failed to indicate any recommendations.</p> <p>4. During an interview on 2-28-12 at 1320 hours, staff A1 confirmed that the event was not reported to the Indiana State Department of Health and confirmed that the policy/procedures failed to describe a process to identify the reportable events indicated by state law.</p>			

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S0334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved; or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>			

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NAME OF PROVIDER OR SUPPLIER MUNCIE CATARACT & LASER EYE CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3300 W PURDUE AVE MUNCIE, IN 47304
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	<p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on document review and interview,</p>	S0334	1. A step by step process was	03/29/2012

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	<p>the center failed to ensure that reportable events were submitted to the department as required by State law 410 IAC 15-2.4-2.2 Reportable Events.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Reportable Surgical Events (approved 10-11) lacked a provision for reporting all events after identification by the center quality assessment and improvement program. 2. During an interview on 2-29-12 at 0920 hours, staff A2 confirmed that the policy/procedure lacked a process for reporting events determined to have occurred at the center. 		<p>initiated to capture State defined reportable events in facility. 2. Reporting events provides safety for current and future clients.3. A step by step process was initiated to easily observe what needs to happen when an event occurs and who is notified, when and the time frame to be completed. In-service for all staff for reporting these events in this facility. See attached process under the Quality Assurance Process Improvement.4. Administrator and medical director will monitoring all reportable events. Ongoing.</p>		

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S0428	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation.</p> <p>Based on observation, policy and procedure review, and staff interview, the facility and infection control practitioner failed to ensure the cleanliness of the women's changing area.</p> <p>Findings:</p> <p>1. at 2:55 PM on 2/28/12, review of the policy and procedure "Housekeeping Cleaning Schedule", 11.1 in the policy manual, indicated:</p> <p>a. under the section "Schedule Nightly", in item "D. Restrooms:", it reads: "...10. Dust locker tops."</p> <p>2. at 2:50 PM on 2/28/12, the surveyor:</p> <p>a. noticed the top of the lockers in the women's changing area were dusty and with debris</p> <p>b. swiped the top of the lockers with a wet paper towel which showed evidence of dust/debris</p>	S0428	<p>1. Review all tasks with housekeeping and cleaning specifications added to housekeeping schedule checklist.</p> <p>2. Ensure cleanliness in all areas for clients, visitors and employees. 3. Reviewed Policy/Procedure and cleaning specifications. Reviewed with housekeeping.4. Infection control nurse will monitor/observe contracted housekeeping staff on a quarterly basis to assess cleaning specifications and sequence as well as weekly monitor to insure cleaning schedule is being completed per checklist. Instruct staff to be alert to any house cleaning issues and correct or report to Infection Control nurse. All staff involved in infection control surveillance.</p>	03/21/2012

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	<p>3. at 3:00 PM on 2/28/12, interview with staff members NA and NB indicated:</p> <p>a. the tops of the lockers in the women's changing room were dirty and had not been cleaned "nightly", as per the housekeeping cleaning schedule</p> <p>b. there has not been direct observation of the contracted housekeeping staff for quite some time</p>			

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S0442	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on document review, personnel file review, and staff interview, the infection control practitioner failed to implement the "Infection Control Education" process for 2 of 6 employee files reviewed (P2 and P5).</p> <p>Findings:</p> <p>1. at 2:10 PM on 2/29/12, review of the document titled "Infection Control Education", indicated:</p> <p>a. on page two it reads (toward the bottom of the page): "Healthcare workers are to have proof of immunity for: A...C. Chicken pox D. Measles/Rubeola E. Rubella/German measles..."</p> <p>2. at 12:10 PM on 2/27/12, review of</p>	S0442	<p>1. Documentation received for vaccination of employee for MMR and placed in employee file. Order given for second employee P5 to receive Varicella Titer. Will add to employee file when results received.2. Having documentation for required vaccinations provides high quality of care for our patients. 3. A master list of employee file requirements was initiated to help with annual review of employee files. 4. Administrator will oversee the annual review of employee files.</p>	03/29/2012			

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	<p>employee files indicated:</p> <p>a. staff member P2 was hired 11/11 and had:</p> <p>A. documentation of one MMR (measles, mumps, rubella) vaccination as a child</p> <p>B. had self reported documentation of having had chicken pox (varicella) in the past</p> <p>b. staff member P5 was hired in 9/06 and had a form in the file with self reporting of their history of chicken pox</p> <p>3. interview with staff member NB at 3:45 PM on 2/29/12 indicated:</p> <p>a. all staff were to have had Varicella titers performed in 2010, so it is unknown why staff member P5 still had a self reported varicella form in the employee file</p> <p>b. ataff member P2, hired 11/11, should have had a varicella titer drawn upon hire, and not a self reported varicella form in the file</p> <p>c. it was unknown that the one MMR for staff member P2 was not sufficient and that the CDC (centers for disease control and prevention) requires/recommends a second Rubeola, which staff member P2 has no documentation of</p>				

