

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001131		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/25/2012	
NAME OF PROVIDER OR SUPPLIER ELKHART CLINIC ENDOSCOPY AND SURGERY CENTER LLC				STREET ADDRESS, CITY, STATE, ZIP CODE 2117 W LEXINGTON AVE ELKHART, IN 46514			
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Q0000	<p>The visit was for a re-certification survey.</p> <p>Facility Number: 003903</p> <p>Survey Date: 01-23-12 to 01-25-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 02/02/12</p>	O0000	3/8/12				

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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Q0082	<p>416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES</p> <p>(b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>(b)(2) The ASC must use the data collected to -</p> <p>(i) Monitor the effectiveness and safety of its services, and quality of its care.</p> <p>(ii) Identify opportunities that could lead to improvements and changes in its patient care.</p> <p>(c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>Based on document review and interview, the center failed to ensure that services were monitored for effectiveness and safety using standards for contracted services provided at the facility.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Assessment / Performance Improvement (QAPI) Plan (approved 4-10) failed to describe a process for documenting and reporting the ongoing evaluation of contracted services. The Plan failed to</p>	O0082	<p>1. The policy QAPI Plan was updated and approved 2/17/12 to include: a description of the process for documenting and reporting the ongoing evaluation of contracted services (dashboard with specific criteria, data maintained from quarter to quarter); an indication of frequency (quarterly) for evaluation of each service. 2. The new dashboard tool includes specific measurable criteria for a quarterly evaluation of services. The report shall be provided to the QAPI Team, MAC committee, and Board of Managers</p>	02/17/2012			

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	<p>indicate a minimum frequency for evaluation sampling of each service using the QAPI Monitoring Tool.</p> <p>2. Review of three (one pharmacist, one radiologist, and one medical records consultant) QAPI Monitoring Tool documents failed to indicate standards for evaluating each service and failed to ensure that 'additional relevant information' recorded on the monitoring tool could be reviewed over multiple periods for ongoing development of the standards in use for monitoring each service. 'Additional relevant information' observed on the radiologist consultant QAPI Monitoring Tool (dated 1-19-12) indicated a plan of action in response to information not reviewed by the consultant being evaluated. No other QAPI Monitoring Tools for contracted services were provided or observed prior to exit.</p> <p>3. The QA/PI Dashboard for Services reports failed to indicate service standards applied to each contracted services provider and failed to distinguish internal processes from a contracted service provision.</p> <p>4. During an interview on 1-18-12 at</p>		<p>quarterly. The policy update was approved by the BOM 2/17/12.3. The Administrator is responsible for numbers 1 and 2 above.4. The policy is updated and approved as of 2/17/12. The Administrator will begin following the updated policy immediately. The policy will be provided to staff the week of 2/20/12. The updated Services dashboard report shall be completed for Quarter 1 2012 by the Administrator and provided to the QAPI Team at the 2 nd quarter meeting. The report shall be provided to the MAC and BOM with 1 st quarter results during the 2 nd quarter at regularly scheduled meetings.</p>		

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	1715 hours, staff #A1 confirmed that the QAPI documentation lacked standards for monitoring the safety and effectiveness of each contracted service. Staff #A1 indicated that the QA/PI Dashboard lacked a means to identify and document opportunities that could lead to improvements with the services and contracted services provided at the center.				

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Q0106	<p>416.44(d) EMERGENCY PERSONNEL Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.</p> <p>Based on policy and procedure review, personnel file review, and staff interview, the facility failed to ensure that personnel with appropriate training, related to PALS (pediatric advanced life support) certification and care of pediatric patients, was lacking for 2 of 3 RNs (registered nurses). (P4 and P6)</p> <p>Findings:</p> <ol style="list-style-type: none"> at 1:00 PM on 1/24/12, review of the "Job description: Pre/postoperative registered nurse" indicated under "Requirements": "...Preferred 1. PALS certification... review of personnel files during the 1/23/12 to 1/25/12 survey process, indicated there was no documentation of PALS certification for RNs P4 and P6 interview with staff member NA at 1:00 PM on 1/24/12 indicated: <ol style="list-style-type: none"> only pre/post op nurses are required to have PALS both P4 and P6 work in the pre/post op areas at times (staff are "cross trained") interview with staff member NA at 	00106	<ol style="list-style-type: none"> The deficiency has been corrected through policy update on 2/17/12 of policy "New Employee Orientation," which specifies nursing staff new to the center shall have 9 months from the date of hire to complete ACLS and PALS certification. During this time, certified nursing staff (in PALS and ACLS) shall be present in the center whenever patients are present. The two nurses uncertified in PALS shall become certified. The updated policy shall be provided to staff at the staff/unit meeting the week of 2/20/12. The deficiency shall be prevented in the future through compliance with the updated policy. The ASC Supervisor shall track completion of ACLS and PALS within the specified time frame for new RN employees. QA audits of new RN employee personnel files shall be performed; any nurse lacking PALS or ACLS certification 9 months from date of hire shall be required to become certified as soon as possible. The ASC Supervisor and ASC Administrator shall be responsible for 1 and 2 above. The deficiency shall be completed by 3/08/12. 	03/08/2012

