

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001128	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 07/17/2014
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NAME OF PROVIDER OR SUPPLIER MEDICAL CONSULTANTS ENDOSCOPY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 800 S TILLOTSON AVE MUNCIE, IN 47304
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S000000	The visit was for a licensure survey. Facility Number: 003754 Survey Date: 7-14/17-2014 Surveyor: Brian Montgomery, RN Public Health Nurse Surveyor QA: cloughlin 08/06/14	S000000		
S000028	410 IAC 15-2.2-2 SURVEY PROCEDURES 410 IAC 15-2.2-2 (c)(1) (c) All documents in legally reproducible form must be maintained within the center for the period required by statutes of limitations and must be made available upon request for inspection, including copying by representatives of the department as follows: (1) Items to include, but not limited to, the following: (A) Documents showing ownership, certified copy of articles of incorporation (if incorporated). (B) Constitution and bylaws of governing body. (C) Minutes of meetings of the			

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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	<p>governing body and committees thereof.</p> <p>(D) Minutes of meetings of the medical staff and committees thereof.</p> <p>(E) All documents pertaining to quality assurance and improvement of patient care and medical care.</p> <p>(F) A current roster of members of the medical staff with designated privileges.</p> <p>(G) Personnel records.</p> <p>(H) Medical records.</p> <p>(I) Reports pursuant to IC 16-21-2-6.</p> <p>Based upon document review and interview, the governing board failed to ensure that all center documentation was maintained and readily available upon request for licensure survey.</p> <p>Findings:</p> <p>1. On 7-14-14 at 1000 hours, the human resources director A9 was requested to provide documentation of supporting documentation presented for review during the governing board meetings and none was provided prior to exit. No evidence of quality assurance studies, fire drills, tornado drills, infection control surveillance, or peer review/chart review documentation was identified with the governing board minutes provided for review.</p> <p>2. A tentative schedule of medical staff meetings in 2013 indicated that a medical staff meeting was scheduled on 5-02-13, 6-06-13, 7-11-13, 8-01-13, 9-05-13,</p>	S000028	<p>Correction: All documents will be maintained for licensure survey and accessible in the center. The QA of drills, infection surveillance, and peer review identified in the governing board minutes and has been printed in dedicated binders. The medical staff meetings reports monthly will be maintained and easily accessible in paper form. The minutes with a quorum to address applicants approval. The emergency preparedness quarterly disaster drill documentation and evidence of center participation with outside agency easily accessible with documentation updated. Review of bylaws and operating agreement by Medical Director and Governing Board will occur. Prevention: Maintain documents in binder easily accessible and mandate provider participation in staff meetings with quorum present. Administrator will attend emergency meeting</p>	09/29/2014			

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	<p>10-03-13, 11-07-13 and 12-05-13. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation of medical staff meetings and none was provided prior to exit.</p> <p>3. The 2014 credential files for MD12, MD13 and MD14 failed to indicate the privileges requested and an effective date or privileges granted by the governing board and no credentialing committee minutes or governing board meeting minutes indicated a discussion or approval of the applicants under consideration.</p> <p>4. One sample of Utilization Review Committee documentation dated 11-13 was available at the time of survey.</p> <p>5. The center binder titled Fire Drills, Safety Surveillance Checklist, Fire Alarm Inspection Report failed to indicate any documentation of quarterly fire drills conducted at the center since March, 2013. On 7-14-14 at 1000 hours, director of human resources A9 was requested to provide documentation of periodic fire drills at the center and none was provided prior to exit.</p> <p>6. The emergency preparedness binder failed to indicate documentation of</p>		with documentation placed in dedicated binder. Bylaws and operating agreement will be review and enforced. Responsible: Administrator, Medical Director and Governing Board		

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S000104	<p>quarterly disaster preparedness drills. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide quarterly disaster drill documentation and evidence of center participation and/or coordination with an emergency and disaster preparedness agency and none was provided prior to exit.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(a)(2)</p> <p>The governing body shall do the following:</p> <p>(2) Adopt bylaws and function accordingly.</p> <p>Based on document review and interview, the governing board failed to maintain and follow its governing board bylaws regarding the replacement of board members to assure that a minimum number of 'management committee' members were present for quarterly governing board meetings for 2 of 4 quarters.</p> <p>Findings:</p> <p>1. The Governing Board bylaws (approved 2-13) indicated the following:</p>	S000104	<p>Correction: Review and update of the governing board bylaws and follow the rules regarding replacement of board member to assure minimum number will be present for a quorum. It will be noted in the minutes recommendation or voting action to address the vacant governing board positions in accordance with the bylaws.Prevention: Ensure the bylaws are reviewed and updated with the governing board compliance to follow these rules.Responsible: Medical Director and Governing Board</p>	09/29/2014