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S0444	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(ix)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>Based on policy and procedure review, observation, and staff interview, the infection control practitioner failed to implement its policy related to surgical masks for two staff observed in the OR (operating room) suite.</p> <p>Findings:</p> <p>1. at 3:25 PM on 2/27/12, review of the policy and procedure "Dress Policy", 5.23 in the policy manual, indicated:</p> <p>a. under the section "Caps and Masks", it reads: "...Masks, when worn, must be tied securely, covering the nose and mouth..."</p> <p>2. while observing a patient in the OR at 1:25 PM on 2/29/12, it was observed that:</p> <p>a. the circulating nurse had gaps on both sides of the surgical mask (large enough</p>	S0444	<p>1. The Infection control nurse re-evaluated Infection control Surveillance and added no gapping (a measurement of 2 -3 finger width) of masks and that they are tied securely. 2. Patients will be more protected from infection if masks are worn properly. 3. Reviewed Policy - no changes made. An in-service to be performed to ensure proper mask fit as defined as mask strings tied securely with no gapping (measurement of 2-3 finger widths). 4. The proper way to wear masks will be observed by all staff during surgery and called out if change needed. This will be ongoing observation. Infection control nurse will continue observing quarterly through surveillance worksheet for QA/PI.</p>	03/21/2012			

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	<p>that would allow two or three fingers to enter the sides of the surgical mask)</p> <p>b. the surgery tech had a gap under the chin area of the surgical mask that kept the mask from fitting securely to the staff member's face</p> <p>3. interview at 4:00 PM on 2/29/12 with staff members NA, NB and NC indicated the surgical masks are to snugly fit to the face, with no gaps, as recommended by AORN (association of perioperative registered nurses)</p>			

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S0612	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(1)</p> <p>(c) An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure the accuracy of medical records for 4 of 20 patient records (N2, N4, N7 and N9).</p> <p>Findings:</p> <p>1. at 3:10 PM on 2/29/12, review of the policy and procedure "Medical Record Completeness", section 7.21 in the policy manual, indicated:</p> <p>a. under "Policy", it reads: "Accurate and complete written medical records shall be maintained for all patients..."</p> <p>2. at 2:45 PM on 2/27/12, review of closed patient medical records indicated:</p> <p>a. pt. N2 had documentation on the "Intraoperative Record" form of an "operation time" of 0853, but a (pre surgical) time out documented at 0950 on the "Procedure Verification Checklist"</p>	S0612	<p>1. Duly noted failure to ensure accuracy of medical records and incorporated the incidents into the survey overview staff education process.2. Accuracy in medical records prevents possible legal accusations in the future.3. The chart audit form was changed to include ASA rating congruent and checking time sequence congruency throughout chart. In-service Medical Record Personnel to observe, in detail for these and any errors.4. Medical Records personnel performing weekly chart audits will be responsible for checking surgery charts weekly and reporting any errors to Administrator.</p>	03/21/2012			

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	<p>form</p> <p>b. pt. N4 had documentation on the "Intraoperative Record" form of an "operation time" of 0755, but a (pre surgical) time out documented at 0954 on the "Procedure Verification Checklist" form</p> <p>3. interview with staff member NA at 3:05 PM on 2/27/12 indicated:</p> <p>a. this staff member made the documentations noted on the patient records of N2 and N4</p> <p>b. a mistake was made in the notation of the time outs for pts. N2 and N4 by this staff member (for pt. N2 the time out should have been documented as 0850 and for pt. N4, it should have documented as 0754)</p> <p>4. at 10:55 AM on 2/28/12, and 9:30 AM on 2/29/12, review of closed patient medical records indicated:</p> <p>a. pt. N7 had documentation that the patient was an "ASA rating" (american society of anesthesiologists) of "II", but on the "Anesthesia Evaluation" form, the physician/anesthesiologist noted the patient had an "ASA Physical Status Class" of "3"</p> <p>b. pt. N9 had final vital signs documented at 1425 hours, but had a "Dismissal: Time:" noted as 1323 hours</p>			

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	5. interview with staff member NB at 3:45 PM on 2/29/12, indicated: a. inaccuracies in the medical records were as noted in 2. and 4. above				

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S0620	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(5)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the center policies.</p> <p>Based upon document review and interview, the center lacked a policy/procedure for including plain paper facsimile documents in the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 2-27-12 at 1030 hours, staff A1 was requested to provide documentation for entering facsimile documents in the MR and none was provided prior to exit. On 2-29-12 at 1430 hours, staff A1 confirmed that the center lacked a policy/procedure that allowed plain paper facsimile documents to be entered in the patient record. 	S0620	<ol style="list-style-type: none"> Policy was written to include allowing plain paper facsimile documents to be permissible as part of the medical record. Plain paper provides protection and confidentiality for the patient. After reviewing our lack of a policy, one was created. Board will review policy. Medical record personnel will monitor all facsimile for clarity and legibility for each facsimile recieved for medical record. 	03/14/2012			

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S0624	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(7)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure the privacy and security of individually identifiable health information.</p> <p>Findings:</p> <p>1. The policy/procedure Medical Record Security (approved 10-11) indicated the following: " To ensure secure storage of medical and personnel records ...all file</p>	S0624	<p>1. All boxes in the mechanical room that had any documents indicating patient names and personal identification information were moved into a locked cabinet. Only authorized personnel have access to keys.2. This provides protection and confidentiality of our patients.3. All boxes in the mechanical room that had any documents that had patient information were moved into a locked cabinet. 4. Monitoring of documents will be done by Medical Records personnel and overseen by Administrator. This will be ongoing.</p>	03/14/2012			