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	<p>3:20 PM on 1/25/12 indicated:</p> <ul style="list-style-type: none"> a. pediatric surgical patients could be at risk for safety with the lack of PALS certified nursing staff b. the RN job description should have PALS certification as a required skill, and not a "preferred" skill 			

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Q0162	<p>416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:</p> <ol style="list-style-type: none"> (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to implement its policy related to legible and complete medical records for 10 of 16 charts reviewed(pts. N1, N2, N4, N5, N6, N7, N8, N9, N13 and N16) and failed to ensure the accuracy of patient medical records for 4 of 16 charts reviewed. (N1, N11, N12 and N13)</p> <p>Findings: 1. at 12:15 PM on 1/25/12, review of the policy and procedure "Medical Record Content and Requirements" with a last revision date of 11/2009, indicated:</p>	Q0162	1. The deficiency shall be corrected by re-orienting staff and physicians to policy "Medical Record Content and Requirements," with specific attention to inaccurate documentation noted in the survey: consistent documentation of one ASA classification per patient per date of service across several patient records as documented by several healthcare providers, and; consistent documentation of the anesthesia plan across several patient records as documented by several healthcare providers. The Advance Directive policy has been updated as on 2/17/12 to reflect the approved method of	03/08/2012			

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	<p>a. under "Policy", it reads: "A medical record shall be maintained for each patient, which is accurate, legible, complete and comprehensive to ensure adequate patient care,..."</p> <p>b. under "Content", it reads: "Accurate and complete medical records are written for all patients;..."</p> <p>c. under "Legibility of Record", it reads: "...All entries in the medical record shall be legible to individuals other than the author..."</p> <p>2. review of patient medical records through out the survey process of 1/23/12 to 1/25/12, indicated:</p> <p>a. pts. N1, N4 and N5 lacked indication that the lungs were examined as part of the "Physical Examination" performed by the surgeon on 1/14/11 on the "GI Lab Physician History & Physical/Orders" form</p> <p>b. pt. N1 had an ASA (American Society of Anesthesiologists) level of 2 circled in the "Anesthesia Physical Exam" section at the bottom of the page on the "GI Nursing Assessment" form, but had an ASA Classification of 3 marked on the "GI Procedure Nursing Record" form and had an ASA of "II" marked on the "Anesthesia Record" form</p> <p>c. pt. N2 had a write over in the IV (intravenous) section of the "Pre-op Record/Patient Physical" form related to</p>		<p>marking medical records/charts containing Advance Directives, and the location/form where nursing staff records information regarding Advance Directives obtained during the preoperative assessment. Staff shall be educated on the policy changes and the importance of accuracy in documenting whether or not Advance Directives are present in patient charts. Staff shall be re-educated on the facility-approved method of error correction per policy. Physicians shall be re-educated on the requirement in medical staff bylaws that a physician shall perform a focused physical exam including pre-anesthetic risk assessment just prior to the scheduled procedure. The form "Anesthesia Record" has been modified to allow the user to mark that the anesthesia machine equipment is checked prior to the procedure when the procedure is being performed in OR 1 or OR 2. Education to the forms and policies shall be provided to the staff at a staff/unit meeting the week of 2/20/12 and provided via email and in person to medical and AHP staff. 2. The deficiency shall be prevented in the future by performing random QA audits on charts marked Advance Directive, and of patient records to determine that ASA and anesthesia plans have been recorded consistently by different providers across several records</p>				

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	<p>the IV site</p> <p>d. pts. N5, N8 and N13 lacked documentation of a pre anesthesia evaluation with ASA (American Society of Anesthesiologists) selection prior to colonoscopy by the surgeon (on the "GI Nursing Assessment" form--bottom of page where "Anesthesia Physical Exam, ASA level and anesthesia plan" are documented with the practitioner's signature line)</p> <p>e. pt. N6:</p> <p>A. lacked documentation of the anesthesia plan selection on the "GI Nursing Assessment" form--bottom of page (a general anesthesia box was checked at the top of the "Anesthesia Record" form)</p> <p>B. lacked documentation of "machine checked" on the "Anesthesia Record" form</p> <p>f. pt. N7:</p> <p>A. had documentation by the surgeon that the "Heart" examination was "Deferred" on the "Physician H & P /Orders" form on 11/23/11, the day of surgery for this 6 year old</p> <p>B. had 7 write overs in the "Post op Vital Signs" area, write overs in the IV section (3), 5 write overs in the "Aldrete Scoring System", and 2 write overs in the lower section of the "PACU Record" form (post anesthesia care unit = PACU)</p> <p>g. pt. N9 lacked documentation of</p>		<p>for the same patient and encounter. Physical exams shall be checked and anesthesia records checked to ensure it is documented that equipment is checked in OR 1 or OR 2. Deficiencies shall be noted and corrected; individuals shall be re-educated on the policies wherever necessary. 3. The Administrator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>		