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	<p>"[Section 6.2] The management committee [endoscopy center governing board] shall consist of ten (10) managers ...The administrator of the ambulatory surgery center shall serve as an ex-officio member of the management committee, with no voting rights ...The current management committee [members] ...are set forth on <u>Exhibit B.</u>" The governing board bylaws Exhibit B (effective date 1-01-13) failed to indicate more than six voting board members (A10, A11, A12, A13, A14 and A15) and the ex-officio administrator A1 and failed to comply with the bylaws provision.</p> <p>2. The Governing Board bylaws (approved 2-13) indicated the following: "[Section 6.22] Any vacancies occurring among the managers shall be filled by the [incomplete] a majority in interest of the members." No documentation indicated that any additional management members were appointed to the vacant governing board positions in compliance with the bylaws provision.</p> <p>3. The Governing Board bylaws (approved 2-13) indicated the following: "[Section 6.18] The attendance of a majority of the managers, then elected and qualified, shall constitute a quorum at any meeting..."</p>						

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S000116	<p>4. The governing board meeting minutes 10-28-13 and 3-31-14 indicated that only 3 voting board members were present (A10, A13 and A14) and failed to establish a quorum. No meeting documentation indicated a recommendation or voting action to address the vacant governing board positions in accordance with the bylaws.</p> <p>5. During an interview on 7-17-14 at 1320 hours, the governing board chairman A10 confirmed that the governing board had not replaced the governing board vacancies and confirmed that the governing board had not met a quorum in accordance with the bylaws for 2 of 4 (10-28-13 and 3-31-14) governing board meetings.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(2)(A-D)</p> <p>The governing body shall do the following:</p> <p>(2) Ensure the following:</p> <p>(A) The requests of practitioners, for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff.</p> <p>(B) Reappointments are acted upon</p>			

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	<p>at least biennially.</p> <p>(C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications.</p> <p>(D) This process occurs within a reasonable period of time as specified by the medical staff bylaws.</p> <p>Based on document review and interview, the governing board failed to document the appointment of its medical staff in accordance with its medical staff bylaws for 4 of 4 medical staff at the center.</p> <p>Findings:</p> <p>1. The medical staff bylaws (approved 8-11) indicated the following: "Application for Appointment ...initial appointments shall be made to the provisional category ...the governing board shall take action on the application ...in the following way: The governing board shall notify the applicant by mail. The written notice of affirmation shall include ...the staff category to which the applicant is appointed ...[and] ...the clinical privileges that he/she may exercise ...In either the appointment or reappointment process, the [governing board] credentialing committee may initially notify the applicant by telephone or personal contact of the ...action; however, this notification does not</p>	S000116	<p>Correction: The governing board shall notify by mail written notice of affirmation of the medical staff clinical privileges and noting temporary or provisional appointment. Prevention: Update and review of credentialing process with privileges requested, category of appointment and letter indicating privileges noted in the governing board minutes. Responsible: Administrator, Medical Director and Governing Board</p>	09/29/2014			

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	<p>relieve the [governing board] credentialing committee from his/her duty to notify the applicant by mail."</p> <p>2. Review of the credential files for MD11, MD12, MD13 and MD14 failed to indicate a copy of the letter sent by a representative of the governing board indicating the appointment category or privileges granted. The credential file for MD11 indicated a list of privileges requested and approved by the governing board chairman; however, the document failed to indicate the category of appointment (temporary or provisional) granted.</p> <p>3. The endoscopy governing board meeting minutes dated 5-28-13, 7-29-13, 10-28-13, and 3-31-14 failed to indicate documentation of governing board appointment approval for the applicants MD11, MD12, MD13 or MD14 including the category of appointment and privileges granted.</p> <p>4. During an interview on 7-17-14 at 1015 hours, the patient care coordinator A2 confirmed that the 4 credential files failed to maintain a copy of the governing board letter indicating the category of appointment and privileges granted.</p>			

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S000153	<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 interview, the center failed to follow its policy/procedure and ensure that personnel were oriented to applicable policies and procedures for 6 of 7 personnel (A1, N12, N13, N14, N15 and N16) files reviewed.</p> <p>Findings:</p> <p>1. The policy/procedure Orientation - All Employees (effective date 1-04; last reviewed 4-11) indicated the following: "The Employee Orientation - Check List for orienting all new employees, will be completed, and kept in the personnel file." The Employee Orientation - Check List indicated a location for the employee to sign and date the checklist on completion of orientation before placing the document in the personnel file.</p>	S000153	<p>Correction: All personnel files will be updated related to " The Employee Orientation Checklist" and each employee will sign their checklist and it will be placed in their personnel file. To address the multiple files presented for each employee the process of personnel files and their content and location will be discussed between the Administrator and the Human Resources Director and a resolution will be forthcoming. Prevention: To prevent this from recurring, each new employee will complete and sign their "Employee Orientation Checklist" at the time of orientation. Responsible: Administrator and Human Resources Director.</p>	09/17/2014			

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S000156	<p>2. Review of 6 of 7 personnel files (staff A1, N12, N13, N14, N15 and N16) failed to indicate documentation of the Employee Orientation - Check List. The personnel files indicated that N12 and N13 began employment 2-14 and indicated that N14 began employment 11-08. Multiple files were presented for each personnel during the document review and a primary location for personnel record maintenance was not identified.</p> <p>3. During an interview on 7-16-14 at 1630 hours, the director of human resources A9 confirmed that the center failed to follow its policy/procedure and failed to ensure that documentation of staff orientation was available for all personnel files at the center.</p> <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</p>			

