

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001022	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 04/24/2013
NAME OF PROVIDER OR SUPPLIER DIGESTIVE HEALTH CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 1120 AAA WAY CARMEL, IN 46032		
(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	
S000000	<p>The visit was for a Licensure survey.</p> <p>Facility Number: 5403</p> <p>Survey Date: 4-22-13 to 4-24-13</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p>	S000000			

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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S000122	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.</p> <p>Based on review of the medical staff rules and regulations, policy and procedure review, observation, and staff interview, the governing body failed to implement, or change if applicable, the medical staff rules and regulations related having no dispensed medications within the facility.</p> <p>Findings:</p> <p>1. at 1:50 PM on 4/24/13, review of the medical staff rules and regulations (last reviewed/approved unknown) indicated:</p> <p>a. under "Section C Drugs", it reads: "1. Drugs will be available only for use in the facility. The Facility will not dispense drugs..."</p> <p>2. at 4:30 PM on 4/24/13, review of the policy and procedure: "Sample Drug Administration", PG.7, with a last "updated" note of 5/1/12, indicated sample medications were distributed/dispensed at the facility</p>	S000122	<p>1. Review policy for sample medications. Administrative manual under Section C Drugs states, "Facility will not dispense drugs...". Standards of Care manual Section 4, Page 7 states, "To provide safe administration of all sample medications...". Medical Advisory Board will motion to revise the Administrative manual policy to read as Standards of Care manual policy. Amendment to Administrative Manual to be approved by the Governing Board at the next quarterly meeting.</p> <p>2. Policies/Procedures manuals to be reviewed, updated, and checked for inconsistencies of policies.</p> <p>3. Administrative Assistant and Director of Nursing to update manuals. Governing Board approval for dispensing sample medications.</p>	05/08/2013			

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	<p>3. while on tour of the facility recovery area at 11:45 AM on 4/23/13, in the company of staff RNs (registered nurses) #50 and #51, it was observed that there was a locked sample cabinet present in the nurses' station</p> <p>4. interview with staff member #51, the director of nursing, and #53, the facility physician, at 4:30 PM on 4/24/13, indicated:</p> <ul style="list-style-type: none"> a. the facility does give out samples to patients b. the medical staff rules and regulations were never changed to reflect the distribution of sample medications 				

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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 policy and procedure review, employee file review, and staff interview, the chief executive officer failed to ensure the orientation of one RN (registered nurse) who was hired 9/17/12, per facility policy (RN N4).</p> <p>Findings:</p> <p>1. at 1:10 PM on 4/23/13, review of the manual titled: "Personnel/H.R." indicated a policy titled: "Employee Orientation" (policy PE-3), with no date of policy origination, and on page 2, a last date "reviewed" of 8/17/04, which read:</p> <p>a. under "Policy" on page one, "Each new employee will receive an orientation to the facility at the start of employment..."</p> <p>b. on pages 2 and 3, the orientation schedule for a three week time frame was listed, with indication that this would be the extent of orientation</p>	S000153	<p>1. Personnel file for RN 4 to be reviewed and proper documentation completed. Orientation for fire and safety dated at time of hire 9/17/2012. Competency validation for specimen collection will be completed upon RN 4 training in Procedures. "Employee File Checklist" will be complete upon documentation of all checklists.2. Orientation of all new employees, including contract and agency personnel, will be assigned to the Administrative Assistant.3. Director of Nursing responsible for completing orientation for RN 4.</p>	05/24/2013			

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	<p>2. at 1:50 PM on 4/22/13, review of personnel files indicated:</p> <p>a. staff RN N4 was hired 9/17/12 and had an orientation packet of forms that lacked completion, which included, but was not limited to:</p> <p>A. "Employee File Checklist" (of various new hire required documents, training, etc.)</p> <p>B. "Competency Validation" for "Specimen Collection"</p> <p>C. the Orientation for Infection Control forms</p> <p>b. Staff RN N4 had a form titled: "Orientation Program for Fire and Safety" that is not dated when it was completed</p> <p>c. Staff RN N4 had various other new hire forms (confidentiality, etc.) signed today, 4/22/13</p> <p>3. interview with staff member #51, the director of nursing, at 3:30 PM on 4/22/13, indicated:</p> <p>a. staff RN N4, hired 9/17/12, had no completed orientation documentation present in the employee file today, 4/22/13</p> <p>b. the orientation for RN N4 was considered completed last Fall (2012), but the documentation is lacking</p>						

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S000156	<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 personnel file review and staff interview, the chief executive officer failed to ensure the provision of a job description for the designated infection control nurse (staff member #51/N1).</p> <p>Findings:</p> <p>1. at 1:50 PM on 4/22/13, review of personnel files indicated:</p> <p>a. staff member N1 lacked a job description for the position of infection control practitioner</p> <p>2. interview with staff member N1 (also #51), the infection control nurse, at 2:30 PM on 4/22/13 indicated:</p> <p>a. this staff member was assigned as the infection control designee/nurse in December 2012</p>	S000156	<p>1. Infection Control Nurse Designee description obtained from the Infection Control manual copied and placed in N1 personnel file along with the Director of Nursing job description.2. Upon assignment of specific role, description of respective assignment to be placed in personnel file.3. Director of Nursing and Administrative Assistant to be responsible for personnel files.</p>	05/08/2013			

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	<p>b. it was thought that the "Director of Nursing" job description, that indicated they participate/serve on the specified committees, worked for an infection control nurse job description</p> <p>c. the Infection Control Plan has a job description titled "Infection control Nurse Designee" that is pages 4 and 5 of the plan</p> <p>d. the infection control nurse employee file is lacking a copy of the "Infection Control Nurse Designee" job description</p>			

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S000166	<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 follow its policy/procedure and verify that all policies and procedures were reviewed and updated at least triennially.</p> <p>Findings:</p> <p>1. The policy/procedure regarding policy and procedures (revised 9-05-12) indicated the following: " All policies and procedures will be approved by the facility administrator before implementation. All policies will be reviewed and revised every three years ... " The policy failed to indicate the date when approved and signed by the administrator to validate compliance. The policy/procedure indicated handwritten revisions and failed to indicate that the facility administrator approved the changes before implementation.</p>	S000166	<p>1. Policy and procedures will be reviewed, updated, and/or approved by Facility Administrator/MD prior to implementation. Policy: Sentinel event to be reported within 15 days has been approved and signed by MD/Facility Administrator. A motion at the next governing board meeting to implement policy. The fire drill revision will be changed from yearly to quarterly. This will be presented at the next governing board meeting by the Safety Director. Policy has been approved on 5/9/2013 by MD and updated by Director of Nursing. 2. Policy/Procedures to be reviewed at least triennially. Due to staff changes in past year, Medical Secretary retiring, then Administrative Assistant turnover, the Facility Administrator will confirm that all revisions and updates be approved by the governing board. To prevent deficiency from recurring, Facility Administrator/Medicarl Director</p>	05/09/2013