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	<p>"machine checked" on the "Anesthesia Record" form</p> <p>h. pt. N11 had a "General" anesthesia consent form in the record, had "General" anesthesia circled in the "Anesthesia Physical Exam" section of the "Pre-op Record/Patient Physical" form, and had general anesthesia documented on both the "Intra-Operative Nursing Record" form and the "Anesthesia Record" form, but had "MAC" (monitored anesthesia care) listed as the "Anesthesia" provided to the patient on the dictated operative report by the surgeon</p> <p>i. pt. N12 had an advance directive document in the chart and an "Advance Directive" sticker on the front of the chart, but had documentation by staff on the "Pre-op Record/Patient Physical" form that the patient had no Advance Directive</p> <p>j. pt. N13 had documentation by staff on the "Pre-op Record/Patient Physical" form that the patient had an Advance Directive, but lacked an "Advance Directive" sticker on the front of the chart--no Advance Directive was found in the chart, making it unknown as to whether or not the patient had an Advance Directive, or not</p> <p>k. pt. N16:</p> <p>A. lacked documentation of the anesthesia plan selection on the "GI Nursing Assessment" form--bottom of page</p> <p>B. had a write over in the Fentanyl</p>						

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	<p>order of the "Anesthesia Pre and Post Op Orders" form</p> <p>C. had a write over in the patient's temperature documentation in the "Discharge" box at the top of the "Post-Op Record" form</p> <p>3. interview with staff member NA and NH at 2:50 PM and 3:20 on 1/25/12 indicated:</p> <p>a. medical records are incomplete or illegible as stated in 2. above</p> <p>b. there are some inaccuracies in the medical record as stated in 2. above</p> <p>c. there is no policy and procedure related to how to document whether a patient has an Advance Directive or not</p> <p>d. the only document related to the Advance Directive stickers on the chart was a May 19, 2009 e-mail to staff by staff member NA indicating an Advance Directive sticker is to be placed on the front of the chart for each patient who, in fact, has an Advance Directive</p>				

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Q0225	<p>416.50(a)(3)(i), (v), (vi), (vii) SUBMISSION AND INVESTIGATION OF GRIEVANCES</p> <p>(i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.</p> <p>(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.</p> <p>(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.</p> <p>Based on document review and interview, the center failed to ensure that the investigation of grievances would be fully documented.</p> <p>Findings:</p> <p>1. On 1-23-12 at 1130 hours, staff #A1 was requested to provide a policy/procedure and documentation of any grievances submitted in 2011.</p>	Q0225	<p>Q225</p> <p>1. The deficiency has been corrected through policy update approved on 2/17/12. The policy language now reflects that the grievance investigation detail shall be documented, and the Grievance Investigation Documentation form has been updated to reflect an "investigation" section which prompts answering the questions "who, what, why, where, and how?"</p> <p>2. The deficiency shall be prevented</p>	02/17/2012			

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	<p>2. The policy/procedure Grievance Process (approved 4-10) indicated the following: "All grievances shall be investigated, in particular grievances related to treatment of care that the ASC provided or failed to provide... [and]...The ASC ensures, in a timely and thorough manner, an objective investigation of all allegations of abuse, neglect, or mistreatment..." The policy/procedure failed to identify the requirement to document the investigation process, failed to indicate an investigation process to follow in response to submission of a grievance, and failed to incorporate by reference or exhibit a facility form for documenting the submission of a complaint or grievance.</p> <p>3. The grievance sample provided for review lacked specific documentation of the investigation process conducted by the center administrator. On 1-24-12 at 1630 hours, staff #A1 was requested to provide additional documentation of the grievance investigation (who, what, when, where, why, etc) and none was provided prior to exit.</p>		<p>in the future through compliance with the updated policy. When investigating a grievance, the ASC Administrator shall use the form Grievance Investigation Documentation and shall complete the form with details (per the form) regarding the investigation of the grievance.</p> <p>3. The ASC Administrator shall be responsible for 1 and 2.</p> <p>4. The deficiency is corrected as of 2/17/12.</p>				

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	<p>4. The center document Grievance Form lacked a provision for documenting the investigation process between the section titled: NATURE OF GRIEVANCE and the section titled: PROPOSED RESOLUTION.</p> <p>5. During an interview on 1-25-12 at 1245 hours, staff #A1 confirmed that the grievance policy/procedure and the Grievance Form lacked a provision for documenting the investigation process.</p>			

