

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001171		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 05/01/2012	
NAME OF PROVIDER OR SUPPLIER EYE CARE SURGERY CENTER OF EVANSVILLE LLC				STREET ADDRESS, CITY, STATE, ZIP CODE 6540 LOGAN DRIVE, SUITE #3 EVANSVILLE, IN 47715			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 004274</p> <p>Dates: 4-30-12 through 5-1-12</p> <p>Surveyors:</p> <p>Billie Jo Fritch RN, BSN, MBA Public Health Nurse Surveyor</p> <p>Jennifer Hembree RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 05/18/12</p>	S0000					

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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S0130	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(7)</p> <p>The governing body shall do the following:</p> <p>(7) Ensure all patients are admitted to the center only upon the recommendation of a practitioner with admitting privileges for the purpose of performing surgical procedures and services.</p> <p>Based on document review and interview, patients have been admitted to the center for surgical procedures by a practitioner without current privileges for 20 of 20 patient's (Pt# 1 - Pt #20) medical records reviewed.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Review of physician credential files on 4-30-12 and 5-1-12 indicated MD# 1's privileges were approved 9-3-09 and expired 9-3-11; the credential file lacked evidence that MD# 1 had been reappointed by the governing body. 2. Review of medical records on 5-1-12 indicated MD# 1 had performed surgical procedures for patients Pt# 1 - Pt# 20 after 9-3-11 without reappointment and current privileges. 3. Interview with B# 1 on 5-1-12 at 1520 hours confirmed the privileges for MD# 1 expired 9-3-11 and that MD# 1 has 	S0130	<p>The medical staff bylaws that were in place called for 3 year appointment. By the terms of our bylaws MD#1 was still current at the time procedures were performed. However, since I was informed IN guidelines call for a maximum 2 year appointment, we have since ammended the bylaws to reflect 2 year appointments, and MD#1 has been reappointed effective 5/1/12. All dates for reappointment, etc have been added to the administrator's electronic calendar and the administrator shall ensure compliance</p>	05/01/2012			

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	continued to perform surgical procedures at the ASC; B# 1 confirmed the surgical procedures completed after 9-3-11 for patients Pt# 1 - Pt# 20 were performed by MD# 1.			

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S0153	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on document review and staff interview, the facility failed to ensure orientation of all new employees per policy for 5 of 9 employee/staff member files reviewed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Facility policy titled "NEW EMPLOYEE ORIENTATION" last reviewed/revised 2/1/12 states under procedure: "One-day classroom review: Education and Training Department.....Two week orientation to Ambulatory Care Services:..... Third Week: Mentor Relationship....." 2. Staff member #N2 was hired 8/17/11. His/her personnel file lacked evidence of completed new employee orientation as indicated in policy. 3. Staff member #N5 was hired 6/11/11. 	S0153	<p>Orientation was provided to all staff and all current staff member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files</p>	06/15/2012

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	<p>His/her personnel file lacked evidence of completed new employee orientation as indicated in policy.</p> <p>4. Staff member #N6 was hired 11/4/10. His/her personnel file lacked evidence of completed new employee orientation as indicated in policy.</p> <p>5. Staff member #N9 was hired 3/22/12. His/her personnel file lacked evidence of completed new employee orientation as indicated in policy.</p> <p>6. Staff member #N10 was hired 9/13/11. His/her personnel file lacked evidence of completed new employee orientation as indicated in policy.</p> <p>7. Staff member #1 verified the above at 3:50 p.m. on 5/1/12.</p>			

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S0154	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (D)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(D) Ensuring that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available upon request. Based on document review and staff interview, the facility failed to maintain certifications for 3 of 4 surgery techs employed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Staff members N7, N9, and N10 personnel files lacked evidence of a surgery tech certification. Staff member #1 verified at 3:50 p.m on 5/1/12 that the above named surgery techs are certified and the files did not contain a certification. 	S0154	All current staff member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files	06/15/2012			