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	<p>or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on document review and interview, the governing board failed to ensure that all personnel files were maintained including annual performance evaluations for 5 of 7 personnel files (staff A1, N11, N14, N15 and N16) reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Employee Performance Appraisal (approved 4-11) indicated the following: "Each employee of MCEC will have an annual performance evaluation ..." 2. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide personnel file documentation for 8 nursing personnel including job descriptions and annual evaluations. 3. Review of 5 of 7 personnel files (staff A1, N11, N14, N15 and N16) failed to indicate documentation of a recent (2012, 2013 or 2014) annual evaluation. Multiple files were presented for each personnel during the document review and a primary location for personnel record maintenance was not identified. 	S000156	<p>Correction: Each employee of the Medical Consultants Endoscopy Center will have an annual performance evaluation completed as stated in our Medical Consultants Employee Handbook on Performance Appraisal Policy and Procedure supported by the Governing Board. Prevention: This will be prevented by following the process of performing these appraisals on the anniversary month of the employees hire date every year after the September 2014 appraisal. Responsible: Administrator/Medical Director and Human Resources Director</p>	10/17/2014			

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S000166	<p>4. During an interview on 7-16-14 at 1630 hours, the director of human resources A9 confirmed that the center failed to follow its policy/procedure and failed to ensure that documentation of annual evaluations was available for all personnel files at the center.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based upon document review and interview, the center failed to maintain, update and review its policy/procedures at least triennially.</p> <p>Findings:</p> <p>1. The policy/procedure Crash Cart Inventory (approved 4-11), Reporting of Patient Care Errors (reviewed 4-11), Occurrence Report (Approved 4-11), Occurrence Reporting (Approved 4-11), Germicides (Approved 4-11), Reportable Disease and Conditions (Approved 4-11), Cleaning of the Procedure Room</p>	S000166	<p>Correction: In reference to the policies listed in this tag they will all be reviewed and updated as required by our Policy and Procedure for triennially review and update. Prevention: We will prevent this lapse in the future by following the triennially requirement and commitment by the Governing Board. The crash cart inventory updated Sept. 12th by Anesthesia, nurse and CPR/ACLS instructor; review and update of occurrence reporting to staff; reportable disease review and update to staff; infection control policy review and update to staff; Employees performance</p>	09/30/2014			

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S000182	<p>(Approved 4-11), Infection Control Program (Approved 4-11), Employee File Requirements (Approved 4-11), Orientation - All Employees (Approved 4-11) and Employee Performance Appraisal (Approved 4-11) failed to indicate that the policy/procedures had been reviewed and approved in the last three years.</p> <p>2. During an interview on 7-17-14 at 0955 hours, the infection prevention nurse A2 confirmed that the policy/procedures lacked documentation of a review within the past 3 years.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (O)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(O) Annual implementation of internal and external disaster preparedness plans with documentation of outcome. Based upon document review and interview, the governing board failed to ensure the performance of an annual internal or external disaster preparedness drill including an evaluation of the outcome to be shared with center staff.</p> <p>Findings:</p>	S000182	<p>appraisal in progress to be completed by Sept. 17th; policy and procedure book in progress review and update present at the Sept. governing board meeting. All of the above is being reviewed and signature by the staff on a individual basis or at the monthly staff meeting depending on the acuity. Responsible: Administrator, Medical Director and Governing Board.</p> <p>Correction: An annual internal or external disaster preparedness drill will take place, the results of the drill will be shared with the staff and it will also be forwarded to the Governing Board for their review. We have had continuing collaboration with local community agencies regarding</p>	09/05/2014

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S000224	<p>1. On 7-14-14 at 1000 hours, the human resources director A9 was requested to provide documentation of an annual disaster preparedness exercise and none was provided prior to exit.</p> <p>2. The Emergency Preparedness Policy (approved 4-11) indicated the following: "Disaster preparedness will be coordinated by contacting the disaster preparedness officer at the ...[community hospital]". No supporting documentation was provided to indicate that a responsible person at the center established contact with the disaster preparedness officer or conducted a disaster preparedness drill prior to exit.</p> <p>3. The emergency preparedness binder failed to indicate documentation of an annual disaster preparedness drill including a written analysis of the drill.</p> <p>4. During an interview on 7-16-14 at 1030 hours, the infection prevention nurse A2 confirmed that no documentation of a disaster preparedness drill was available prior to exit.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(2)</p> <p>The governing body is responsible for services delivered in the center whether or not they are</p>		<p>such disasters however these documents were not readily available at the time of the state's visit. We will place these documents and drills in our Emergency Preparedness binder. Prevention: In the future we will meet these guidelines by performing these drills and reviewing this policy on an annual basis and have ongoing collaboration with community coalition and place it in the appropriate Emergency Preparedness Binder. Responsible: Administrator ,Medical Director and Governing Board</p>				