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	<p>cabinets will be locked at the end of each working day. "</p> <p>2. During a facility tour on 2-28-12 at 1125 hours, the following condition was observed in the mechanical equipment room: 4 boxes containing documents indicating patient names and personal identification information were stored on open metal shelving.</p> <p>3. During an interview on 2-28-12 at 1130 hours, staff A1 confirmed that the records were unprotected from viewing by unauthorized persons.</p>				

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based on policy and procedure review, facility document review, patient medical record review and staff interview, the facility failed to ensure the legibility of records for 5 of 20 patient records (pts. N7, N9, N12, N18 and N20) and lacked a policy/procedure ensuring that all entries in the medical record (MR) were legible.</p> <p>Findings:</p> <p>1. at 3:10 PM on 2/29/12, review of the policy and procedure (section 7.103 in the policy and procedure manual) "Identification of Authors and Authentication of Medical Record Entries", indicated:</p> <p>a. under "Policy", it reads: "The ambulatory surgery center has a method for identification of the author of each entry. An entry in the medical record is defined as legible documentation by a physician and other licensed health care professionals..."</p> <p>2. at 3:10 PM on 2/29/12, review of the "Internal Medical Record Audit</p>	S0640	<p>1. After reviewing policy, a No Write over entry was added to our Policy/Procedure: Medical Record Policy Chart Completeness and Legibility. Added No Write overs to our legibility line on our chart audit form to capture those. Staff in-service conducted to emphasize the importance of legibility and NO write overs. See attached.2. Legible medical records is required to protect the facility and the practice if a legal issue ever arose.3. In-service conducted for all staff. Added no write overs to chart audit list.4. Administrator or medical record personnel will audit charts after surgery to check legibility and contact staff if corrections need to be made.</p>	03/21/2012			

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	<p>Checklist" document used for internal medical record review (section 7.113 of the policy and procedure manual) indicated:</p> <p>a. the next to last item, of things reviewed in each medical record, on the page was "Legibility"</p> <p>3. at 2:45 PM on 2/27/12, 10:55 AM on 2/28/12, and 9:30 AM on 2/29/12, review of closed patient medical records indicated:</p> <p>a. pt. N7 had a write over in the "time" section of the intra operative area on the "Anesthesia Evaluation" form (on 9/7/11)</p> <p>b. pt. N9 had a write over in the "date" section of the intra operative area on the "Anesthesia Evaluation" form (on 10/26/11)</p> <p>c. pt. N12 had a write over, by nursing staff, of the oxygen saturation level (top of the page) on the "Nursing Assessment" form on 8/31/11</p> <p>d. pt. N18 had a write over in the "Dismissal: Time:" area of the "Recovery Room Record" form on 1/25/11</p> <p>e. pt. N20 had a write over in the second vital signs time of the "Recovery Room Record" form on 1/25/11</p> <p>4. at 3:45 PM on 2/29/12, interview with staff member NB indicated:</p> <p>a. the legibility was compromised in each of the five records listed in 3. above</p>				

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	<p>b. surgery center staff should be capturing these write overs with the internal survey process</p> <p>5. The policy/procedure Incomplete Charts (approved 10-11) and Medical Record Policy: Chart Completeness (approved 10-11) failed to indicate a process for verifying entries of questionable legibility.</p> <p>6. On 2-29-12 at 0940 hours, staff A2 confirmed that the center lacked a policy/procedure for verifying illegible information in the patient record.</p>				

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S0644	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(2)</p> <p>All entries in the medical record must be as follows:</p> <p>(2) Made only by authorized individuals as specified in center and medical staff policies.</p> <p>Based on document review and interview, the center lacked a policy/procedure specifying which individuals, staff members and medical professionals are permitted to make entries in the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Identification of Authors and Authentication of Medical Record Entries (approved 10-11) failed to clearly specify all individuals that were authorized to make entries in the MR. During an interview on 2-29-12 at 0935 hours, staff A2 confirmed that the policy/procedure failed to ensure that only specified health care providers and medical professionals were authorized to make MR entries. 	S0644	<ol style="list-style-type: none"> Policy/Procedure Identification of Authors and Authentication of Medical Record Entries now specifies that currently credentialed medical staff, current facility employed registered nurses, licensed practical nurses, surgery technicians and medical professionals are permitted to make entries in the medical record. Client protection from unauthorized persons from making entries in medical records. Board reviewed policy update. Medical record personnel will be monitoring charts for entries made ensuring authorized personnel only. This will be ongoing monitoring. Chart audits performed on every chart after every surgery day will also be observed for entries made by unauthorized personnel. <p>Addendum: We will also have our Mecalcal Record Consultant check for permissible entries on a quarterly basis.</p>	03/29/2012	

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S0772	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based upon document review and interview, the center failed to ensure that a History and Physical (H&P) assessment was completed within 30 days of the surgical procedure in accordance with the time frame specified by the medical staff.</p>	S0772	<p>1. The Medical Staff Rules and Regulations and the Policy/Procedure Patient History were reviewed and changed to be congruent.2. All History and Physicals are performed within 30 days of procedure which is being done but both pieces of paperwork reflect the same thing</p>	03/29/2012			