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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 document review and staff interview, the facility failed to complete annual performance evaluations for 3 of 3 applicable staff members.</p> <p>Findings include:</p> <p>1. Facility policy titled "CLINICAL COMPETENCY CLINICAL SKILLS ASSESSMENT" last reviewed/revised 2/1/12 states under procedure: "The Director of Ambulatory Care Services and/or the Ambulatory Care Services Nurse Manager will review the clinical competencies inventory and discuss with the employee. This document will be utilized in the annual performance evaluation."</p>	S0156	<p>All current staff member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files.</p>	06/15/2012			

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	<p>2. Staff member #N1 personnel file indicated he/she had not had a performance evaluation since 1/4/11.</p> <p>3. Staff member #N3 personnel file indicated he/she was hired 2/10/11. The file lacked documentation of a performance evaluation.</p> <p>4. Staff member #N6 personnel file indicated he/she had not had a performance evaluation since 4/12/11.</p> <p>5. Staff member #1 verified the above beginning at 3:50 p.m. on 5/1/12.</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 document review and staff interview, the chief executive officer failed to ensure CPR competence per facility policy and medical staff bylaws for 3 of 5 registered nurses, 4 of 4 surgery techs and for 3 of 3 physicians reviewed.</p> <p>Findings included:</p> <p>1. Medical staff bylaws last approved 5/1/09 states under "REGISTERED NURSE": ".....They must hold a current CPR card and/ ACLS....." Under "SURGICAL SCRUB TECHNICIAN", the bylaws state: ".....Must have CPR card."</p> <p>2. Facility policy titled "EDUCATION AND TRAINING" last reviewed/revised 2/1/12 states on page 1: "CPR and ACLS certification will be kept up-to-date by all</p>	S0162	All current staff and physicians member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files.	06/15/2012			

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	<p>appropriate professional personnel who work in the facility."</p> <p>3. Staff members #N2 and N4 (RN's) personnel files lacked documentation of ACLS competence.</p> <p>4. Staff member #N5 (RN) personnel file lacked documentation of current ACLS competence. His/her ACLS expired in November 2011.</p> <p>5. Staff members #N6, N7, N9, and N10 (surgery techs) personnel files lacked documentation of CPR competence.</p> <p>6. Staff member #1 verified the personnel file information above at 3:50 p.m. on 5/1/12.</p> <p>7. Review of the Medical Staff Bylaws/Rules and Regulations on 4-30-12 and 5-1-12 lacked evidence that the requirements for CPR competency for the medical staff were addressed.</p> <p>8. Review of physician credential files on 4-30-12 and 5-1-12 lacked evidence that 3 of 3 physicians (MD#1 - MD# 2) had documented CPR competency.</p> <p>9. Interview with B#1 on 5-1-12 confirmed the medical staff bylaws/rules and regulations do not address the requirements for CPR competency for the</p>			

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	medical staff; B#1 confirmed 3 of 3 physician credential files (MD# 1 - MD# 3) lack evidence of CPR competency.				

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S0172	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.</p> <p>Based on document review and staff interview, the facility failed to ensure personnel files contained evidence of tuberculin tests or chest x-rays for 5 of 7 staff members.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of staff members #N2, N7, and N9 personnel files lacked documentation of a tuberculin test or chest x-ray. 2. Review of staff member #N6 personnel file indicated he/she had not had a tuberculin test since 2/7/11. 3. Review of staff member #N10 personnel file indicated he/she had not had a tuberculin test since 2/9/11. 	S0172	All current staff member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files.	06/15/2012			

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	4. Staff member #1 verified the above beginning at 3:50 p.m. on 5/1/12.			

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S0176	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on document review and staff interview, the facility failed to ensure competency of staff prior to allowing staff to provide patient care for 3 of 4 staff members.</p> <p>Findings include:</p> <p>1. Facility policy titled "CLINICAL COMPETENCY CLINICAL SKILLS ASSESSMENT" last reviewed/revised 2/1/12 states under policy: "Clinical competencies and profession development form will be completed during orientation and annually for each RN, LPN/LVN and surgical technician by immediate supervisor."</p> <p>2. Staff member #N6 was hired on 11/4/10. His/her personnel file lacked evidence of the clinical competencies and professional development form. Review of operative records indicated he/she was</p>	S0176	All current staff member files are being updated with the missing or documentation establishing competency. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files.	06/15/2012	