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	<p>2. During an interview on 4-23-13 at 1545 hours, staff A1 confirmed that the policy/procedure failed to indicate that the revisions were dated and approved by the medical director to validate compliance.</p> <p>3. The policy/procedure Sentinel Event (reviewed 7-11-12) indicated the following handwritten revisions: " Notify ISDH ...(illegible entry) ... upon conclusion of the sentinel event via email and/or telephone ... " and failed to indicate that the revisions were dated and approved by the medical director to validate compliance.</p> <p>4. During an interview on 4-23-13 at 1545 hours, staff A1 confirmed that the policy/procedure failed to clearly indicate the 15 day timeframe for reporting as required by State law and failed to indicate that the policy revisions were dated and approved by the medical director to validate compliance.</p> <p>5. The policy/procedure Fire Drill (updated 4-12) indicated the following: " A fire drill will be held and documented every year. " The handwritten revision from every three months failed to indicate that the changes were dated and approved by the medical director.</p>		and Governing Board will discuss and document revisions, then get approval by Governing Board.3. Administrative Assistant will be responsible that revisions and updates are presented and approved at the governing board meetings.				

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	6. During an interview on 4-23-13 at 1545 hours, staff A1 confirmed that the policy/procedure failed to indicate that the revisions were dated and approved by the medical director to validate compliance.			

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S000172	<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 policy and procedure review, employee file review and staff interview, the chief executive officer failed to ensure the implementation of the facility policy related to annual TB (tuberculin) testing for 2 (N1 and N2) of 4 RNs (registered nurses).</p> <p>Findings: 1. at 2:55 PM on 4/22/13, review of the policy titled: "Employee Health Program" (no policy number or date) indicated: a. under "Procedure", it reads in item #3. "...A PPD (purified protein derivative) test will be administered to all employees who provide direct patient contact on a yearly basis..."</p>	S000172	<p>1. Annual PPD test to be provided by the Infection Control Nurse Designee or other RN. N1, N2, N3, and N4 given PPD test 5/8/2013. All RNs will have PPD test administered at the same time each year.2. To prevent deficiency from recurring, the Administrative Assistant will monitor personnel files for upcoming vaccinations, PPD tests, CPR and ACLS certifications, etc.3. Infection Control Nurse Designee responsible for PPD tests to be performed. N1 and N4 performed testing on 5/8/2013.</p>	05/08/2013			

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	<p>2. at 1:35 PM on 4/23/13, review of personnel files indicated:</p> <p>a. RNs N1 and N2 had documentation of the last TB tests as being given on 3/20/12</p> <p>3. interview with staff member #51, the director of nursing, at 3:25 PM on 4/23/13 indicated:</p> <p>a. staff members N1 and N2 were due for annual/yearly TB testing in March of 2013</p> <p>b. annual TB testing is behind schedule and not per policy</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 center failed to maintain a list of all contracted services, including the scope and nature of services provided, for 5 of 20 services.</p> <p>Findings:</p> <p>1. The document Physician Consulting Agreements provided as the list of contracted services failed to include 5 services (copier service by V1, endoscope service and repair by V2, medical transcription by V3, medical records consulting by V4, and pharmaceutical supply by V5) identified through a document review.</p> <p>2. On 4-24-13 at 1510 hours, staff A2 confirmed that the list of contracted services had not been maintained and lacked the indicated providers.</p>	S000226	<p>1. List of contracted services to be updated and maintained. Contract Service manual will be reviewed by Administrative Assistant. Five services noted for being omitted from list: 1. Copier service noted on page 2 of list as Ikon Business Solution 2. Endoscope repair service does not require contract 3. Medical transcription added to list 4. Med Rec Systems for medical records consulting revised to new consultant 5. Pharmaceutical supply contract with Henry Schein which is noted on page 2 of DHC-Indirect Patient Care Contracts.2. To prevent deficiency from recurring in the future, Administrative Assistant will be responsible for the Contracts Agreement book. The Administrative Assistant will update the book upon contract agreement with scope repair company. As of this date, no</p>	05/08/2013

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			contract needed with Olympus.3. Director of Nursing updated and revised list of contracts agreement book. Administrative Assistant will be responsible for contract services. New contracts and/or change in contracts will be noted through Quality Assurance.		

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S000230	<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. Based upon document review and interview, the center lacked documentation of periodic utilization review by a group of at least three licensed physicians without financial interest in the center.</p> <p>Findings:</p> <p>1. On 4-22-13 at 1030 hours, staff A2 was requested to provide documentation of utilization review or peer review activity for 2012 and 2013 and no documentation was provided prior to exit.</p> <p>2. The Administrative Calendar indicated peer review was scheduled to be performed each February and August and documentation provided for review indicated the most recent peer review was</p>	S000230	<p>1. Facility implementing Electronic Medical Records. Walk through with company for computer software/hardware on 5/9/2013. Facility will be changing lab contract. Upon change, Miraca Life Sciences will be new contracted pathology lab. Peer review will be reported quarterly by new lab. MD will be reviewed and compared with 2,000 MDs which are with Miraca Life Sciences Laboratory. Three (3) licensed physicians with no financial interest in facility to provide utilization review. 2. Upon implementing Electronic Medical Records, reports will be generated by computer. 3. Administrative Assistant will be responsible for placing peer review reports in manual.</p>	05/09/2013

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	<p>performed on 2-19-10.</p> <p>3. During an interview on 4-24-13 at 1500 hours, staff A2 confirmed that no additional documentation of utilization or peer review was available.</p> <p>4. During an interview on 4-24-13 at 1630 hours, staff A1 confirmed that no documentation of recent peer review was available.</p>				