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	<p>delivered under contracts. The governing body shall do the following:</p> <p>(2) Ensure that the services performed under a contract are provided in a safe and effective manner and are included in the center's quality assessment and improvement program. Based on document review and interview, the governing body failed to ensure that services performed under contract were provided in a safe and effective manner and included in the quality assessment and improvement (QA) program for 13 contracted services.</p> <p>Findings:</p> <p>1. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation indicating that all contracted services were periodically reviewed through the QA program and none was provided prior to exit.</p> <p>2. The available documentation titled Indirect Patient Care Vendors Statement of Quality Annual Review for a biohazardous waste disposal service CS1, fire detection and suppression service CS4, pharmacy consultant CS11 and automatic door service CS13 failed to indicate that a periodic review had been performed since 8-11. No periodic review documentation was provided for</p>	S000224	<p>Correction: This deficiency will be corrected by the way of a tracking system tool that we already have in place in which these contracted services can be reviewed and evaluated to be performing within their contract and in a safe and effective manner for the Endoscopy Center. This document will be forwarded to the QA committee section of the Governing Board meeting as required. Many of these contracted services did have up to date reviews and evaluations on this tracking tool however it was unavailable at the time of the state's visit. Prevention: This will be prevented by continually using this tool to review and evaluate these contracted services and by forwarding this information on to the QA committee section of the Governing Board as required and having it readily available at all times. Responsible: Administrator, Medical Director and Governing Board</p>	09/17/2014			

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	<p>the contracted services of biomedical engineering CS2, endoscope service and support CS3, heating and air conditioning service CS5, laboratory service CS6, laundry service CS7, medical record consultant CS8, pest control service CS9, radiology service CS11, or ultrasonic cleaner support service CS12 prior to exit.</p> <p>3. The QA committee section of the endoscopy governing board meeting minutes dated 3-18-13, 5-28-13, 7-29-13, 10-28-13, and 3-31-14 lacked documentation to indicate that the contracted service providers had been reviewed by the committee. The board minutes dated 10-28-13 indicated a report of service activity by the fire detection and suppression service CS4 and indicated a discussion regarding a report prepared by the medical record consultant CS8; however, no documentation indicated that an evaluation of the service provider based on outcome or process indicators was performed.</p> <p>4. During an interview on 7-14-14 at 1555 hours, the patient care coordinator A3 and the director of human resources A9 confirmed that no documentation indicating a periodic evaluation and review of the contracted services was available.</p>			

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S000226	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review, the facility failed to maintain a list of all contracted services, including the scope and nature of services provided, for 13 services.</p> <p>Findings:</p> <p>1. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide a list of all contracted service providers for the center and none was provided prior to exit.</p> <p>2. Review of center documentation indicated the following: biohazardous waste disposal by CS1, biomedical engineering by CS2, endoscope service and support by CS3, fire detection and suppression by CS4, heating and air conditioning service by CS5, laboratory services were provided by CS6, laundry service by CS7, medical record consulting by CS8, pest control service by CS9, pharmacy consulting by CS10, radiology services by CS11, ultrasonic cleaner support service by CS12, and automatic door service by CS13.</p> <p>3. On 7-16-14 at 1645 hours, the patient care coordinator A3 confirmed that the center failed to</p>	S000226	Correction: As related to the S224 Tag we do already have a list of all contracted services however it was not readily available at the time of the survey. We will be reviewing and updating this list and making sure that it includes the scope and nature of the services provided as required by this rule. Prevention: This will be prevented by having this list readily available at all times and accurately updated as needed. Responsible: Administrator	08/22/2014			

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S000230	<p>maintain a list of contracted services including the 13 providers indicated above.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based upon document review and interview, the governing body failed to assure that utilization review (UR) was conducted in accordance with its governing board bylaws for 3 of 4 quarters by a group of at least three licensed physicians without financial interest in the center.</p> <p>Findings:</p> <p>1. The governing body bylaws (approved 2-13) indicated the following: "The utilization review committee shall be composed of at least three physicians who hold an unlimited license to practice medicine ...and who have no financial</p>	S000230	<p>Correction: As related to the Utilization Review requirements we do have 2 physicians currently in place for this purpose. The third physician is now providing anesthesia services to our facility and needs replaced. We will bump that back to 3 physicians as the rule requires and we will also be more diligent in completing these UR audits on a quarterly basis as required. Our last three of four gastroenterologist joined in April, May and July. We will also be sure that they maintain a permanent record of their report and that all reviews or recommendations be forwarded to the Governing Board.Prevention: We will prevent this by following the</p>	09/17/2014

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	<p>interest in the ...ambulatory surgery centerThe UR committee ...shall meet at least quarterly ...[and] ...maintain a permanent record of its proceedings and actions and shall report its activities, the results of its reviews and its recommendations, if any, to the ... [endoscopy center governing board]."</p> <p>2. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation of quarterly UR committee activity and UR documentation dated 11-13 was presented for review.</p> <p>3. A tentative schedule of medical staff, peer review and governing board meetings in 2013 indicated that the peer review committee was scheduled to meet on four occasions (2-18-13, 4-01-13, 7-08-13 and 9-30-13) in 2013.</p> <p>4. No endoscopy governing board meeting documentation dated 3-18-13, 5-28-13, 7-29-13, and 3-31-14 indicated that UR committee activity was presented or reviewed. The endoscopy governing board meeting minutes dated 10-28-13 indicated that ' peer review/chart review ' had been performed and no additional documentation was provided to confirm reporting of UR committee activity or confirm that the results of monthly chart</p>		<p>recommendations listed in the correction and having these documents readily available for future purposes with regularly scheduled Governing Board meetings.Responsible: Adminsitrator, Medical Director and Governing Board</p>				