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Q0234	<p>416.50(d) CONFIDENTIALITY OF CLINICAL RECORDS</p> <p>The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.</p> <p>Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure the privacy and security of individually identifiable health information.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Medical Record Content and Requirements (approved 4-10) indicated the following: " Access to medical records shall be protected from viewing by unauthorized persons ... " During a tour of the facility on 1-23-12 at 1440 hours, the following condition was observed in the center basement back hall across from the exit stairwell: patient records including personal and financial identification information were contained in unsecured cardboard banker boxes on pallets. On 1-23-12 at 1440 hours, staff #A3 	Q0234	<ol style="list-style-type: none"> The deficiency was corrected on 1/26/12. The deficiency shall be prevented in the future by educating all Elkhart Clinic Patient Business/Billing Office staff of the requirement to ensure that unauthorized individuals cannot gain access to patient records. The ASC Supervisor shall perform random QA audits of unsecured areas throughout the facility, to check for unsecured records in conjunction with the facility walk through for safety/security/preventive maintenance purposes. Any deficiencies noted shall be corrected immediately and reported to the ASC Administrator. The ASC Supervisor and ASC Administrator shall be responsible for 1 and 2 above. The deficiency was corrected on 1/26/12. 	01/26/2012	

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	confirmed that the observed hallway records were unprotected from viewing by unauthorized persons.				

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Q0242	<p>416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>Based on facility policy and procedure review, employee personnel file review, and staff interview, the infection control practitioner failed to ensure an effective, on going, infection control program was maintained related to the lack of communicable disease documentation and current TB testing for 1 of 2 MAs (medical assistants). (staff member P3)</p> <p>Findings: 1. at 3:20 PM on 1/25/12, review of the "Clinic Convenience Care" form for "Vaccine Orders" indicated that new employees must have: "Rubella, TITER and if non-reactive Booster to be given; Rubeola, TITER and if non-reactive Booster to be given; Varicella TITER and if non-reactive Booster to be given"</p> <p>2. review of staff personnel files at 3:00 PM on 1/23/12 and 10:00 AM on 1/24/12, indicated: a. staff member P3 was a MA that transferred from the clinic setting to the MA position on 11/16/09, and became an</p>	O0242	<p>1. The deficiency shall be corrected as follows: A TB test for staff member P3 was completed on 1/25/12. A new policy has been drafted entitled "Employee Health Service" which lists employee immunizations required at the Center; the policy was approved 2/17/12. The Elkhart Clinic Human Resources Administrator has been provided with a copy of the new policy and shall work to correct any deficiency in employee P3's personnel file per the new policy. 2. The deficiency shall be prevented from happening in the future through random QA audits of both new and existing ASC personnel files. Files shall be audited per the Employee Health Service policy to ensure required testing is performed and documentation is filed as required per policy. Deficiencies noted in QA audits shall be brought to the attention of the Human Resources administrator and corrected. Deficiencies shall be noted in the quarterly QAPI dashboard for evaluation of services. The Infection Control</p>	03/08/2012			

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	<p>endoscopy tech on 3/14/11, and lacked:</p> <p>A. any documentation related to history of disease, titer results, or history of immunization for: Rubella, Rubeola and Varicella</p> <p>B. a current TB (tuberculosis) test with the most recent dated as read on 11/19/10</p> <p>3. interview with staff member NB at 4:15 PM on 1/23/12 indicated:</p> <p>a. staff member P3 "fell through the cracks" after transfer from the clinical area where immunization status is not required</p> <p>b. per the MA status on 11/16/09, staff member P3 should have had titers drawn at that time</p> <p>c. it is unknown why a TB test was not given in November 2011, as required by facility practice of annual TB testing</p> <p>4. interview with staff member NA at 8:30 AM on 1/24/12 and 4:15 PM on 1/25/12, indicated:</p> <p>a. it is confirmed that there is no immunization documentation for staff member P3</p> <p>b. the infection control practitioner, and committee, at the surgery center, has no indication of any personnel immunization status as the HR (human resource) department at the clinic controls this</p> <p>c. there is no infection control policy</p>		<p>Coordinator shall be provided with the schedule of updates required per policy and shall prompt and track timely updating of TST (TB testing). 3. The Elkhart Clinic Human Resources Administrator, the Infection Control Coordinator, and the ASC Administrator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>		

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	<p>related to the immunizations required for staff, as the clinic HR staff provide this service to the surgery center (the form listed in 1. above is a clinic document, not a surgery center form)</p> <p>d. it is unknown how, or why, staff member P3 did not receive a TB test in November of 2011, as required for annual TB testing of staff</p>			