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S000310	<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 center failed to assure that contracted services were evaluated through its quality assurance (QA) program for 20 contracted services.</p> <p>Findings:</p> <p>1. The policy/procedure Continuous Quality Improvement (CQI) Plan (reviewed 7-12) failed to assure that all contracted services were evaluated through the QA program.</p> <p>2. The Contract Manual documentation Indirect Patient Care Vendors Statement of Quality Review for 20 contracted services (alarm monitoring, biomedical engineering, computer support, copier maintenance, endoscope service, generator service, heating/air conditioning, housekeeping, information technology, laboratory services, laundry services, medical record consulting,</p>	S000310	<p>1. All twenty (20) contract services have been added to Quality Assurance program. Contract service agreements will be maintained by Administrative Assistant. At the bottom of each Indirect Patient Care Vendors Statement of Quality Review form which reads: Contract Renewed, Administrative Assistant will initial and date. At bottom of page, Administrative Assitant will sign and date at time of review. Upon review of renewed contract, each individual contract will be listed one by one to state contract renewed through the Quality Assurance Program. 2. To prevent deficiency from recurring in future, contract service agreement will be noted upon renewal and review, instead of as needed and annually, through Quality Assurance minutes. 3. Administrative Assistant will be responsible for contract services and presenting to Quality Assurance/Risk Management committee.</p>	05/09/2013	

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	<p>medical and pharmacy supplies, medical transcription, medical waste disposal, pest control, pathology service, pharmacy consulting, waste disposal, water supplier) indicated that a review was conducted 7-15-11 and on 7-27-12 and failed to indicate a determination (recommend for renewal or non-renewal) by the responsible person.</p> <p>3. The Quality Assurance/Risk Management (QA/RM) minutes dated 8-31-12 indicated the following: "Contract Services/Agreements: Reviewed as needed and annually." The minutes failed to indicate that any contracted services were reviewed on 7-27-12 or indicate a recommendation for any service provider.</p> <p>4. During an interview on 4-23-13 at 1555 hours, staff A1 confirmed that the CQI Plan lacked a provision for including contracted services in the QA program and confirmed that the QA/RM minutes failed to document the periodic review and evaluation of each contracted service.</p>				

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S000320	<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 center failed to ensure that all functions including incident reports, medication errors, and fire drills were evaluated by the Quality Improvement (QI) program.</p> <p>Findings:</p> <p>1. The policy/procedure Continuous Quality Improvement (CQI) Plan (reviewed 7-12) indicated the following: " Incident Reports ...the minutes of this section should reflect a discussion of any new reports made since the last meeting. If there have been no new reports, the minutes should include a follow-up on previous reports ...Fire Drill Reports ...for each drill conducted, a Fire Drill Critique should be completed and the</p>	S000320	<p>1. Incident reports/Medication errors were placed incorrectly in book; Staff member has been shown correct placement in binder. New Safety Director will conduct and critique drill then have open discussion regarding the drill. Drill will be documented and placed in Safety Minutes and Quality Assurance minutes, respectfully.2. To prevent this deficiency from recurring in future, staff has been educated on proper placement of incident reports in specific binder marked "Incident Reports". Most current report on top. Incident reports not to be placed in folder section of manual binder. Fire drill reports will be documented and discussed at both Safety Meeting and Quality Assurance/Risk Management meeting. Minutes will be documented, respectfully.3. Safety Director will</p>	05/10/2013

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	<p>results of this drill should be discussed by the committee. "</p> <p>2. The Quality Assurance/Risk Management (QA/RM) minutes dated 8-31-12 indicated the following: " Medication Errors: 0 reported ...[and] ...Incident Reports: No report this month. "</p> <p>3. Center documentation indicated that 2 medication errors occurred 8-15-12.</p> <p>4. During an interview on 4-23-13 at 1555 hours, staff A1 confirmed that the QA/RM minutes dated 8-31-12 failed to document a review of the 2 medication errors.</p> <p>5. The Quality Assurance/Risk Management (QA/RM) minutes dated 9-30-12 indicated the following: " Incident Reports: No report this month ... [and]Fire Drill Reports: No drills this month. "</p> <p>6. Center documentation indicated that a breach of information privacy occurred 9-13-12 and an incident report was completed.</p> <p>7. Center documentation indicated that a fire drill inservice was conducted 9-07-12. No Fire Drill Critique was</p>		<p>be responsible for fire drill critique and documentation for Safety Minutes. Administrative Assistant will be responsible for Incident Reports and documentation through Quality Assurance minutes.</p>				

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	<p>observed regarding the drill/in-service.</p> <p>8. During an interview on 4-23-13 at 1555 hours, staff A1 confirmed that the QA/RM minutes dated 9-30-12 failed to document a review and discussion of a breach of information privacy or a fire drill and critique by the committee.</p>			

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S000328	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(b)</p> <p>(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:</p> <p>(1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.</p> <p>Based on document review and interview, the center failed to document the action taken and evaluation of the action for deficiencies identified by the quality assurance (QA) program for 1 contracted service.</p> <p>Findings:</p> <p>1. The policy/procedure Continuous Quality Improvement (CQI) Plan (reviewed 7-12) lacked a provision for evaluating the contracted services including the housekeeping services through the QA program.</p> <p>2. The document Statement of Quality Review for the housekeeping service provider V8 dated 7-27-12 failed to indicate any concerns under the headings: Problems Encountered with Service,</p>	S000328	<p>1. Administrative Assistant in 2012 did not document concerns in proper places: Problems encountered... New Administrative Assistant has been educated on proper documentation. Infection Control Nurse has been educated on documenting in Housekeeper Log Book of annual inspections and monthly inspections. Annual inspection completed and will be documented in respective meeting minutes.2. To prevent deficiency from recurring in future, proper documentation of ongoing monitoring and evaluation of housekeepers will be identified through Quality Assurance program.3. Infection Control Nurse will be responsible for evaluating and documenting concerns with housekeeping. Administrative Assistant will be responsible for documenting any meetings.</p>	05/10/2013			