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S000332	<p>audits performed by nursing staff was provided for review.</p> <p>5. During an interview on 7-16-14 at 1645 hours, the director of human resources A9 confirmed that the center lacked documentation of recent UR committee activity for 3 of 4 quarters.</p> <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</p>			

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	<p>that patient. Excluded are emergent situations:</p> <p>(AA) that occur in the course of surgery; or</p> <p>(BB) whose exigency precludes obtaining informed consent;</p> <p>or both</p> <p>(iv) Retention of a foreign object in a patient after surgery or other invasive procedure.</p> <p>The following are excluded:</p> <p>(AA) Objects intentionally implanted as part of a planned intervention.</p> <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>			

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	<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 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</p>			

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	<p>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 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: (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</p>			

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	<p>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> <p>Based on document review and interview, the center quality assessment and improvement program failed to develop and maintain a policy/procedure for determining the reportable events identified by State law 410 IAC 15-2.4-2.2 Reportable Events.</p> <p>Findings:</p> <p>1. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation indicating the events to be reported to the Indiana State Department of Health (ISDH) and none was provided prior to exit.</p> <p>2. The policy/procedure table of contents failed to indicate a listing for Reportable Events.</p>	S000332	<p>Correction: We will develop a policy and procedure to be compliant with this rule related to Reportable Events. We do currently have separate policies that reflect some of these categories such as patient care errors and incident/events errors but we will review and update our policy and procedure to cover all required items in one policy. We will title this as Reportable Events and place it in the index of the Policy and Procedure Manual for easy accessibility. The Administrator/Medical Director does complete the state reportable event form requirement annually. Prevention: This will be prevented by having a complete policy and procedure in place and having it easily accessible in the Policy and Procedure Manual under Reportable Events reviewed and</p>	09/30/2014			

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S000334	<p>3. During an interview on 7-17-14 at 1245 hours, the infection prevention nurse A2 confirmed that no policy/procedure indicating the events to be reported to the ISDH was available prior to exit.</p> <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)</p>		signed by the staff.Responsible: Administrator and Medical Director	

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	<p>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;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p> <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</p>			

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	<p>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, the center lacked a process for reporting each reportable event that was determined by the quality assurance/performance improvement (QAPI) program to have occurred at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation of the process for reporting events to the Indiana State Department of Health (ISDH) and none was provided prior to exit. The policy/procedure table of contents failed to indicate a listing for Reportable Events. During an interview on 7-17-14 at 1245 hours, the infection prevention nurse A2 confirmed that no policy/procedure for reporting events to 	S000334	<p>Correction: We will add to our Reportable Events policy and procedure a reporting component that will meet this requirement determined by the QAPI program at least to state no issues by required reportable events. Prevention: We will prevent this deficiency by following the guidelines on Reportable Event in a QAPI program with adequate documentation of this process and presented at the Governing Board meeting Responsible: Administrator, Medical Director and Governing Board.</p>	09/17/2014	

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S000428	<p>the ISDH was available prior to exit.</p> <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. Based on document review and interview, the infection control (IC) committee failed to ensure that the procedure room cleaning was performed in a safe and effective manner in between patient procedures at the center.</p> <p>Findings:</p> <p>1. The policy/procedure manual and Infection Control manual failed to indicate a policy/procedure for cleaning and disinfecting the procedure room by nursing staff between procedures. No documentation indicated a specific room cleaning and disinfecting process to be performed by nursing staff between procedures.</p>	S000428	<p>Correction: A new policy for procedure room cleaning in between patient procedures at the center has been written. We did already have a process in place for this cleaning requirement but not a specific detailed policy and procedure to reflect that requirement. This policy and procedure will be presented to all endoscopy staff at the next staff meeting. Policy and procedure e-mailed to ISDH.Prevention: This policy and procedure is now in place and with an audit tool to prevent being deficient in future surveys. Staff has reviewed and signed at staff meeting or on individual basis. After review will be an audit at the end of September for quality compliance.Responsible: Administrator and Infection Control Leader</p>	09/04/2014			

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S000438	<p>2. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation indicating the process for procedure room cleaning in between patient procedures at the center and none was provided prior to exit.</p> <p>3. On 7-17-14 at 0910 hours, the infection prevention nurse A2 was requested to provide documentation indicating the process for procedure room cleaning in between patient procedures at the center and none was provided prior to exit.</p> <p>4. During an interview on 7-17-14 at 1120 hours, the infection prevention nurse A2 confirmed that no policy/procedure indicating the process for procedure room cleaning in between patient procedures was available.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(vi)</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>						