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	<p>Findings:</p> <ol style="list-style-type: none"> 1. The Medical Staff Rules and Regulations (approved 12-10) indicated the following: " A pertinent history and physical examination shall be performed within one month to the admission of the patient and updated the day of surgery. " 2. The policy/procedure Patient History (approved 10-11) indicated the following: " The History and Physical that is older than 30 days can be revalidated ... " 3. During an interview on 2-29-12 at 0925 hours, staff A2 confirmed that the center lacked a uniform policy/procedure consistent with medical staff requirements. 		<p>now.3. Reviewed the Policy/Procedure as stated and Medical Staff Rules and Regulations.4. Statements changed to ensure that they were congruent. See attached.5. The monitoring of History and Physicals done within the 30 day limit will be monitored by Medical Records personel and reported to Administrator according to Medical Rules and Regulations policy and History and Physical policy.6. The Board will be shown changes for review and approval.</p>		

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S0780	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based upon document review and interview, the center lacked a uniform policy/procedure for authenticating verbal orders in the medical record (MR). Findings:</p> <p>1. The Medical Staff Rules and Regulations (approved 12-10) indicated the following: " The ...physician must sign all such dictated orders at his/her next visit or within ...(24) Hours, whichever is sooner. " The rule failed to ensure compliance by not requiring the physician to date and time the order when authenticated.</p> <p>2. The policy/procedure Identification of Authors and Authentication of Medical</p>	S0780	<p>1. All physicians will now be required to date, time and sign all verbal orders within 24 hours. Medical Staff Rules and Regulations and Policy/Procedure Identification of Authors and Authentication of Medical Record Entries are now uniform in authenticating entry requirements.2. Compliance ensures patient safety.3. All physicians will be required to sign, date and time their verbal orders before leaving the facility for the day. Policy and Regulations reviewed and changes made. In-service to be done for all staff 3/21/2012 including physician and anesthesiologist present that day.</p> <p>4. Medical Record personnel will be responsible to check for</p>	03/29/2012	

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	Record Entries (approved 10-11) indicated the following: " Each verbal order is also dated and authenticated within thirty days by the person who gave it. " 3. During an interview on 2-29-12 at 0920 hours, staff A2 confirmed that the center lacked a uniform standard for authenticating entries in the MR.		signatures if one is needed before physician leaves for the day. Administrator will be notified if verbal order not signed, dated and timed. Physician will be called to return to sign the order. Ongoing monitoring. 5. Board will be notified of Policy and Regulation changes and approval sought at next meeting.		

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S0782	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(O)</p> <p>These bylaws and rule must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(O) A provision for personnel authorized to take a verbal order.</p> <p>Based upon document review and interview, the center lacked a uniform policy/procedure indicating what personnel were authorized to receive a verbal order.</p> <p>Findings:</p> <p>1. The policy/procedure Medication Administration (approved 10-11) indicated the following: "Only R.N. 's [Registered Nurses] may receive verbal orders. "</p> <p>2. The policy/procedures Physician Verbal Orders (approved 10-11) and Identification of Authors and Authentication of Medical Record Entries (approved 10-11) failed to indicate that only RNs may receive verbal order.</p> <p>3. During an interview on 2-29-12 at 0930 hours, staff A2 confirmed that the center lacked a uniform standard indicating the licensed professionals</p>	S0782	<p>1. Changes were made in Policy/Procedures to define that Registered Nurses were authorized to receive verbal orders.2. Clients are kept safe by stating that Registered Nurses are the only ones who may authorize verbal orders, promoting safe practice.3. Reviewed Policies on Physician Verbal Orders, Medication Administration and Identification of Authors and Authentication of Medical Record Entries. Changes made to make each policy congruent.4. In-service to be done for education.5. The Board will review changes in policies, put to vote for approval and will be documented in meeting minutes by Administrator.</p>	03/29/2012			

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	authorized to receive verbal orders at the facility.			

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S0912	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)(5)</p> <p>(a) Patient care services must require the following:</p> <p>(5) That an experienced registered nurse supervise all nursing personnel, including, but not limited to, registered nurses, licensed practical nurses, and surgical technologists, in surgical areas and recovery unit(s) as follows:</p> <p>(A) Licensed practical nurses, and surgical technologist may serve as scrub personnel under the supervision of a qualified registered nurse.</p> <p>(B) Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved medical staff policies and procedures.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure that nursing staff followed physician post operative orders for 5 of 20 patients (N7, N9, N12, N17 and N18).</p> <p>Findings: 1. at 2:45 PM on 2/27/12, 10:55 AM on 2/28/12, and 9:30 AM on 2/29/12, review</p>	S0912	<p>1. Dr. Makris changed order for BP readings: Systolic B/P higher than 200 and Diastolic B/P higher than 100.2. Clients will continue to be monitored for 30 minutes after a B/P reading higher than ordered and Dr. Makris will be notified to ensure patient safety in the Recovery Room.3. Staff will be educated on the change in B/P readings per Dr. Makris.4. All</p>	03/21/2012			