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	<p>Actions to Resolve Problems, or Outcome of Action Plan.</p> <p>3. Review of the Quality Assurance/Risk Management (QA/RM) minutes for 2012 failed to indicate any performance issues with the housekeeping service provider.</p> <p>4. The Governing Board minutes and Medical Advisory minutes dated March 2012 indicated issues regarding the housekeeping service had resulted in a meeting with the medical director and indicated that a new cleaning crew was to begin in April.</p> <p>5. The Governing Board minutes dated 6-12-12, Medical Advisory minutes dated 6-13-12, and QA/RM minutes for June, July, and August 2012 failed to indicate that the housekeeping concerns were evaluated and ongoing or had been resolved.</p> <p>6. During an interview on 4-23-13 at 1555 hours, staff A1 confirmed that no additional documentation was available regarding the housekeeping service and confirmed that the QA program failed to document the ongoing monitoring and evaluation of the housekeeping provider V8 in response to identified concerns through the QA program.</p>						

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S000334	<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 center lacked a process for reporting a potential reportable event or a reportable event that was determined by the quality assurance (QA) program to have occurred at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 4-22-13 at 1030 hours, staff A2 was requested to provide documentation of the process for reporting events to the Indiana State Department of Health (ISDH) per State law 410 IAC 15-2.4-2.2(a)(2) and none was provided prior to exit. The policy/procedure Sentinel Event (reviewed 7-11-12) failed to indicate the following: <ol style="list-style-type: none"> the process and timeframe for reporting events determined by the QA program to have occurred to the ISDH the process for reporting a potential reportable event and timeframe to the ISDH the information to be reported (or not reported) During an interview on 4-22-13 at 1450 hours, staff A2 confirmed that the policy/procedure lacked the process for reporting events to the ISDH in accordance with State law 410 IAC 	S000334	<p>1. Policy for handling sentinel/reportable events has been updated to read: Notify Indiana State Department of Health upon conclusion of sentinel/reportable event via email and/or telephone within 15 days. The process for reporting a reportable event is stated clearly in the Quality Assurance/Risk Management manual Section 2, Page QA19A, Reportable Event Process. If reportable event occurs, then begin root cause analysis. Root cause analysis process in Quality Assurance/Risk Management manual Section 2, Page QA21.2. To prevent deficiency from recurring in future, policy has been approved by Medical Director and updated by Director of Nursing at the Medical Advisory meeting, then presented at th governing board meeting.3. Medical Director, Administrative Assistant, Quality Assurance/Risk Manager responsible upon occurrence of reportable event.</p>	05/08/2013	

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	15-2.4-2.2(a)(2). 4. During an interview on 4-23-13 at 1600 hours, staff A1 confirmed that the policy/procedure lacked the process for reporting events to the ISDH.				

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S000404	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(b)</p> <p>(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p> <p>Based on infection control plan review, committee meeting minute review, annual infection control report review, and staff interview, the facility failed to ensure that an active and effective infection control program was developed and implemented.</p> <p>Findings: 1. at 2:55 PM on 4/22/13, review of the Infection Control Manual indicated: a. the staff roster/committee member roster in the front of the manual shows that contracted staff member #55 (contracted "Infection Control Consultant"), was to conduct an "inspection of facility every 3 years..." b. the policy "Gluteraldehyde Testing Badges Protocol", with a last noted reviewed date of 1/2005 and an unknown policy number, indicated: A. under "Policy", it reads: "1. Annual testing of all personnel who work with gluteraldehyde disinfectant</p>	S000404	<p>1. Infection Control Consultant is no longer available. The Medical Director has approved the removal of the Infection Control Consultant from the committee roster. At the next Medical Advisory Board meeting, the Infection Control Consultant will be removed from the Committee roster and the the Governing Board will approve. The Infection Control Committee will monitor the infection control activities and the Infection Control Nurse will manage the infection control activities. The Infection Control Nurse will note at each Quality Assurance/Risk Management meeting each individual sterilization practice under infection control. Instead of ongoing and continuous (in which all sterilization practices are logged daily, weekly, and monthly in respective log books), the Infection Control Nurse will state all sterilization practices through the Quality Assurance/Risk</p>	05/15/2013			

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	<p>solutions..."</p> <p>2. at 2:30 PM on 4/23/13, review of the document "Quality Assurance/Risk Management", ORG 3, with no date noted, indicated:</p> <p>a. on page 5 (of 6), under "Infection Reports", it reads: "The infection control consultant should do an on-site review of the facility every three years to monitor whether proper sterile technique and cleaning procedures are being followed. She should issue a written report that reflects her findings and the committee should discuss steps to be taken to resolve any problems that are identified..."</p> <p>3. at 10:20 AM on 4/23/13, a letter/note in the Infection Control Manual dated January 4, 2008 indicated the last facility review was conducted 12/17/2007</p> <p>4. at 3:30 PM on 4/23/13, review of the document "Assay Technology" labs gluteraldehyde badge testing report indicated the last badge testing was performed 1/23/12</p> <p>5. interview with staff member #51, the director of nursing and infection control nurse, at 1:00 PM on 4/23/13, indicated:</p> <p>a. the gluteraldehyde badge testing is late, and should have been done in January of 2013, as per facility policy</p>		<p>Management program. The infection control communication log with housekeeping will be used for annual and monthly inspections. Inspections will be taken from log book and communicated through Quality Assurance/Risk Management program. Annual reports for Infection Control will be presented and approved by Medical Advisory Board and Governing Board. Gluteraldehyde Testing Badges protocol policy reviewed and approved by Medical Director on 5/15/2013. Monitoring to be done upon receiving respective badges shipment. 2. To prevent the deficiency from recurring in the future, the Medical Director, Infection Control Nurse, Medical Advisory Committee, and Governing Board will keep an administrative calendar to organize all meetings and activities of infection control program. All activities will be presented through the Medical Advisory Board, the Governing Board, Infection Control Committee, and the Quality Assurance/Risk Management program. 3. The responsibility will be the Infection Control Nurse and the Administrative Assistant.</p>				

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	<p>b. the contracted infection control consultant has not done a facility review since 2007, even though the policy indicates it is to be done every 3 years</p> <p>6. at 2:30 PM on 4/24/13, review of the meeting minutes for "Quality Assurance/Risk Management" for 12/31/12; 1/31/13; 2/28/13; and 3/29/13 each indicated the "Infection Control Report" read: "Infections control is ongoing and continuous" for each of the 4 meetings</p> <p>7. interview with staff member #51, the director of nursing and infection control nurse, at 2:45 PM on 4/23/13, indicated:</p> <p>a. the infection control processes have been combined with the quality assurance/risk management meetings, there is no separate/stand alone infection control committee</p> <p>b. this staff member monitors the cleaning and processing of scopes, the biologicals testing, autoclave use and testing, did handwashing observation 3 times in September and once in December, along with other duties that were not reported during the meetings listed in 6. above</p> <p>c. it cannot be determined, due to lack of documentation and reporting, that the facility infection control plan and policies are active and effective</p>			