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	<p>(vi) A patient isolation system.</p> <p>Based on document review and interview, the infection control (IC) program failed to establish and maintain a terminal cleaning process for patients suspected of being infected or recently diagnosed with the communicable disease Clostridium difficile (C diff) at the center.</p> <p>Findings:</p> <p>1. The policy/procedure Routine and Terminal Cleaning of Patient Rooms (reviewed 11-13) indicated the following: "As a general rule, the patient's room should be cleaned the same upon terminal cleaning regardless of isolation status ...The only difference when cleaning rooms of patients in isolation is that the environmental services department staff will disinfect their cleaning equipment before proceeding on to the next patient room." The policy/procedure failed to indicate a process for disinfecting surfaces contaminated with C diff. using a EPA- registered 1:10 dilution sodium hypochlorite solution (per 2003 CDC Guidelines for Environmental Infection Control in Health Care Facilities E. Recommendations - Environmental Services Section IV. Special Pathogens (G.)).</p>	S000438	<p>Correction: A new policy for patients suspected or diagnosed with C Diff has already been written. This follows the requirement of using an EPA Registered 1:10 dilution sodium hypochlorite solution in caring for the environment after an encounter with a C Diff patient. We will educate the staff on this policy at next staff meeting. Staff will also watch a C Diff DVD. Again as previously stated we already were completing this cleaning task appropriately with C Diff patients but we did not have a policy and procedure in place to reflect this process. Prevention: This policy and procedure is now in place so that will prevent it from being deficient in future surveys. Responsible: Administrator, Infection Control Leader</p>	09/04/2014			

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S000442	<p>2. On 7-17-14 at 0910 hours, the infection prevention nurse A2 was requested to provide documentation indicating the room cleaning process for patients suspected or diagnosed with C diff at the center and none was provided prior to exit.</p> <p>3. During an interview on 7-17-14 at 1120 hours, the infection prevention nurse A2 confirmed that no policy/procedure indicating the room cleaning process for patients suspected or diagnosed with C diff was available.</p> <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 interview, the center failed to follow its</p>	S000442	Correction: We will be ensuring that our employee/physican immunization status program and	09/17/2014			

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	<p>infection control plan and failed to determine the communicable disease status for all employees at the center for 6 of 7 personnel health files reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Infection Control Program (approved 4-11) indicated the following: "The infection control committee responsibilities must include, but are not limited to ...an employee immunization status program [and] an employee health program to determine communicable disease history ..." The policy/procedure Employee File Requirements (approved 4-11) indicated the following: "A personnel file will be maintained on each employee ...and will be reviewed annually ...The contents of the personnel files will ...include the following ...Rubella, Rubeola, Chickenpox [varicella] vaccination or immunity status [titer]." The policy/procedure Employee/Physician Statement of Health (approved 4-11) indicated the following: "Each employee will have documentation of either vaccination or immunity to Rubella, Rubeola and chicken pox [varicella]. Self reporting of disease will 		<p>an adequate health program to derermine communicable disease history will be implemented. We will not allow self reporting of disease as an acceptable method of documentation. We will ensure that each personnel file will indicate immunity (titre) or written documentation of vaccination against rubella, rubeola, and/or varicella. This personnel file will be reviewed annually as states in our policy and procedure entitled Employee File Requirements.Prevention: This deficiency will be prevented by activating this plan of correction and enforcing this policy and procedure on each employees's date of hire through the human resource director and reviewed annually.Responsible: Administrator, Infection Control Leader and Human Resource Director</p>				

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S000606	<p>not be an acceptable method of documentation."</p> <p>4. The personnel health files for staff A1, N11, N12, N13, N14 and N15 failed to indicate either documentation of immunity [titer] or failed to indicate written documentation of vaccination against rubella, rubeola, and/or varicella from a health care provider, County or State health department or military health record.</p> <p>5. During an interview on 7-16-14 at 1630 hours, the director of human resources A9 confirmed that the center failed to follow its policy/procedures and failed to ensure that documentation of immunity to communicable disease was available for all personnel files at the center.</p> <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(b)(1)</p> <p>(b) The organization of the medical record service must be appropriate to the scope and complexity of the services provided as follows:</p> <p>(1) The services must be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time</p>			

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	<p>and/or part-time RRA or ART is not employed, then a consultant RRA or ART must be provided to assist the qualified person in charge. Documentation of the findings and recommendations of the consultant must be maintained.</p> <p>Based on document review and interview, the center failed to maintain documentation of the findings and recommendations of the medical records (MR) consultant under agreement to supervise the MR service for 1 of 4 quarterly (11-07-13) reviews.</p> <p>Findings:</p> <ol style="list-style-type: none"> Quarterly MR consultant reports indicated that a review was performed on 8-14-13, 2-06-14, and 5-21-14. The 8-14-13 MR report indicated that the next review was to be performed on 11-07-14. On 7-16-14 at 0900 hours, the director of human resources A9 was requested to provide documentation of the MR consultant report dated 11-07-13 and no documentation was provided prior to exit. On 7-16-14 at 1535 hours, the infection prevention nurse A2 confirmed that no documentation of the MR 	S000606	<p>Correction: The medical records consultants report in the computer and also available in the Governing Board minutes will be printed and accessible in a binder available at all times. The 11/7/13 dated report was not found in the current binder at the state's visit. Prevention: This will be prevented by keeping the binder updated with all reports printed out and properly placed. Missing report e-mailed to ISDH. Responsible: Administrator</p>	08/22/2014