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	<p>of closed patient medical records indicated that patients N7, N9, N12, N17 and N18 had cataract surgery with physician post op orders that read: "1. Notify Dr. Makris if systolic B/P is higher than 170, diastolic B/P is higher than 90. If elevated keep patient for 30 minutes, recheck B/P and notify Dr. Makris prior to discharge..." :</p> <p>a. pt. N7 had "recovery room record" form documentation of a B/P of 197/95 at 1435 hours, and 182/90 at 1450 hours, with discharge at 1510 hours and lacked any documentation of notification of the physician, nor was the patient kept for 30 minutes more with a B/P out of the range as per the physician's orders</p> <p>b. pt. N9 had "recovery room record" form documentation of a B/P of 174/87 at 1410 hours, and 176/80 at 1425 hours and lacked any documentation of notification of the physician (the documented discharge time was written as 1323 hours, so could not be a correct time of discharge--confirmed per staff member NB)</p> <p>c. pt. N12 had "recovery room record" form documentation of a B/P of 171/63 at 1450 hours, 194/88 at 1505 hours, and 196/88 at 1520 hours with discharge at 1523 hours and lacked any documentation of notification of the physician, nor was the patient kept for 30 minutes more with a B/P out of the range permitted by the</p>		nurses will be responsible for monitoring their patients each surgery day and keeping Dr. Makris informed of elevated B/P readings.To continue to monitor this for compliance a QAPI will be done next quarter specifically making sure that the policy is being adhered to. Results of this study will show if further studies are required for compliance.Our Mecial Record consultant will be asked to add monitoring of post op B/P readings and necessary reporting to their quarterly chart audits and check for nursing compliance according to our orders and policy and then report to Administrator.				

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	<p>physician's orders</p> <p>d. pt. N17 had "recovery room record" form documentation of a B/P of 166/95 at 1037 hours, and 170/95 at 1100 hours with discharge at 1115 hours and lacked any documentation of notification of the physician, nor was the patient kept for 30 minutes more with a B/P out of the range permitted by the physician's orders</p> <p>e. pt. N18 had "recovery room record" form documentation of a B/P of 156/93 at 1116 hours with discharge at 1130 hours and lacked any documentation of notification of the physician, nor was the patient kept for 30 minutes more with a B/P out of the range permitted by the physician's orders</p> <p>2. interview with staff member NB at 2:45 PM on 2/29/12 indicated staff has not been following the physician orders as written for each of the patients as listed in 1. above</p>				

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S1000	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6</p> <p>The center shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Pharmaceutical services must have the following:</p> <p>Based on observation and interview, the nursing supervisor failed to ensure the safety of patients in regard to expired medications in the anesthesia carts in 2 of 2 OR (operating room) suites.</p> <p>Findings:</p> <ol style="list-style-type: none"> at 2:10 PM on 2/28/12, while on tour of OR room #2 in the company of staff member NA, it was observed in the anesthesia cart that the only vial of Atropine (0.4 mg/ml--1 ml vial) had expired 11/11 at 2:30 PM on 2/28/12, while on tour of OR room #1 in the company of staff member NA, it was observed in the anesthesia cart that the only vial of Atropine (0.4 mg/ml--1 ml vial) had expired 11/11 at 2:30 PM on 2/28/12, interview with staff member NA indicated: <ol style="list-style-type: none"> the contracted pharmacist does not 	S1000	<ol style="list-style-type: none"> A complete list of medications was compiled according to location ie: crash cart, anesthesia cart 1, 2, medication cabinet, medication refridgerator. All medications will be checked for expiration date against master list. All outdated medication will be stored in container in locked drawer. The administrator will pull anesthesia carts from OR rooms quarterly so that contracted pharmacist can check all medications contained in those particular carts. Policy was found on Reclamation of Outdated Supplies. See attached. 2. Newly implemented monthly rounding tool to eliminate expired drugs to increase patient safety. See attached. 3. Found and reviewed policy with no changes. Master list of medications and locations created for monthly review. 4. Administrator will perform monthly checks using newly tooled form for all medications. 	03/21/2012			

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	<p>dress in scrubs and enter the OR suites to review medications stored in those areas</p> <p>b. there is no policy or procedure related to the checking of supplies and expiration dates, nor is there a schedule related to the frequency of this duty</p> <p>c. this staff member is responsible for checking the anesthesia carts stored in the OR suites for expired medications</p> <p>d. it is unclear how these medications have been missed with the monthly checks this staff member has performed</p>			

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S1006	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(2)</p> <p>Pharmaceutical services must have the following:</p> <p>(2) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.</p> <p>Based upon document review, observation and interview, the center failed to follow its policy/procedure to maintain records of all scheduled substances stocked and maintained for use at the facility for 33 bottles of Propofol medication.</p> <p>Findings:</p> <p>1. The Nursing 5.130 policy/procedure and Pharmacy 10.18 policy/procedure Controlled Substances Control and Record Keeping (approved 10-11) indicated the following: " The Surgery Administrator shall ...maintain a controlled substance inventory record to record all Schedule II, and any other controlled substances ...that are received and administered in the facility. "</p> <p>2. During a tour on 2-28-12 at 1100 hours, (33) 100ml bottles of Propofol (Diprivan) were observed in a secure pharmacy storage cabinet in the</p>	S1006	<p>1. Propofol/Diprovan will be inventoried via a log sheet per Administrator.2. By recording beginning and ending values of Propofol provides protection for staff and facility from theft and misuse.3. Reviewed Policy/Procedure Controlled Substances Control And Record Keeping. Made changes - See attached. Initiated Log inventory for Propofol/Diprovan.4. Administrator will monitor when shipment of Propofol received and count before and after surgery day and record on log sheet.</p>	03/21/2012	