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	<p>8. at 4:00 PM on 4/24/13, review of the 2011 and 2012 "Annual Infection Control Report" documents indicated:</p> <p>a. In 2011, the first three quarters listed "Daily logs kept with [contracted housekeeping provider] for communication issues. Ongoing verbal communication with new RN's (registered nurses)"</p> <p>b. the fourth quarter note for 2011 read: "Vaccine purchased for Dr..., staff and family members of staff. See personnel files for vaccination logs. Ongoing daily."</p> <p>c. the notes for the first quarter of 2012 read: "Discussion for TB (tuberculin) testing to be performed in March. Daily logs kept with [contracted housekeeping provider] for communication issues. Ongoing verbal communication with new RN's regarding infection control."</p> <p>d. the second quarter report indicated: "Daily logs kept with [contracted housekeeping provider] for communication issues. Ongoing verbal communication with new RN's regarding infection control."</p> <p>e. 3rd quarter read: "Ongoing communication with [contracted housekeeping provider] with spiral notebook."</p> <p>f. 4th quarter stated: "Vaccine purchased for Dr..., staff and family</p>						

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	<p>members of staff. See personnel files for vaccination logs. Ongoing daily."</p> <p>9. Interview with staff member #51, the director of nursing and infection control nurse, at 4:30 PM on 4/24/13, indicated:</p> <ul style="list-style-type: none"> a. the communication/spiral notebook kept for ongoing discussion/contact with the housekeeping company only lists needs, such as "low on paper towels" (or toilet paper), etc. b. the spiral notebook used for communication with the housekeeping provider does not constitute infection control issues, measures, surveillance, etc. c. "ongoing daily" does not indicate measurable, quantifiable infection control standards/practices/processes d. this staff member monitors sterilization practices and biologicals, but does not report on them e. the 2011 and 2012 annual reports were not presented to the quality assurance/risk committee, the medical staff, or the governing body f. the 2011 and 2012 annual reports for infection control do no meet the requirements of an active/effective infection control program 						

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S000408	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(d)</p> <p>(d) The center shall designate a person qualified by training or experience as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases. Based on employee file review and staff interview, the facility failed to ensure specifications and qualifications of the infection control nurse (staff member #51).</p> <p>Findings:</p> <p>1. at 1:50 PM on 4/22/13, review of personnel files indicated staff member N1 (the designated infection control nurse):</p> <p>a. lacked documentation of any infection control training in surveillance, data gathering, or other infection processes related to serving as the infection control practitioner for the facility</p> <p>b. had a job description in the file for "Director of Nursing" that indicated on page 2, under "Job Relationships": "...May serve as Nursing Representative on Quality Assurance, Infection Control an Medical Advisory Committees..."</p> <p>c. lacked a job description that would state the specific duties to be performed related to the position of infection control</p>	S000408	<p>1. Corrected job description for Infection Control Nurse designee placed in personnel file. MD has been providing periodicals for Infection Control Nurse to review for additional training. Upon review, copies of periodicals will be placed in personnel chart by Administrative Assistant. Upon completion of a webinar or website infection control training, any certifications will be placed in Infection Control Nurse's personnel chart. Infection Control Nurse will provide Quality Assurance committee with weekly biological outcomes, daily autoclave results, metricide strip results for each scope, and handwashing surveillance results.2. To prevent deficiency from recurring in future, Infection Control Nurse will create checklist of above mentioned results to provide to Quality Assurance Committee.3. Infection Control Nurse will be responsible for providing information. Director of Nursing will be responsible for placing job description for Infection Control Nurse designee</p>	05/08/2013			

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	nurse/practitioner 2. interview with staff member N1 (also #51), the infection control nurse, at 2:30 PM on 4/22/13 indicated: a. this staff member was assigned as the infection control designee/nurse in December 2012 b. it was thought that the "Director of Nursing" job description, that indicated they participate/serve on the specified committees, worked for an infection control nurse job description c. the Infection Control Plan has a job description titled "Infection control Nurse Designee" that is pages 4 and 5 of the plan d. the infection control nurse employee file is lacking a copy of the "Infection control Nurse Designee" job description e. this staff member has researched some periodicals to order literature for review for extra training, but hasn't begun this to date f. no webinars or other infection control practitioner training has been accomplished since the December 2012 designation as infection control nurse		in personnel file.		

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S000414	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1)</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>Based on review of the infection control plan, committee meeting minutes, and staff interview, the facility failed to ensure that the physician participated in infection control activities and committee meetings as required by policy.</p> <p>Findings: 1. at 2:55 PM on 4/22/13, review of the "Infection Control Plan" indicated: a. on page 2 under section "A.</p>	S000414	<p>1. Facility Administrator/Medical Director signs all committee meetings and infection control activities. To correct this deficiency under staff present, facility MD name will be included in facility MD meetings.2. To prevent deficiency from recurring in future, facility MD will sign minutes and be noted as present at each of his meetings.3. Administrative Assistant will be responsible for attendance of each meeting.</p>	05/09/2013			

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	<p>Committee Membership", that: "Committee members will include...2. Nursing staff and Dr..."(staff member #53)</p> <p>2. at 2:30 PM on 4/24/13, review of the meeting minutes for "Quality Assurance/Risk Management" for 12/31/12; 1/31/13; 2/28/13; and 3/29/13 indicated:</p> <p>a. listed as "Staff Present" was nursing staff</p> <p>b. the physician was not listed as being present at these 4 meetings</p> <p>3. interview with staff member #51, the director of nursing and the infection control nurse, at 2:45 PM on 4/23/13, indicated:</p> <p>a. the infection control processes have been combined with the quality assurance/risk management meetings, there is no separate/stand alone infection control committee</p> <p>b. the physician signed off on all four of the committee meetings listed in 2. above, but is not listed as being in attendance and his signature was not dated</p> <p>c. it cannot be determined, by the documentation provided, that the facility physician was present at the quality assurance (which includes infection control) meetings and that he participates in infection control processes of the</p>			