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	<p>the surgery tech on numerous cases the previous 4 months.</p> <p>3. Staff member #N9 was hired on 3/22/12. His/her personnel file lacked evidence of the clinical competencies and professional development form. He/she was listed on the daily staffing form for 3/22/12 as the only surgery tech for > 10 patient procedures.</p> <p>4. Staff member #N10 was hired on 9/13/11. His/her personnel file lacked evidence of the clinical competencies and professional development form. He/she was listed on the daily staffing form for 11/10/11 as the only surgery tech for > 5 patient procedures and the only surgery tech listed on the staffing form on 2/23/12 for > 10 patient procedures.</p> <p>5. Staff member #1 verified in interview at 3:50 p.m. on 5/1/12 that the personnel files lacked orientation and competency documents as indicated above.</p>				

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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. Based on document review and interview, the facility failed to include the contracted service of security and the direct service of laboratory in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings included:</p> <p>1. Review of facility documents on 4-30-12 and 5-1-12 lacked evidence that the contracted service of security and the direct service of laboratory were included in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p> <p>2. Interview with B# 1 on 5-1-12 at 1520 hours confirmed the contracted service of security and the direct service of laboratory were not included in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p>	S0310	ADT security and Labcorp have been added to the quarterly QAPI schedule, and will be submitted to Governing board quarterly. The administrator will ensure ongoing compliance.	06/01/2012

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NAME OF PROVIDER OR SUPPLIER EYE CARE SURGERY CENTER OF EVANSVILLE LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 6540 LOGAN DRIVE, SUITE #3 EVANSVILLE, IN 47715
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S0320	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(2)</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>(2) All functions, including, but not limited to, the following:</p> <p>(A) Discharge and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the facility failed to include transfers, medication errors, and the response to patient emergencies in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings included:</p> <p>1. Review of facility documents on 4-30-12 and 5-1-12 lacked evidence that transfers, medication errors, and the response to patient emergencies were included in the facility's QAPI program.</p> <p>2. Interview with B# 1 on 5-1-12 at 1520 hours confirmed that transfers, medication errors, and the response to patient emergencies are not included in the facility's QAPI program.</p>	S0320	Patient transfers, medication errors, and responses to patient emergencies have been added to the quarterly QAPI review, and will also be reviewed by the governing board every quarter. The Administrator will ensure ongoing compliance.	06/01/2012			

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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:</p> <p>(1) A process for determining the occurrence of the following reportable events within the center:</p> <p>(A) The following surgical events:</p> <p>(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</p> <p>(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.</p> <p>(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</p> <p>(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.</p>			

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	<p>(BB) Objects present before surgery that were intentionally retained.</p> <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</p>			

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	<p>resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to 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>			

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	<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 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</p> <p>(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</p>			

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	<p>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> <p>Based on document review and interview, the facility failed to include serious adverse events, reportable to the Indiana State Department of Health (ISDH), in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility documents on 4-30-12 and 5-1-12 lacked evidence that serious adverse events, reportable to the ISDH, were included in the facility QAPI program. 2. Interview with B#1 on 5-1-12 at 1520 hours confirmed that serious adverse events, reportable to the ISDH, are not included in the facility's QAPI program. 	S0332	<p>None of these events have occurred at our facility, however a quarterly review of reportable events has been added to QAPI review action items. The Governing board shall review every quarter, and the administrator shall ensure compliance.</p>	06/01/2012

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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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	<p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge;</p> <p>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>			

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	<p>Based on document review and interview, the facility failed to develop a policy and procedure to determine the occurrence of reportable events and a procedure to report the events to the Indiana State Department of Health (ISDH).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility policies and procedures on 4-30-12 and 5-1-12 lacked evidence that the facility had developed a policy and procedure to determine the occurrence of reportable events and a procedure to report events to the ISDH. 2. Interview with B#1 on 5-1-12 at 1520 hours confirmed the facility has not developed a policy/procedure to identify and report the occurrence of reportable events to the ISDH. 	S0334	<p>Policy entitled Mandatory Reporting has been modified to reflect specific requirements for determining and reporting events to the ISDH. These events shall be reported within 15 days of the center's QAPI committee determining that a reportable event occurred. The Administrator shall ensure ongoing compliance.</p>	06/01/2012	