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S000710	<p>consultant review dated 11-07-13 was currently available.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(4)</p> <p>The medical staff shall do the following:</p> <p>(4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following:</p> <p>(A) A completed, signed application.</p> <p>(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.</p> <p>(C) A current copy of the individual's:</p> <p>(i) Indiana license showing date of licensure and number or available data provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the appropriate licensing board.</p> <p>(ii) Indiana controlled substance registration showing number as applicable.</p>						

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	<p>(iii) Drug Enforcement Agency registration showing number as applicable.</p> <p>(iv) Documentation of experience in the practice of medicine.</p> <p>(v) Documentation of specialty board certification as applicable.</p> <p>(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).</p> <p>(D) Category of medical staff appointment and delineation of privileges approved.</p> <p>(E) A signed statement to abide by the rules of the center.</p> <p>(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.</p> <p>(G) Other items specified by the center and medical staff.</p> <p>Based on document review and interview, the governing body failed to ensure that its medical staff followed its bylaws and its credential files were maintained including a signed application for 1 of 4 (MD11) credential files, a list of privileges requested and privileges granted for 3 of 4 (MD12, MD13 and MD14) credential files, a copy of the written notice provided to each practitioner indicating the category of</p>	S000710	Correction: Medical staff appointment with signed acknowledgement of obligation to abide by rules, regulations and staff policies. The privileges requested and granted by the governing board with initial provisional category and then followed by a written notice of affirmation of staff category. Correction: Update and review of Medical Staff bylaws by the governing board and to follow	09/29/2014			

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	<p>privileges granted for 4 of 4 (MD11, MD12, MD13 and MD14) credential files, and a signed statement to abide by the rules of the center for 1 of 4 (MD11) credential files reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The medical staff bylaws (approved 8-11) indicated the following: "Every application for the medical staff appointment shall be signed by the applicant and specifically acknowledge his/her personal obligation ...to abide by the [center] rules, regulations and staff policies ..." 2. The credential file for MD11 failed to indicate a signed application including a signed statement to abide by the rules of the center. 3. During an interview on 7-16-14 at 1610 hours, the patient care coordinator A3 confirmed that the credential file for MD11 lacked a signed application. 4. The medical staff bylaws (approved 8-11) indicated the following: "Application for Appointment: ...The following documents shall be obtained and ...maintainedd. Letter delineating privileges and approval by medical staff." 		its bylaws and credential files maintained in hard copy. Letter will be signed and sent by Medical Director/Endoscopy Center Governing Board PresidentResponsible: Administrator, Human Resource Director, Medical Director and Governing Board				

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	<p>5. The credential files for MD12, MD13 and MD14 failed to indicate the privileges requested and privileges granted by the governing board.</p> <p>6. During an interview on 7-17-14 at 1015 hours, the infection prevention nurse A2 confirmed that the credential files for MD12, MD13 and MD14 failed to indicate the privileges requested and granted by the governing board.</p> <p>7. The medical staff bylaws (approved 8-11) indicated the following: "All initial appointments shall be made to the provisional category ...The governing board shall notify the applicant by mail. The written notice of affirmation shall include ...the staff category to which the applicant is appointed ..."</p> <p>8. The credential files for MD11, MD12, MD13 and MD14 lacked a copy of the written notice provided to each provider indicating the category of staff appointment.</p> <p>9. During an interview on 7-17-14 at 1015 hours, the infection prevention nurse A2 confirmed that the credential files for MD11, MD12, MD13 and MD14 lacked documentation of the written notice to indicate the category of staff appointment.</p>						

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S000736	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(B)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(B) Meeting requirements of the medical staff to include, at a minimum, the following:</p> <p>(i) Frequency, at least quarterly. (ii) Attendance.</p> <p>Based upon document review and interview, the medical staff failed to maintain and follow its medical staff bylaws regarding quarterly medical staff meetings for 5 of 5 quarters.</p> <p>Findings:</p> <p>1. The medical staff bylaws (approved 8-11) indicated the following: "At least 50% of the active medical staff must be present at each annual staff meeting ...the executive committee ...shall meet a minimum of one meeting per quarter and maintain a permanent record of its proceedings and actions..." The medical staff bylaws failed to indicate a minimum attendance requirement (quorum) for quarterly executive committee meetings</p>	S000736	<p>Correction: Medical staff will meet monthly with documentation presented at the quarterly governing board meeting. The established quorum of 50% must be present. The meeting is the first Thursday of the month unless holiday conflict or if more than one medical staff member is out on planned vacation/CMEs. The date than would be changed to the next following Thursday. If a last minute conflict or emergency, the meeting would be held on the following day, which is Friday.</p> <p>Prevention: Planned and posted medical staff monthly meeting and documentation will be presented at the quarterly governing board meeting.</p> <p>Enforcement of the medical staff obligation to the rules and regulation of attendance of the</p>	09/30/2014			