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S000526	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed. Based on policy and procedure review, review of 4 RN (registered nurse) employee files, and staff interview, the facility failed to ensure the orientation and skills competency check of one newly hired nurse (7/2/12 =N3), and the annual lab competency check, related to blood glucose testing, for one other RN (N1).</p> <p>Findings:</p> <p>1. at 12:30 PM on 4/22/13, review of the policy and procedure "Bayer Contour Blood Glucose Monitoring System", policy PG.35A, with a date of 3/9/09, indicated:</p> <p>a. on page two under "Testing Using the Contour Blood Glucose Monitoring System", it reads in item #13.: "Competency will be done on a yearly basis. All new R.N. employees must complete competency."</p> <p>2. at 1:50 PM on 4/22/13, review of personnel files indicated:</p> <p>a. staff RN N3 was hired on 7/2/12 and was not signed off for Glucometer</p>	S000526	<p>1. All RNs have Glucometer competency skills yearly. Competency for Bayer Contour Blood Glucose Monitoring System completed on 4/22/2013. 2. Director of Nursing will be responsible for completing competency for Bayer Contour Blood Glucose Monitoring System in RNs' personnel charts. 3. Administrative Assistant will notify Director of Nursing of upcoming competency due dates in RN personnel charts.</p>	04/24/2013			

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	<p>competency until the first survey date of 4/22/13</p> <p>b. staff RN N1 had a most recent annual Glucometer competency/skills form signed 11/11, (but had another staff member sign off on it while the survey was in progress at 3:55 PM on 4/22/13)</p> <p>3. at 4:00 PM on 4/22/13, interview with staff member #51, the director of nursing, indicated:</p> <p>a. annual competency is expected related to Glucometer testing, per policy</p> <p>b. the newly hired RN, N3, lacked completed Glucometer competency documentation that should have been done with orientation in July 2012</p> <p>c. the Glucometer competency for this staff member (N1/#51) was due to have been completed in October of 2012</p>				

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S000616	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(3)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(3) The center shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the center and medical staff policies.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to implement its policy related to the authentication of medical record entries for 20 of 20 records reviewed (#1 through #20).</p> <p>Findings: 1. at 2:05 PM on 4/24/13, review of the policy: "Policy and Procedure for Identification of Authors and Authentication of Medical Record Entries", policy MR-6 with a date of 7/11/12, indicated: a. under "Purpose", it reads: "To provide a method for verifying and identifying the authentication of all entries in the medical record..." b. under "Procedure:...II.</p>	S000616	<p>1. Full signature at bottom of pre-operative order will be signed by physician. RNs will sign and date pre-operative orders.2. All RNs and physician educated regarding pre-operative orders. To prevent deficiency from recurring in the future, when finalizing medical records at the end of day, staff will check medical records for accuracy.3. All RNs and physician responsible for signing and dating pre-operative orders.</p>	05/14/2013			

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	<p>Authentication of Signatures", it reads: "...1. A full signature, including first initial last name, and discipline; or 1. Written initials if full signature appears on the same page; or..."</p> <p>2. review of patient medical records #1 through #20 indicated all pre operative standing order pages: a. lacked a date and time of the order b. lacked a full signature of the physician anywhere on the order page c. had only initials of the physician used as authentication of the pre op orders</p> <p>3. interview with staff members #51, the director of nursing, and # 53, the physician, at 4:00 PM on 4/24/13, indicated: a. there is no "full signature" on the pre operative order page for any of the 20 patient medical records b. the physician is only authenticating pre operative orders with initials, which is not per facility policy</p>			

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S000710	<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> <p>(iii) Drug Enforcement Agency registration showing number as applicable.</p>						

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	<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 the medical staff credential files included documentation of current hospital appointment and privileges for 1 credentialed staff at the center.</p> <p>Findings:</p> <p>1. The medical staff policy procedure Medical Staff Application (approved 8-08) indicated the following: "Obtain confirmation of hospital medical staff affiliation and related privileges from</p>	S000710	1. St Vincent Carmel Hospital Medical Staff Affairs Department contacted, verification letter faxed to facility on 4/24/2013. Letter dated 8/2/2012 with reappointment on 7/12/14. Letter placed in credentials manual on 5/10/2013.2&3. Administrative Assistant will be responsible for this deficiency not recurring in the future. Administrative Assistant will have running calendar for administrative duties to be completed.	05/10/2013			

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	<p>hospitals indicated in the application."</p> <p>2. The credential file for A1 failed to indicate documentation of privileges to perform surgical procedures at a hospital located within the same county or adjacent to the county where the Surgery Center is located.</p> <p>3. During an interview on 4-24-13 at 1500 hours, staff A2 confirmed that the credential file lacked documentation of current hospital privileges.</p>			

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S000732	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p> <p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially. Based upon document review and interview, the medical staff failed to ensure that its bylaws, rules and regulations were reviewed at least triennially.</p> <p>Findings:</p> <p>1. On 4-22-13 at 1030 hours, staff A2 was requested to provide documentation indicating that the medical staff had reviewed its medical staff bylaws, rules and regulations within the past 3 years and none was provided prior to exit.</p> <p>2. Review of the Medical Staff Bylaws, Rules and Regulations (approved 8-08) failed to indicate a provision ensuring that the bylaws would be periodically reviewed by its medical staff at least triennially.</p> <p>3. The medical staff meeting minutes for June and September, 2011 failed to indicate that the medical staff bylaws had been reviewed or revised and approved by the medical staff.</p>	S000732	<p>1. Future documentation for reviewing, revising, and approving medical staff bylaws will be documented triennially. Next Governing Board meeting scheduled for June, 2013. Review, revision, and/or updates will be approved at meeting. 2. Administrative Assistant will present any review and revision to the Medical Advisory Board and the Governing Board. 3. Administrative Assistant will be responsible.</p>	06/17/2013			

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	4. During an interview on 4-23-13 at 1445 hours, staff A2 and A6 confirmed that the medical staff bylaws, rules and regulations had not been reviewed and approved by the medical staff within the past 3 years.			