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Q0245	<p>416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>Based on policy and procedure review, observation, and staff interview, the infection control practitioner failed to implement facility polices related to surgical attire and operating room cleanliness.</p> <p>Findings: 1. at 12:35 PM on 1/25/12, review of the "Infection Control Plan", with a most recent revision date of 10/11, indicated: a. under "Practices", in section "6. Weekly...a. Procedure rooms are terminally cleaned at the end of each day of use..." b. under "Practices", in section "7. Procedure Related controls:", it reads in section "d. Surgical/Protective Attire:...4. All scrub personnel in procedure rooms shall wear a hat and mask...6. Jewelry shall be totally confined/covered or removed when in sterile attire..."</p> <p>2. at 3:20 PM on 1/25/12, review of the policy "Surgical Attire", with no effective or revision date, indicated:</p>	O0245	<p>1. The deficiency shall be corrected by re-orienting staff, physicians, and AHPs of the current Infection Control Plan, Housekeeping in the Surgery Center (includes Terminal Cleaning), and Surgical Attire policies. ASC staff shall be reoriented to the policies at the staff/unit meeting during the week of 2/20/12. All health care workers/providers shall be re-oriented to the policies by 3/08/12. 2. The deficiency shall be prevented from recurring in the future by conducting random QA audits of compliance with the Infection Control Plan, Housekeeping, and Surgical Attire policies after re-education to the policies has been completed. Individuals found in non-compliance with the policies shall be corrected; additional education shall be provided where needed. Review of the Infection Control Plan, Housekeeping, and Surgical Attire policies by physicians and staff shall be performed on an annual basis.3. The ASC Administrator and Infection</p>	03/08/2012			

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	<p>a. on page two in section 2., it reads: "Personnel will cover head and facial hair, including sideburns and necklines, when in the semi restricted and restricted areas of the surgical suite. a. A clean, low-lint surgical head cover or hood that confines all hair will be worn..."</p> <p>b. on page two in section 3., it reads: "All personnel entering restricted areas of the OR (operating room) suite will wear a mask when open sterile items and equipment are present...b. Masks are removed carefully by handling only the ties, and they are discarded immediately. Masks are not saved by hanging them around the neck or tucking them into a pocket for future use..."</p> <p>c. on page two in section 4., it reads: "All personnel entering the semi restricted and restricted areas of the surgical suite will confine or remove all jewelry and watches...b. Other jewelry (e.g. watches, earrings, bracelets, necklaces, piercings) should be removed or totally confined within the scrub attire."</p> <p>3. at 10:35 AM on 1/25/12, while observing pt. N17, a 6 year old, in the pre/post op area of bay # 16, it was observed that the OR nurse (ND) who transported the patient to the OR suite #2, had hair out of the cloth hood cap along the ears and neckline; had earrings that were not confined within the head</p>		Control Coordinator shall be responsible for numbers 1 and 2 above.4. The deficiency shall be corrected by 3/08/12.				

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	<p>covering, and had a surgical mask dangling about the neck that was pulled up over the mouth and nose just prior to entering the OR suite</p> <p>4. at 10:40 AM on 1/25/12, while observing pt. N17 in OR suite #2, it was observed that the CRNA (certified registered nurse anesthetist), staff member NG, had 1 1/2 inch dangling hoop earrings that were not confined within the cloth head covering</p> <p>5. at 11:00 AM on 1/25/12, while observing the terminal cleaning process of OR suite #1, it was observed that one staff member had hair escaping the cloth head covering around the neckline, had earrings (dangling) that were not covered by the surgical cap, and had a necklace that fell out of the V neck scrub top when bending over the surgical table while washing it down</p> <p>6. at 11:41 AM on 1/25/12, in the company of staff member NE, it was observed in the OR suite #2 that:</p> <p>a. a layer of dust was on the ledge of the connecting window between rooms 1 and 2--dust that when swiped by fingers fell in clumps to the floor</p> <p>b. a small amount of dust was swiped on the top of the Oxygen "boom" (that has the room's gases passing through it)</p>			

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	<p>7. interview with staff member NE on 1/25/12 at 11:50 AM, indicated other staff informed NE that suite #2 hadn't been utilized since "last week" and that maybe created the dust source found</p> <p>8. at 12:00 PM on 1/25/12, it was observed that the CRNA, staff member NG, walked past the conference room, on the way to the staff break room, with the surgical mask dangling about the neck</p> <p>9. interview with staff member NA at 3:20 PM on 1/25/12 indicated:</p> <ul style="list-style-type: none"> a. all jewelry and hair are to be confined within the surgical cap b. per facility policy, masks are not to be dangling about the neck c. there should not have been dust on either the window ledge in suite #2 or on the oxygen "boom", even if the room had not been used for a week 			

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S0000	<p>The visit was for a State licensure survey.</p> <p>Facility Number: 003903</p> <p>Survey Date: 01-23-12 to 01-25-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 02/02/12 4/19/12 revised due to IDR</p>	S0000	3/8/12				