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S001188	<p>or medical staff meetings if held more frequently than annually.</p> <p>2. A tentative schedule of medical staff, peer review and governing board meetings in 2013 indicated that a medical staff meeting was scheduled on 5-02-13, 6-06-13, 7-11-13, 8-01-13, 9-05-13, 10-03-13, 11-07-13 and 12-05-13.</p> <p>3. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide documentation of quarterly medical staff meetings and none was provided prior to exit.</p> <p>4. The endoscopy governing board meeting minutes dated 5-28-13, 7-29-13, 10-28-13, and 3-31-14 failed to indicate that the medical staff meeting minutes were presented and reviewed if medical staff meetings were held as scheduled.</p> <p>5. On 7-14-14 at 1540 hours, the director of human resources A9 confirmed that no documentation of a recent medical staff meeting was available.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4)</p> <p>(c) A safety management program must</p>		meetings with signature. Responsible: Administrator, Medical Director, Medical Staff and Governing Board				

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	<p>include, but not be limited to, the following:</p> <p>(4) A written fire control plan that contains provisions for the following:</p> <p>(A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of patients, personnel, and guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills.</p> <p>Based on document review and interview, the center failed to follow its fire control plan and failed to maintain documentation of quarterly fire drills.</p> <p>Findings:</p> <p>1. The policy/procedure Fire Safety Program (no approval date) indicated the following: "The [center] will support an ongoing fire safety program to include ...the use of and response to the fire/smoke alarm systemthere will be a fire alarm drill quarterly." The policy/procedure included a two page fire drill report to be completed at the time of the drill by the safety officer or designee.</p> <p>2. On 7-14-14 at 1000 hours, director of human resources A9 was requested to provide documentation of periodic fire drills at the center and none was provided prior to exit.</p>	S001188	<p>Correction: As per the rule requirement and our Policy and Procedure Fire Center Program we will complete and have adequate documentation of quarterly fire alarm drill completed in the Endoscopy Center. We do have a policy in place for this requirement and these drills have been in process however the documentation was not readily available at the time of the state's visit. Prevention: Drills completed on a quarterly basis and reported to the Governing Board was met as required but the detailed report needs printed out and immediately available in the binder in the Administrator absence. The report will be e-mailed to ISDH. Responsible: Administrator</p>	08/22/2014	

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S001198	<p>3. The center binder titled Fire Drills, Safety Surveillance Checklist, Fire Alarm Inspection Report failed to indicate any documentation of quarterly fire drills conducted at the center since March, 2013.</p> <p>4. During an interview on 7-15-14 at 1330 hours, the patient care coordinator A3 confirmed that no recent fire drill documentation was present in the binder titled Fire Drills.</p> <p>5. During an interview on 7-16-14 at 1035 hours, the infection prevention nurse A2 confirmed that no additional fire drill documentation was available prior to exit.</p> <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 failed to follow its emergency plan, failed to maintain</p>	S001198	Correction: We will follow our Emergency Preparedness Policy as it relates Disaster	09/26/2014	

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	<p>documentation of periodic disaster drills, and failed to establish and maintain documentation of participation with a community, State or federal emergency preparedness agency.</p> <p>Findings:</p> <p>1. The Emergency Preparedness Policy (approved 4-11) indicated the following: "Disaster preparedness will be coordinated by contacting the disaster preparedness officer at ...[the] ...County Fire Department and ...[community hospital]." The policy/procedure failed to establish the relevant information (office phone, cell phone) needed to contact the responsible person prior to an actual event.</p> <p>2. The policy/procedure Emergency Plan (no approval date) indicated the following: "The [center] will have an emergency plan in place designed to address response to internal and external hazards ...[the center] will coordinate emergency planning with the city ...county, and State of Indiana, tribal, and public health agencies as appropriate ... [the center] will clarify the role [the center] will have in response to a community-wide disaster, and plan accordingly ...[the center] disaster/emergency plan will be reviewed</p>		<p>preparedness and show coordination within our local and state public health agencies. We will perform a disaster/emergency drill quarterly and complete an annual review of our Emergency Preparedness Policy as required. As per previous tags we have had ongoing effort on this topic with local agencies at the county level and with the hospital emergency director but the documentation was not readily available at the time of the state's visit. MOU being updated with the local hospital and coalition meeting is planned for October following the local Emergency Preparedness meeting. Prevention: We will complete these drills on a quarterly basis as necessary and keep adequate records and place them in the labeled binder for ease of access. Responsible: Administrator and Medical Director</p>				

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	<p>at least annually. The disaster/emergency plan will be evaluated by conducting a drill quarterly. A written analysis of the drill will be developed."</p> <p>3. On 7-14-14 at 1000 hours, the director of human resources A9 was requested to provide quarterly disaster drill documentation and evidence of center participation and/or coordination with an emergency and disaster preparedness agency and none was provided prior to exit.</p> <p>4. The emergency preparedness binder failed to indicate documentation of an annual plan review, failed to indicate documentation of quarterly disaster drills including a written analysis of the drill, and failed to indicate documentation of participation and/or coordination with a local, regional or other emergency preparedness agency.</p> <p>5. During an interview on 7-16-14 at 1030 hours, the infection prevention nurse A2 confirmed that no documentation of a 2014 tornado drill other quarterly disaster drill was available and confirmed that no documentation of center coordination or staff participation with local or district emergency preparedness agency was available prior to exit.</p>			

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

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