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S0418	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(A)</p> <p>(2) The infection control committee responsibilities must include, but are not limited to the following:</p> <p>(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the center.</p> <p>Based on document review and staff interview, the infection control committee failed to include all practitioners in system to identify infections in the center.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of documents titled "Monthly Infection Control Surveillance Report" indicated M.D. #1 was the only practitioner included in the surveillance. 2. Review of daily staffing forms indicated M.D. #3 had performed procedures at the center on 2/16/12. 3. Staff member #1 verified in interview beginning at 3:50 p.m. on 5/1/12 that M.D. #3 was not included in the surveillance. 	S0418	MD#3 had performed only ophthalmic laser procedures in which there was no direct contact by any equipment. The facility's computer system has been changed to include these procedures in the infection control reports. The Administrator shall ensure ongoing compliance	06/01/2012			

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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 and staff interview, the facility failed to ensure documentation of the communicable disease history for 7 of 9 staff members.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Staff members #N1 and N2 personnel files lacked documentation of immunity to Varicella. 2. Staff members #N3 and N9 personnel files lacked documentation of immunity to Rubella, Rubeola, Varicella. and Hepatitis B. 3. Staff members #N6, N7, and N10 personnel files lacked documentation of 	S0442	All current staff member files are being updated with the missing or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files.	06/15/2012			

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	immunity to Rubella, Rubeola, and Varicella. 4. Staff member #1 verified the above at 3:50 p.m. on 5/1/12.				

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S0708	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(3)</p> <p>The medical staff shall do the following:</p> <p>(3) Make recommendations to the governing body on the appointment or reappointment of the applicant for a period not to exceed two (2) years. Based on document review and interview, the medical staff failed to make recommendations to the governing body for the reappointment of 1 of 1 physicians (MD# 1) to ensure the appointment period did not exceed a period of two years.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Review of physician credential files on 4-30-12 and 5-1-12 indicated MD# 1's privileges were approved 9-3-09 and expired 9-3-11; the credential file lacked evidence that MD# 1 had been recommended for reappointment by the medical staff or approved for reappointment by the governing body. 2. Interview with B# 1 on 5-1-12 at 1520 hours confirmed the privileges for MD# 1 expired 9-3-11 and that MD# 1 has not been recommended for reappointment by the medical staff. 	S0708	<p>The medical staff bylaws that were in place called for 3 year appointment. By the terms of our bylaws MD#1 was still current at the time procedures were performed. However, since I was informed IN guidelines call for a maximum 2 year appointment, we have since changed the bylaws to reflect 2 year appointments, and MD#1 has been reappointed effective 5/1/12. All dates for reappointment, etc have been added to the administrator's electronic calendar and the administrator shall ensure compliance.</p>	05/01/2012			

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S0930	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(b)(5)</p> <p>(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:</p> <p>(5) A provision that all nursing personnel meet annual inservice requirements as established by center and federal and state requirements. Based on document review and staff interview, the facility failed to ensure staff members met annual inservice requirements for 3 of 9 staff member personnel files reviewed.</p> <p>Findings include:</p> <p>1. Facility policy titled "ANNUAL REQUIRED TRAINING UPDATE" last reviewed/revised 2/1/12 states under policy: "All facility personnel will receive annual update training in general safety, fire safety, electrical safety, emergency management, infection control and CPR....."</p> <p>2. Facility policy titled "MANDATORY INSERVICE EDUCATION" last reviewed/revised 2/1/12 states under policy: "The facility recognizes its responsibilities to provide inservices to its personnel to satisfy and maintain state</p>	S0930	<p>Annual Training was completed however documentation was missing. All current staff member files are being updated with the missing 6/15/12 or incomplete documents. Expiration dates, etc will be added to the administrator's electronic calendar for reminders. The administrator will ensure compliance in maintaining files</p>	06/15/2012			