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S0164	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (H)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program.</p> <p>Based on policy and procedure review, personnel file review, and staff interview, the governing board failed to implement its policy related to annual health updates for 5 of 7 employees. (P1, P2, P3, P5, and P7)</p> <p>Findings: 1. at 3:20 PM on 1/25/12, review of the policy "Employee Physical Examination", with a most recent revision date of 11/2009, indicated: a. under "Policy", it reads: "Employees of the Center shall have a post-offer physical examination and annual update in accordance with the infection control program." b. under "Practice", it reads: "A post-offer physical examination is required for all employees and shall be scheduled by Human Resources... Thereafter, the history and physical examination shall be updated</p>	S0164	<p>1. The deficiency has already been corrected by having each staff member complete the form "Annual Health History Update." An annual update for 2012 has been placed in each employee's personnel file as of 2/17/12.</p> <p>2. The Elkhart Clinic Human Resources Administrator and the ASC Administrator shall ensure each employee completes the update form annually by setting reminders to prompt distribution of the forms as per policy. The ASC Administrator shall perform random QA audits of personnel files to ensure forms are filed annually in each employee's file.</p> <p>3. The Elkhart Clinic Human Resources Administrator and the ASC Administrator are responsible for 1 and 2 above.</p> <p>4. The deficiency is corrected as of 2/17/12.</p>	02/17/2012			

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	<p>annually consistent with the employees intervening health history..."</p> <p>c. an attachment to the policy was a form titled "Annual Health History Update"</p> <p>2. review of the personnel files on 1/23/12 at 3:00 PM and on 1/24/12 at 10:00 AM indicated:</p> <p>a. staff members P1, P2, P3, P5, and P7 had history and physical examinations in either November 2009 or December 2009</p> <p>b. staff members P1, P2, P3, P5, and P7 lacked annual updates to their physical examinations in 2010 or 2011</p> <p>3. interview with staff member NA at 3:20 PM on 1/25/12, indicated:</p> <p>a. the attachment to the "Employee Physical Examination" policy is to be handed out to each employee in November/December each year and given back to the Human Resources staff for placement in the employee health files</p> <p>b. it was unknown that the annual updates had not been completed and placed in employee files as this staff member has no control over employee health files</p>						

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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the center failed to maintain a written quality assurance (QA) plan and failed to ensure services were evaluated using standards for contracted services provided at the facility.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Assessment / Performance Improvement (QAPI) Plan (approved 4-10) failed to describe a process for documenting and reporting the ongoing evaluation of contracted services. The Plan failed to indicate a minimum frequency for evaluation sampling of each service using the QAPI Monitoring Tool.</p> <p>2. Review of three (one pharmacist, one radiologist, and one medical records consultant) QAPI Monitoring Tool documents failed to indicate specific, measurable and objective standards for</p>	S0310	<p>1. The policy QAPI Plan was updated and approved 2/17/12 to include: a description of the process for documenting and reporting the ongoing evaluation of contracted services (dashboard with specific criteria, data maintained from quarter to quarter); an indication of frequency (quarterly) for evaluation of each service. 2. The new dashboard tool includes specific measurable criteria for a quarterly evaluation of services. The report shall be provided to the QAPI Team, MAC committee, and Board of Managers quarterly. The policy update was approved by the BOM 2/17/12.3. The Administrator is responsible for numbers 1 and 2 above.4. The policy is updated and approved as of 2/17/12. The Administrator will begin following the updated policy immediately. The policy will be provided to staff the week of 2/20/12. The updated Services dashboard report shall be completed for Quarter 1 2012 by the</p>	02/17/2012			

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	<p>evaluating each service and failed to ensure that 'additional relevant information' recorded on the monitoring tool could be reviewed over multiple periods for ongoing development of the standards in use for monitoring each service. 'Additional relevant information' observed on the radiologist consultant QAPI Monitoring Tool (dated 1-19-12) indicated a plan of action in response to information not reviewed by the consultant being evaluated. No other QAPI Monitoring Tools for contracted services were provided or observed prior to exit.</p> <p>3. The QA/PI Dashboard for Services reports failed to indicate specific service standards applied to each contracted services provider and failed to distinguish internal processes from a contracted service provision.</p> <p>4. During an interview on 1-18-12 at 1715 hours, staff #A1 confirmed that the QAPI plan lacked a provision for documenting and reporting the evaluation of contracted services. Staff #A1 confirmed that the QAPI documentation lacked standards and failed to ensure the ongoing review and revision of the</p>		<p>Administrator and provided to the QAPI Team at the 2 nd quarter meeting. The report shall be provided to the MAC and BOM with 1 st quarter results during the 2 nd quarter at regularly scheduled meetings.</p>				

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	standards used for evaluation of each contracted service.				