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	<p>medication room at the center.</p> <p>3. During an interview on 2-28-12 at 1100 hours, staff A1 indicated that no inventory records were maintained for the Propofol once the medication was placed in the storage cabinet. Staff A1 confirmed that it could not be determined how many bottles of the medication should be on hand at the time of the audit and indicated that the center only maintained inventory records for the narcotic medications. Staff A1 confirmed that staff was not conducting monthly audits to compare the available medication supplies with expected amounts when checking for outdated medications.</p> <p>4. During an interview on 2-29-12 at 0950 hours, staff A2 confirmed that the two policy/procedures were duplicates and that the facility failed to follow its policy/procedure regarding controlled substance inventory records.</p>						

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S1010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on document review and interview, the center failed to ensure that outdated or recalled medications were safely stored in accordance with acceptable standards of practice until destroyed, returned, or released to a reverse distributor.</p> <p>Findings:</p> <p>1. The policy/procedure Drug Storage and Review (approved 10-11) Recalled Items (approved 10-11) and Medication Control and Accountability (approved 10-11) failed to indicate a location for securing outdated or recalled medications or medical equipment until a final disposition may occur.</p> <p>2. During an interview on 2-29-12 at 1000 hours, staff A2 confirmed the policy/procedures lacked the indicated provision.</p>	S1010	<p>1. A small clear container was purchased and labeled with outdated/ recalled medications and placed it in a locked drawer until able to properly dispose or return.2.A large tote was purchased and labeled recalled medical equipment for our medical equipment to be fixed or returned. Tote is placed out of traffic paths in lounge area.3. Clients are kept safe by removing and locking medications or equipment that is expired or recalled.4. Reviewed Policies and Procedures and made changes to reflect our new process. In-service to be done to educate staff on new procedure.5. All medication expiration dates will be checked by looking at all medications in drug cabinet, anesthesia carts, crash cart on a monthly basis to ensure removal of expired drugs to locked drawer. Surgical tech will be responsible and report to</p>	03/21/2012

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			Administrator.	

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S1020	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(D)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(D) Reporting of adverse reactions and medication errors to the practitioner responsible for the patient and the appropriate committee, and documented in the patient's record.</p> <p>Based on document review and interview, the center failed to ensure that medication errors would be documented in the patient record.</p> <p>Findings:</p> <p>1. The policy/procedures Medication Administration (approved 10-11) and Conscious Sedation (approved 10-11) failed to indicate a requirement to document the medication error in the patient record when a medication was administered in error.</p> <p>3. During an interview on 2-29-12 at 0945 hours, staff A2 confirmed the policy/procedures lacked the requirement to document the error in the patient record.</p>	S1020	<p>1. Changed Policy/Procedure to reflect that documentation on medication errors are included in patient records.2. Policy/ Procedure for Conscious Sedation and Medication Administration reviewed and changes made to reflect required documentation in patient record when medication error has been made. In-service to be done with all staff regarding this policy.3. Administrator will be notified of any medication errors and proper reporting will follow.</p>	03/21/2012			

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S1040	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAc 15-2.5-6(3)(F)</p> <p>Pharmaceutical service must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.</p> <p>Based upon document review and interview, the center failed to have a policy/procedure regarding the physician responsibility of instructing the patient on the use of take home medication when dispensed by the facility.</p> <p>Findings:</p> <p>1. The policy/procedure Administration of Medications (approved 10-11) indicated the following: " Any take-home narcotic prescription will require a hand-written order by a physician. " The policy/procedure failed to indicate the responsibility for the prescribing practitioner to instruct the patient on the use of take home medication if dispensed by the facility.</p>	S1040	<p>1. Changed Policy/Procedure Administrations of Medications to include use and instructions to patients and take home medications.2. The addition will document education that has or will taken place.3. Policy reviewed and changed. See attached.4. Physician is responsible for education on prescribed medication sent home with client.</p>	03/13/2012

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	2. On 2-29-12 at 0945 hours, staff A2 confirmed that the policy/procedure failed to indicate the physician responsibility for instructing the patient on the use of take home medication. Staff A2 confirmed that the center policy/procedure did not indicate that the facility would not dispense medications.			

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S1146	<p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation and interview, the facility failed to safely store and maintain flammable materials which resulted in a hazard to patients, personnel, and the public.</p> <p>Findings:</p> <p>1. During a tour on 2-28-12 at 1132 hours, in the presence of staff A1, the following hazardous condition was observed in the mechanical equipment room: 11 cans of spray paint and cleaner labeled " Extremely Flammable " and " Danger: Flammable " and 1 gallon of mineral spirits labeled " Danger: Flammable " were stored on an open wire rack shelving unit among cardboard boxes, light bulbs, and other miscellaneous articles.</p>	S1146	<p>1. All flammable cans/chemicals were removed from the mechanical room. A flame-retardant cabinet was installed in a locked storage unit that is separate from the building to house all flammable items. 2. By removing these flammable items and insuring a flame retardant cabinet for such items provides patients, staff and visitors safety from potential fire hazaard.3. Policy for Hazardous Chemicals changed to reflect addition of flame-retardant cabinet for flammable chemicals. In-service for staff to educate on proper storage of flammables on 3/21/2012. 4. Safety nurse or designated person will monitor mechanical room quarterly using Safety Inspection Form. See attached form.5. Board reviewed Policy/Procedure at meeing.</p>	03/29/2012

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	2. During an interview on 2-28-12 at 1135 hours, staff A1 confirmed that the flammable materials were not stored in a fire-resistant cabinet as required.			