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	<p>regulations, accreditation requirements and professional standards. The mandatory inservices include, but are not limited to cardiopulmonary resuscitation training, emergency medical equipment training and annual safety and infection control updates....."</p> <p>3. Staff member #N1 was hired on 5/27/10. His/her personnel file lacked evidence of annual training and inservice education as outlined in above policies with the exception of infection control. He/she had completed infection control training.</p> <p>4. Staff member #N3 was hired on 2/10/11. His/her personnel file lacked evidence of annual training and inservice education as outlined in above policies with exception of infection control. He/she had completed infection control training.</p> <p>5. Staff member #N6 was hired on 11/4/10. His/her personnel file lacked evidence of annual training and inservice education as outlined in above policies.</p> <p>6. Staff member #1 verified in interview beginning at 3:50 p.m. on 5/1/12 that the files did not contain the required training/education per policy.</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: Based on document review, observation and interview, the facility failed to ensure expired medications or opened multi dose vials were removed from patient stock and the pharmacy consultant failed to conduct quarterly visits to ensure drugs and biologicals are provided in a safe and effective manner for 3 of 4 quarters during 2011.</p> <p>Findings include:</p> <p>1. CDC document titled "Infection Safety" states "The United States Pharmacopeia (USP) General Chapter 797 injection safety/providers/references recommends the following for multi-dose vials of sterile pharmaceuticals: If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial."</p>	S1000	A new pharmacy consultant has been engaged and is scheduled to inspect the facility's pharmaceutical services. All quarterly visits are going to be scheduled in advance, and the administrator shall have a hands on role to verify a complete, and accurate audit of the center is done every quarter. The Administrator shall ensure ongoing compliance.	06/15/2012			

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	<p>2. During tour of the pre/post surgical area beginning at 11:25 a.m. on 5/1/12, the following was observed in a wall mounted medication cabinet behind the nurses station:</p> <p>(A) One (1) 50 ml opened and partially used multi dose vial (MDV) of Lidocaine 2% with epinephrine was dated as opened on 1/5/12.</p> <p>(B) One (1) 10 ml opened and partially used MDV of Lidocaine 1% with no date of when the vial was opened.</p> <p>3. During the tour, the following was observed in the crash cart:</p> <p>(A) One (1) 20 ml vial of Lebetalol 100 mg/20 ml with an expiration date of 2/1/12.</p> <p>(B) Two (2) 30 ml vials of Bacteriostatic Sodium Chloride with an expiration date of 3/1/12.</p> <p>(C) One (1) 2 ml vial of Mag Sulfate with an expiration date of 12/11.</p> <p>(D) One (1) 1000 ml bag of .9% Sodium Chloride with an expiration date of 1/1/12.</p> <p>4. Review of facility documents lacked evidence that the pharmacy consultant conducted quarterly visits to the ASC to ensure drugs and biologicals were provided in a safe and effective manner during the 1st, 3rd, or 4th quarter of 2011.</p>			

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	5. Interview with B# 1 on 5-1-12 at 1500 hours confirmed the ASC has an agreement with B# 3, a pharmacy consultant, to provide quarterly pharmaceutical audits/visits to the ASC to ensure drugs and biologicals are provided in a safe and effective manner; B# 1 confirmed B#3 did not conduct audits/visits at the ASC during 3 of 4 quarters during 2011 (1st, 3rd, and 4th quarters) as required.			

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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 on interview, observation, and document review, it could not be determined that accounting of scheduled substances was correct for stock supply of scheduled substances.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Staff member #1 indicated in interview at 11:25 a.m. on 5/1/12 that he/she did not have a key to unlock the narcotic cabinet. (He/she was the only staff member at the facility during survey) A double locked cabinet was observed on the wall behind the nurse station at 11:25 a.m. identified by staff member #1 as the narcotic cabinet. He/she could unlock the outer cabinet but not the narcotic cabinet. Review of document titled "CONTROLLED SUBSTANCE ADMINISTRATION RECORD" indicated the facility administers Valium, 	S1006	<p>A new pharmacy consultant has been engaged and is scheduled to inspect the facility's pharmaceutical services. All quarterly visits are going to be scheduled in advance, and the administrator shall have a hands on role to verify a complete, and accurate audit of the center is done every quarter. The pharmacy consultant shall also verify the narcotic count and method of counting is correct. The DON, or other licensed shall be on call to provide the keys in the event of audits, surveys, or inventories. The Administrator shall ensure ongoing compliance.</p>	06/15/2012	