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S0434	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iv)</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>(iv) Aseptic technique, invasive procedures, and equipment usage.</p> <p>Based on policy and procedure review, observation, and staff interview, the infection control practitioner failed to implement facility polices related to surgical attire and operating room cleanliness.</p> <p>Findings: 1. at 12:35 PM on 1/25/12, review of the "Infection Control Plan", with a most recent revision date of 10/11, indicated: a. under "Practices", in section "6. Weekly...a. Procedure rooms are terminally cleaned at the end of each day of use..." b. under "Practices", in section "7. Procedure Related controls:", it reads in section "d. Surgical/Protective Attire:...4. All scrub personnel in procedure rooms shall wear a hat and mask...6. Jewelry shall be totally confined/covered or</p>	S0434	<p>1. The deficiency shall be corrected by re-orienting staff, physicians, and AHPs of the current Infection Control Plan, Housekeeping in the Surgery Center (including Terminal Cleaning), and Surgical Attire policies. ASC staff shall be reoriented to the policies at the staff/unit meeting during the week of 2/20/12. All health care workers/providers shall be re-oriented to the policies by 3/08/12. 2. The deficiency shall be prevented from recurring in the future by conducting random QA audits of compliance with the Infection Control Plan, Housekeeping, and Surgical Attire policies after re-education to the policies has been completed. Individuals found in non-compliance with the policies shall be corrected; additional education shall be provided where needed. Review of the</p>	03/08/2012			

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	<p>removed when in sterile attire..."</p> <p>2. at 3:20 PM on 1/25/12, review of the policy "Surgical Attire", with no effective or revision date, indicated:</p> <p>a. on page two in section 2., it reads: "Personnel will cover head and facial hair, including sideburns and necklines, when in the semi restricted and restricted areas of the surgical suite. a. A clean, low-lint surgical head cover or hood that confines all hair will be worn..."</p> <p>b. on page two in section 3., it reads: "All personnel entering restricted areas of the OR (operating room) suite will wear a mask when open sterile items and equipment are present...b. Masks are removed carefully by handling only the ties, and they are discarded immediately. Masks are not saved by hanging them around the neck or tucking them into a pocket for future use..."</p> <p>c. on page two in section 4., it reads: "All personnel entering the semi restricted and restricted areas of the surgical suite will confine or remove all jewelry and watches...b. Other jewelry (e.g. watches, earrings, bracelets, necklaces, piercings) should be removed or totally confined within the scrub attire."</p> <p>3. at 10:35 AM on 1/25/12, while observing pt. N17, a 6 year old, in the pre/post op area of bay # 16, it was</p>		<p>Infection Control Plan, Housekeeping, and Surgical Attire policies by physicians and staff shall be performed on an annual basis. 3. The ASC Administrator and Infection Control Coordinator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>				

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	<p>observed that the OR nurse (ND) who transported the patient to the OR suite #2, had hair out of the cloth hood cap along the ears and neckline; had earrings that were not confined within the head covering, and had a surgical mask dangling about the neck that was pulled up over the mouth and nose just prior to entering the OR suite</p> <p>4. at 10:40 AM on 1/25/12, while observing pt. N17 in OR suite #2, it was observed that the CRNA (certified registered nurse anesthetist), staff member NG, had 1 1/2 inch dangling hoop earrings that were not confined within the cloth head covering</p> <p>5. at 11:00 AM on 1/25/12, while observing the terminal cleaning process of OR suite #1, it was observed that one staff member had hair escaping the cloth head covering around the neckline, had earrings (dangling) that were not covered by the surgical cap, and had a necklace that fell out of the V neck scrub top when bending over the surgical table while washing it down</p> <p>6. at 11:41 AM on 1/25/12, in the company of staff member NE, it was observed in the OR suite #2 that:</p> <p>a. a layer of dust was on the ledge of the connecting window between rooms 1</p>			

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	<p>and 2--dust that when swiped by fingers fell in clumps to the floor</p> <p>b. a small amount of dust was swiped on the top of the Oxygen "boom" (that has the room's gases passing through it)</p> <p>7. interview with staff member NE on 1/25/12 at 11:50 AM, indicated other staff informed NE that suite #2 hadn't been utilized since "last week" and that maybe created the dust source found</p> <p>8. at 12:00 PM on 1/25/12, it was observed that the CRNA, staff member NG, walked past the conference room, on the way to the staff break room, with the surgical mask dangling about the neck</p> <p>9. interview with staff member NA at 3:20 PM on 1/25/12 indicated:</p> <p>a. all jewelry and hair are to be confined within the surgical cap</p> <p>b. per facility policy, masks are not to be dangling about the neck</p> <p>c. there should not have been dust on either the window ledge in suite #2 or on the oxygen "boom", even if the room had not been used for a week</p>			