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S1152	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(B)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plan and equipment by qualified personnel as follows:</p> <p>(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the center failed to establish a periodic maintenance schedule to ensure that preventive maintenance (PM) was performed on mechanical equipment at the facility.</p> <p>Findings:</p> <p>1. On 2-27-12 at 1000 hours, staff A1 was requested to provide documentation of periodic maintenance schedules for PM of center equipment and none was</p>	S1152	<p>1. Policies Equipment Use Guidelines and Scheduled Medical Equipment Management/Preventative Maintenance were changed to reflect our Master Operations Calendar already in place. See attached Master Operations Calendar as well as list of equipment, with serial number maintained and date of next maintainance.2. Our patients and employees will be safe by keeping current maintenance records.3. Administrator will be responsible for maintaining the</p>	03/29/2012			

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	<p>received prior to exit.</p> <p>2. The policy/procedure Equipment Use Guidelines (approved 10-11) and Scheduled Medical Equipment Management/Preventative Maintenance (approved 10-11) failed to indicate a specific schedule including facility assets or equipment and a PM frequency or dates for periodic service by a manufacturer or contracted service.</p> <p>3. During an interview on 2-29-12 at 1005 hours, staff A2 confirmed that the center lacked a master maintenance schedule for ensuring that equipment received periodic PM.</p>		<p>Master Operations Calendar. 4. The Board will review the policy changes.</p>	

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S1154	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(C)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.</p> <p>Based on document review and interview, the center failed to perform a triennial analysis on its operational and maintenance records for all mechanical equipment at the center.</p> <p>Findings:</p> <p>1. On 2-27-12 at 1030 hours, staff A1 was requested to provide documentation of triennial analysis for the mechanical equipment in use at the center and none was provided prior to exit.</p>	S1154	<p>1. Added to our policy: Scheduled Medical Equipment Management/Preventative Maintenance and Equipment Use Guidelines that mechanical and patient care equipment maintenance, repairs and electrical current leakage check will be analyzed and data captured and reported triennially.2. Provide safety to the facility, employee, patients and visitors by documenting electrical current and evaluating any changes to prevent future fire hazaard.3. After reviewing our policies against state regulations, we added reporting triennially to our policies and to our Master</p>	03/29/2012			

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	<p>2. The policy/procedure Equipment Use Guidelines (approved 10-11) and Scheduled Medical Equipment Management/Preventative Maintenance (approved 10-11) lacked a provision for performing a triennial review of maintenance records on mechanical equipment in use at the center.</p> <p>3. During an interview on 2-29-12 at 1005 hours, staff A2 confirmed that the center was not performing a triennial analysis of its operational and maintenance control records.</p>		<p>Operations Plan.4. Preventative maintenance performed by contracted service will be responsible for documenting all of their maintenance according to their agreement and reporting to Administrator. Administrator will quarterly, yearly and triennially review services performed, capture data as required and report to governing body.</p>	

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S1164	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(i)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the center failed to establish a maintenance schedule to ensure that preventive maintenance (PM) was performed on all patient care equipment. Findings:</p> <p>1. On 2-27-12 at 1000 hours, staff A1 was requested to provide maintenance schedules for PM of patient care equipment and none was received prior to exit.</p> <p>2. The policy/procedure Equipment Use</p>	S1164	<p>1. Policies Equipment Use Guidelines and Scheduled Medical Equipment Management/Preventative Maintenance were changed to reflect our Master Operations Calendar already in place. See attached Master Operations Calendar as well as list of equipment, with serial number maintained and date of next maintainance.2. Our patients and employees will be safe by keeping current maintenance records.3. Administrator will be responsible for maintaining the Master Operations Calendar. 4.</p>	03/29/2012			

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	<p>Guidelines (approved 10-11) and Scheduled Medical Equipment Management/Preventative Maintenance (approved 10-11) failed to indicate a specific schedule including patient care equipment and a PM frequency or dates for periodic service by a manufacturer or contracted service.</p> <p>3. During an interview on 2-29-12 at 1005 hours, staff A2 confirmed that the center lacked a master maintenance schedule for its patient care equipment.</p>		The Board will review the policy changes.		