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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 bylaws lacked a requirement for quarterly medical staff meetings.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 8-08) indicated the following: " The Medical Advisory committee shall act on behalf of the Medical Staff ...pursuant to the Medical Staff Bylaws and Rules and Regulations. The Medical Advisory Committee shall meet at least semi-annually ... " The bylaws failed to indicate a quarterly minimum frequency for holding a medical staff or medical advisory committee meeting.</p> <p>2. Center documentation indicated that a Medical Advisory committee meeting was</p>	S000736	<p>1. Facility has updated and approved revision of Medical Staff By-Laws to read: The Medical Advisory Committee shall meet at least quarterly... Change of policy will be presented at the next Medical Advisory Committee meeting and presented at the next Governing Board meeting.2. To prevent this deficiency from recurring in the future, the Administrative Assistant will manage an administrative calendar for all committee meetings.3. Administrative Assisnat will be responsible for maintaining policy and procedure manuals.</p>	05/15/2013	

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	<p>held on 6-13-12, 9-14-12, 12-14-14 and 4-22-13.</p> <p>3. During an interview on 4-23-13 at 1445 hours, staff A2 confirmed that the medical staff bylaws failed to indicate a quarterly attendance requirement for holding a medical staff or medical advisory committee meeting and confirmed that no medical staff meeting was held in the 1st quarter 2013.</p>				

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S000930	<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 policy and procedure review, employee file review, other document review, and staff interview, the facility failed to implement its policy related to biannual education for 2 of 2 RNs (registered nurses) hired prior to 2012 (N1 and N2); and failed to implement its policy indicating staff education on "clostridium difficile" will occur for 4 of 4 RNs (N1 through N4).</p> <p>Findings:</p> <p>1. at 2:55 PM on 4/22/13, review of the infection control manual indicated:</p> <p>a. a document titled: "Infection Control and Aseptic Technique Education" (no policy number) with a date of April 11, 2008, which read under "Policy": "The inservice program will provide at least two annual programs concerning infection control and aseptic technique."</p> <p>b. a document titled: "Targeted</p>	S000930	<p>1. C. Diff article from CDC website and Target Risks/Goals provided to RNs for Inservice Education on 5/15/2013. All RNs to read article by 5/16/2013. Inservice will be reviewed at Infection Control Committee meeting.2. To prevent this deficiency from recurring in the future, the Infection Control Nurse will place infection control inservice on administrative calendar biannually. Articles from CDC, Becker's Clinical Quality and Infection Control, etc will be provided to staff for education.3. Infection Control Nurse will be responsible for researching articles and providing staff with educational material regarding infection control.</p>	05/16/2013			

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	<p>Risks/Goals" (no date or policy number), that reads under "Strategies for reducing Risk": "1. Educate staff on clostridium difficile, transmission and prevention..."</p> <p>2. review of 4 RN employee files indicated:</p> <p>a. RNs N1 and N2 were hired 5/14/08 and 11/16/10, respectively, and lacked documentation of biannual infection control or aseptic technique education</p> <p>b. all 4 RNs (N1 through N4) lacked documentation of education related to clostridium difficile</p> <p>3. review of the education binder on 4/24/13 indicated:</p> <p>a. the last document of staff education related to "Infection Control" was on 10/1/10 and was information about the influenza vaccine</p> <p>4. interview with staff member #51, the director of nursing and infection control nurse, at 3:20 PM on 4/24/13, indicated:</p> <p>a. it was unknown that there was an expectation for biannual (two times/year) infection control/aseptic technique education for staff</p> <p>b. biannual education has not been completed</p> <p>c. the last documented infection control education was the 10/1/10 document in the education file</p>			

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	d. no education documentation related to clostridium difficile can be found				

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S001004	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(1)</p> <p>Pharmaceutical services must have the following:</p> <p>(1) A designated professional person with prescriptive authority, or a pharmacist, who is responsible for the control of drug stocks in the center. Based upon document review and interview, the center failed to designate a professional with prescriptive authority or a pharmacist as the responsible person for the control of drug stocks.</p> <p>Findings:</p> <p>1. The Governing Board minutes dated 12-13-12 indicated the following: " The pharmacy consultant ...retired in October 2011 ...After a discussion with the Governing Board, it was decided that we will no longer have a pharmacy consultant. " The governing board failed to designate a professional with prescriptive authority as the responsible person for the center drug stocks in the absence of a pharmacist consultant.</p> <p>2. During an interview on 4-22-13 at 1145 hours, staff A2 indicated that no pharmacy consultant has been available since 2011. Staff A2 was requested to provide documentation of an appointment by the medical advisory committee or governing board of a responsible person with prescriptive authority and none was</p>	S001004	<p>1. Medical Director has been appointed as the designated professional person with prescriptive authority as the responsible person for the center's drug stocks due to the inability of employing a pharmacy consultant.2. To prevent this deficiency from recurring in the future, the Medical Director will be responsible for the center's drug stocks. The new appointment will be approved at the next medical advisory meeting and Governing Board meeting.3. Medical Director will be responsible for center's drug stocks.</p>	05/15/2013			

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	<p>provided prior to exit.</p> <p>3. During an interview on 4-24-13 at 1630 hours, staff A1 confirmed that the center failed to designate a professional with prescriptive authority as the responsible person for drug stocks in the center.</p>			

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S001146	<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 policy and procedure review, observation, and interview the facility failed to ensure that no condition might be created that could result in a hazard to patients in relation to an unknown expiration date for the control solution for the glucometer machine, and expired IV (intravenous) solutions and patient care products.</p> <p>Findings: 1. at 12:30 PM on 4/22/13, review of the policy and procedure "Bayer Contour Blood Glucose Monitoring System", policy PG.35A, with a date of 3/9/09, indicated: a. under "Important Facts about Monitor", it reads in item #5. "Check the expiration dates on your test strips and control solution. Check the printed date on the bottles as well as the date of</p>	S001146	<p>1. The Bayer Contour Blood Glucose monitoring system policy was placed in log book. Strips and control solution were dated and six month expirations noted on bottles, respectively. The four NACL 250 ml IV bags were disposed of. The 30 mL multidose vial of Morruate Sodium was disposed of and taken off master formulary. All items mentioned on S1146 #4 A through E have been disposed of by proper method.2. Medical supply cabinet has been cleaned. All inventory will have expiration date facing out for easy check off. RNs re-educated on Bayer Contour Blood Glucose Monitoring System. Upon opening new control solution and/or test strips, dates will be marked with open and expiration dates. New lot number will be documented in log book under column marked "strip" and "control solution", respectfully.3. Pharmacy RN to</p>	05/08/2013			