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	<p>Versed, Morphine, and Propofol.</p> <p>4. Unable to determine if the count on the controlled substance administration record was accurate due to inability to unlock the controlled substance cabinet.</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 observation, the facility failed to ensure single dose vials (SDV) were destroyed per policy for 1 medication cabinet observed.</p> <p>Findings include:</p> <p>1. Facility policy titled "INFECTION CONTROL POLICES" last reviewed/revised 2/1/12 states on page 1: "D. Single use vials will be discarded after use."</p> <p>2. During tour of the pre/post surgical area beginning at 11:25 a.m. on 5/1/12, the following was observed in a wall mounted medication cabinet behind the nurses station:</p> <p>(A) One (1) 30 ml vial of Marcaine .75% opened and 1/2 of the contents had been used. The vial was marked as a single</p>	S1010	<p>A nursing personnel in service on single and multi dose vials, as well as medication administration and storage shall be conducted with all nursing staff and documented in their respective records. The Director of Nursing is charged with this responsibility and the administrator shall ensure compliance</p>	06/15/2012	

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	<p>dose vial by the manufacturers and had been dated as opened on 2/16/12.</p> <p>(B) One (1) 30 ml vial of Marcaine .5 % opened and 3/4 of the contents had been used. The vial was marked by manufacturer as a single dose vial. There was no date to determine when the vial had been opened.</p>			

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S1116	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(a)(4)(A)</p> <p>(4) In new construction, renovations, and additions, the center site and facilities, or nonlicensed facilities acquired for the purpose of providing center services shall meet the following:</p> <p>(A) The 2001 edition of the national "Guidelines for Design and Construction of Hospitals and Health Care Facilities" (Guidelines). Based on document review, the facility continues to operate as a class B ambulatory surgery center and is licensed as a class A ambulatory surgery center.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of floor plan for surgery center indicated that the OR and procedure room are < 250 square feet. Review of controlled substance administration log indicated that patients receive IV Versed, IV Morphine, IV Propofol, for sedation. Additionally, patients receive po Valium preoperatively. Per AIA guidelines, a class A OR should be 120 sq. ft and facility would allow for minor procedures under topical, 	S1116	The facility shall adhere to Class A guidelines, giving oral sedation as we were unaware of any previous issues with this. We will file a request for a waiver with the ISDH to be able to administer a maximum of 2 mg of versed in our 192 sqft operating rooms as we have proper emergency equipment, and this does not pose a threat to patient safety.	06/01/2012

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	<p>local, or regional anesthesia without preoperative sedation.</p> <p>4. Per AIA guidelines, a class B OR should be 250 sq. ft and would allow for minor or major procedures with oral, parenteral, or IV sedation or under analgesic or dissociative drugs.</p>			

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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 document review and observation, the facility failed to provide an environment that minimized a hazard to patients for 2 supply areas observed.</p> <p>Findings include:</p> <p>1. Facility policy titled "INFECTION CONTROL POLICIES" last reviewed/revised 2/1/12 states on page 1 of 2: "e.Store all equipment and medications at least 6 inches off the floor."</p> <p>2. During tour of the facility beginning at 11:25 a.m. on 5/1/12, the following hazards were observed:</p> <p>(A) Numerous items including, but not limited to, a cardboard box of detergent and specimen containers were observed under the sink in the utility room. The</p>	S1146	All items have been relocated and proper storage shall be noted to the quarterly safety checklist to ensure continued compliance. The administrator shall ensure ongoing compliance.	06/01/2012

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	<p>items could become hazardous if there were a plumbing/drainage leak under the sink.</p> <p>(B) Several cardboard boxes of supplies were observed directly on the floor in the supply closet. The items were not stored according to policy.</p>			

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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 on document review and interview, the facility failed to coordinate emergency and disaster preparedness with an appropriate community, state, or federal agency.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility documents on 4-30-12 and 5-1-12 lacked documentation that the facility had coordinated emergency and disaster preparedness with an appropriate community, state, or federal agency. 2. Interview with B#1 on 5-1-12 at 1255 hours confirmed the facility has not coordinated emergency and disaster preparedness with a community, state, or federal agency. 	S1198	The policy of this facility has been to remain closed during a disaster or emergency, but the facility shall coordinate with one of the two hospitals we currently have transfer agreements with. The administrator shall ensure ongoing compliance.	06/15/2012			