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S1168	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iii)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.</p> <p>Based on document review and interview, the center failed to ensure that a triennial analysis was performed on all patient care equipment in use at the center.</p> <p>Findings:</p> <p>1. On 2-27-12 at 1030 hours, staff A1 was requested to provide documentation of triennial analysis of the patient care equipment maintenance records at the center and none was provided prior to</p>	S1168	<p>1. Added to our policy: Scheduled Medical Equipment Management/Preventative Maintenance and Equipment Use Guidelines that mechanical and patient care equipment maintenance, repairs and electrical current leakage check will be analyzed and data captured and reported triennially.2. Provide safety to the facility, employee, patients and visitors by documenting electrical current and evaluating any changes to prevent future fire hazaard.3. After reviewing our policies against state regulations, we added reporting triennially to</p>	03/29/2012			

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	<p>exit.</p> <p>2. The policy/procedure Equipment Use Guidelines (approved 10-11) and Scheduled Medical Equipment Management/Preventative Maintenance (approved 10-11) lacked a provision for performing a triennial review of maintenance records on its patient care equipment.</p> <p>3. During an interview on 2-29-12 at 1005 hours, staff A2 confirmed that the center was not performing a triennial analysis of its patient care equipment maintenance records.</p>		<p>our policies and to our Master Operations Plan.4. Preventative maintenance performed by contracted service will be responsible for documenting all of their maintenance according to their agreement and reporting to Administrator. Administrator will quarterly, yearly and triennially review services performed, capture data as required and report to governing body.</p>		

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S1170	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iv)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p> <p>Based on document review and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer.</p> <p>Findings: 1. On 2-27-12 at 1030 hours, staff A1 was requested to provide a policy/procedure for defibrillator checks that indicated a process or reference for checking the equipment according to the manufacturer's recommendations and none was provided prior to exit.</p>	S1170	<p>1. Lifepak 9 instructions for inspection and testing according to the manual were received and added to the daily defibrillator checks.2. Increased client safety due to a more detailed check of defibrillator to ensure proper function.3. The Policy/Procedure for Defibrillation Procedure was reviewed and the Lifepak 9 Manual checklist was added. See attached.4. Safety Nurse will be responsible for daily defibrillator checks and inspection.5. Board will be presented with addition of checklist.</p>	03/29/2012			

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	<p>2. The document Recovery Room Checklist dated February 2012 failed to indicate or reference a process for checking the defibrillator or discharge according to the manufacturer's recommendations.</p> <p>3. The Physio Control Defibrillator service manual (1994) indicated the following under the heading Maintaining the Equipment: "A separate checklist entitled " Manual Defibrillators: Operators Shift Checklist " is included with shipment of your LIFEPAK 9P defibrillator/monitor/pacemaker. " The manual included a separate Table 6-1 entitled " Recommended maintenance and testing for clinical personnel " which listed criteria for completing daily defibrillator checks by direct care staff.</p> <p>4. During an interview on 2-29-12 at 1025 hours, staff A2 confirmed that the center lacked a policy/procedure and the Crash Cart checklist lacked a process or reference guide for daily defibrillator checks or discharge per the manufacturer 's recommendations.</p>			

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S1184	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 2.5-7(c)(3)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(3) The safety program includes, but is not limited to, the following:</p> <p>(A) Patient safety. (B) Health care worker safety. (C) Public and visitor safety.</p> <p>Based on document review and interview, the center failed to establish a safety management program that included provisions for patient, public, visitor, and health care worker safety.</p> <p>Findings:</p> <p>1. On 2-27-12 at 1030 hours, staff A1 was requested to provide documentation of an organized safety management program and none was provided prior to exit.</p> <p>2. The policy/procedure Safety Officer/Safety Plan (approved 10-11) failed to indicate that a core function of the safety program is to ensure patient safety, public/visitor safety and health care worker safety.</p> <p>3. During an interview on 2-28-12 at 1610 hours, staff A1 indicated that the safety management functions were integrated in the Quality Assurance Program at the center.</p> <p>4. The Quality Assurance Plan (approved 12-10) failed to indicate a standing safety committee with accountability for patient, public, visitor and health care worker safety issues and problems. The 2011 Quality Assurance/Performance</p>	S1184	<p>1. Expanded our safety management program to include provisions for patient, visitor and employee safety. Identified practices already in place(drills, in-services, surveillance, employee health) that are appropriate for the safety arena and in compliance with the state requirements. 2. Our safety plan addresses the physical plant, employee, visitor and patient concerns for added safety measures.3. Educated staff on how to report and to whom to report a safety issue. 4. Administrator will manage safety program and report to governing body quarterly.</p>	03/29/2012			

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	Improvement Committee minutes for Safety failed to indicate participation by more than one staff and failed to indicate a group discussion of ongoing committee processes and activities. 5. During an interview on 2-29-12 at 1410 hours, staff A1 confirmed that the safety management plan failed to organize and integrate its policies and practices regarding patient, public, and personnel safety to comply with state requirements.			

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S1198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the center lacked documentation of a disaster preparedness and participation with community, state and federal emergency and disaster preparedness agencies.</p> <p>Findings:</p> <p>1. On 2-27-12 at 1030 hours, staff A1 was requested to provide documentation of recent (2011) participation with a local, state, and/or federal emergency and disaster agency and none was provided prior to exit.</p> <p>2. During an interview on 2-29-12 at 1040 hours, staff A2 confirmed that the center lacked documentation of recent participation with an emergency/disaster</p>	S1198	<p>1. Facility had already established contact with Delaware County Emergency Management, and FEMA and they are aware of our services and what we are able to offer. Consultant spoke to Red Cross director LeAnn Mingle and the goal is to set up a meeting, introduce our staff to the Red Cross agency and give an overview of their services. 2. Use of our facility to benefit the community.3. New relationship with the Red Cross initiated and encourage employees to become involved with the community.4. The Administrator will be responsible to set up meeting with the Red Cross and have further contact with LeAnn Mingle.</p>	03/29/2012			

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