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	<p>expiration. The test strips and control solution expire six months once opened..."</p> <p>2. at 12:30 PM on 4/22/13, it was observed that the glucometer control (Normal control solution) solution lacked documentation of a 6 month expiration date (to be noted upon opening the new vial)</p> <p>3. at 11:55 AM on 4/23/13, while on tour of the nursing medication area of the facility in the company of staff member #50, a staff RN (registered nurse), it was observed in a drawer that:</p> <p>a. four 0.9% NACL (sodium chloride) 250 ml IV bags expired 3/13</p> <p>b. one 30 ml multi dose vial of Morruate Sodium expired 10/12</p> <p>4. at 12:35 PM on 4/23/13, while on tour of the storage room in the company of staff member #51, the director of nursing, it was observed that:</p> <p>a. one box of >20 Terumo insulin syringes (29 gauge x 1/2 inch--3/10 cc) had expired 10/09</p> <p>b. one box of >50 Integra precision glide needles (25 G 5/8 inch) expired 8/12</p> <p>c. one box of 30 BD safety glide injection needles (25 G 5/8) expired 7/11</p> <p>d. one full box of 50 Prospore @ Biological Indicators expired 12/11</p>		<p>be responsible for maintaining look book along with all RNs who use Bayer Contour Blood Glucose Monitoring System.</p>				

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	<p>e. one box of >35 BD Eclipse injection needles (25G by 1 inch) expired 5/12</p> <p>5. interview with staff member #51, the director of nursing, at 12:30 PM on 4/22/13 and 12:40 PM on 4/23/13 indicated:</p> <p>a. it cannot be determined when the glucometer control solutions were opened, or when the six month expiration date is because staff did not write a date on the opened vial</p> <p>b. the test strips were noted as opened in 2/13 on the control log, but the opening of the control solution is not documented on this log</p> <p>c. the items listed in 3. and 4. above were expired as noted</p> <p>d. the Morruate Sodium was "on order" as a back ordered item</p>			

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S001182	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(2)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Based on document review and interview, the center failed to establish an ongoing, center-wide process for assessing and evaluating hazards and safety practices by a committee.</p> <p>Findings:</p> <p>1. Safety committee minutes for 2012 and 2013 failed to indicate the following:</p> <p>A. the date and time of each meeting B. staff that attended the meeting C. staff that did not attend the meeting D. discussion of the subject areas reviewed E. recommendations for the reported subject areas F. committee actions to correct and improve center safety G. follow-up reporting for committee actions</p> <p>2. During an interview on 4-23-13 at</p>	S001182	<p>1. Safety Committee meeting minutes will have date, time, number of staff present, staff that did not attend the meeting, discussion of subject ares, recommendations for the reported subject areas, committee actions to correct and improve center safety, and follow-up reporting for committee actions.2. To prevent the deficiency from recurring in the future, the Safety Director will conduct safety meetings with evaluations of safety issues and practices at the facility.3. The person responsible for safety practices is the Safety Director, during next safety meeting in June 2013.</p>	06/17/2013			

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	1340 hours, staff A6 confirmed that the safety committee failed to hold meetings associated with the committee minutes and evaluate safety issues and practices at the center.				

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S001188	<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 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 maintain and follow its policy/procedure for conducting quarterly fire drills for 3 of 5 required drills.</p> <p>Findings:</p> <p>1. The policy/procedure Fire Drill (revised 4-12) and the Environment of Care and Safety Manual heading Emergency Management Drills (approved 1-12) lacked a provision for quarterly fire drills and lacked a provision that an audible fire alarm will sound when</p>	S001188	<p>1. New Safety Director will be properly trained on conducting fire drills. Fire drills will be conducted quarterly with audible signal. Alarm company and proper authorities will be notified of drill. A "Fire Drill Observation Evaluation" form will be filled out at the conclusion of each drill. Attendance will be tracked for each employee. 2. Fire drills will be noted on administrative calendar quarterly by Administrative Assistant to prevent their deficiency from recurring in the future. 3. Safety Director will be responsible for holding fire drills and contacting the alarm agencies for notification of drill.</p>	06/17/2013			

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	<p>conducting a fire drill per NFPA 101, 2000 Edition Chapter 21.7.1.2 NFPA 101, 2000 Edition Chapter 21.7.1.2 indicates the following: [Fire exit drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with signals and emergency action required under varied conditions ...]</p> <p>2. The policy/procedure Fire Drill (revised 4-12) and the Environment of Care and Safety Manual heading Emergency Management Drills (approved 1-12) lacked a provision for notifying the alarm monitoring service prior to conducting the drill or sounding the alarm during the drill performance.</p> <p>3. Center documentation failed to indicate that an alarm was sounded or heard during the Inservice Education Roster titled fire drill performed 9-07-12 or 4-18-13. The documentation failed to indicate the time that the drill was</p>			

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>conducted and failed to indicate that all center staff participated in the drill. The documentation failed to indicate that a fire drill was conducted in the 2nd quarter 2012, 4th quarter 2012 or the 1st quarter 2013.</p> <p>4. During an interview on 4-23-13 at 1030 hours, staff A6 confirmed that the fire drill policy lacked a provision for sounding the alarm or conducting quarterly fire drills. A6 confirmed that the Inservice Education Fire Drill dated 9-07-12 and 4-18-13 failed to indicate the time that the drill was conducted or that all staff participated in the Inservice/Fire Drill.</p> <p>5. During an interview on 4-23-13 at 1335 hours, staff A6 confirmed that the Inservice Education Fire Drill conducted 4-18-13 did not include sounding the alarm and confirmed that no fire drill was performed for the 2nd quarter 2012, 4th quarter 2012 and 1st quarter 2013.</p>				

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S001198	<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 coordinate its emergency preparedness program and document its participation with community, state and/or federal emergency and disaster preparedness agencies.</p> <p>Findings:</p> <p>1. On 4-22-13 at 1030 hours, staff A2 was requested to provide documentation of participation with community, state and/or federal emergency and disaster preparedness agencies and no documentation was provided prior to exit.</p> <p>2. During an interview on 4-23-13 at 1515 hours, staff A6 confirmed that no documentation was available regarding participation with District 5 disaster management events or quarterly district 5 meetings.</p>	S001198	<p>1. District 5 emailed on 4/24/2013 at 1411 regarding emergency preparedness.2. Upon contact from District 5, Administrative Assistanct will document participation with District 5.3. Safety Director will be responsible for documenting and coordinating emergency preparedness program.</p>	06/17/2013

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