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S0442	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on facility policy and procedure review, employee personnel file review, and staff interview, the infection control practitioner failed to ensure an effective, on going, infection control program was maintained related to the lack of communicable disease documentation and current TB testing for 1 of 2 MAs (medical assistants). (staff member P3)</p> <p>Findings: 1. at 3:20 PM on 1/25/12, review of the "Clinic Convenience Care" form for "Vaccine Orders" indicated that new employees must have: "Rubella, TITER and if non-reactive Booster to be given; Rubeola, TITER and if non-reactive Booster to be given; Varicella TITER and</p>	S0442	<p>1. The deficiency shall be corrected as follows: A TB test for staff member P3 was completed on 1/25/12. A new policy has been drafted entitled "Employee Health Service" which lists employee immunizations required at the Center; the policy was approved 2/17/12. The Elkhart Clinic Human Resources Administrator has been provided with a copy of the new policy and shall work to correct any deficiency in employee P3's personnel file per the new policy. 2. The deficiency shall be prevented from happening in the future through random QA audits of both new and existing ASC personnel files. Files shall be audited per the Employee Health Service policy to ensure required</p>	03/08/2012			

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	<p>if non-reactive Booster to be given"</p> <p>2. review of staff personnel files at 3:00 PM on 1/23/12 and 10:00 AM on 1/24/12, indicated:</p> <p>a. staff member P3 was a MA that transferred from the clinic setting to the MA position on 11/16/09, and became an endoscopy tech on 3/14/11, and lacked:</p> <p>A. any documentation related to history of disease, titer results, or history of immunization for: Rubella, Rubeola and Varicella</p> <p>B. a current TB (tuberculosis) test with the most recent dated as read on 11/19/10</p> <p>3. interview with staff member NB at 4:15 PM on 1/23/12 indicated:</p> <p>a. staff member P3 "fell through the cracks" after transfer from the clinical area where immunization status is not required</p> <p>b. per the MA status on 11/16/09, staff member P3 should have had titers drawn at that time</p> <p>c. it is unknown why a TB test was not given in November 2011, as required by facility practice of annual TB testing</p> <p>4. interview with staff member NA at 8:30 AM on 1/24/12 and 4:15 PM on 1/25/12, indicated:</p> <p>a. it is confirmed that there is no</p>		<p>testing is performed and documentation is filed as required per policy. Deficiencies noted in QA audits shall be brought to the attention of the Human Resources administrator and corrected. Deficiencies shall be noted in the quarterly QAPI dashboard for evaluation of services. The Infection Control Coordinator shall be provided with the schedule of updates required per policy and shall prompt and track timely updating of TST (TB testing). 3. The Elkhart Clinic Human Resources Administrator, the Infection Control Coordinator, and the ASC Administrator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>				

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	<p>immunization documentation for staff member P3</p> <p>b. the infection control practitioner, and committee, at the surgery center, has no indication of any personnel immunization status as the HR (human resource) department at the clinic controls this</p> <p>c. there is no infection control policy related to the immunizations required for staff, as the clinic HR staff provide this service to the surgery center (the form listed in 1. above is a clinic document, not a surgery center form)</p> <p>d. it is unknown how, or why, staff member P3 did not receive a TB test in November of 2011, as required for annual TB testing of staff</p>			

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S0612	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(1)</p> <p>(c) An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure the accuracy of patient medical records for 4 of 16 charts reviewed. (N1, N11, N12 and N13)</p> <p>Findings: 1. at 12:15 PM on 1/25/12, review of the policy and procedure "Medical Record Content and Requirements" with a last revision date of 11/2009, indicated: a. under "Policy", it reads: "A medical record shall be maintained for each patient, which is accurate, legible, complete and comprehensive to ensure adequate patient care,..." b. under "Content", it reads: "Accurate and complete medical records are written for all patients;..."</p> <p>2. review of patient medical records</p>	S0612	<p>1. The deficiency shall be corrected by re-orienting staff and physicians to policy "Medical Record Content and Requirements," with specific attention to inaccurate documentation noted in the survey: consistent documentation of one ASA classification per patient per date of service across several patient records as documented by several healthcare providers, and; consistent documentation of the anesthesia plan across several patient records as documented by several healthcare providers. The Advance Directive policy has been updated as on 2/17/12 to reflect the approved method of marking medical records/charts containing Advance Directives, and the location/form where nursing staff records information regarding Advance Directives obtained during the preoperative assessment. Staff shall be educated on the policy changes</p>	03/08/2012			

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	<p>through out the survey process of 1/23/12 to 1/25/12, indicated:</p> <p>a. pt. N1 had an ASA (American Society of Anesthesiologists) level of 2 circled in the "Anesthesia Physical Exam" section at the bottom of the page on the "GI Nursing Assessment" form, but had an ASA Classification of 3 marked on the "GI Procedure Nursing Record" form and had an ASA of "II" marked on the "Anesthesia Record" form</p> <p>b. pt. N11 had a "General" anesthesia consent form in the record, had "General" anesthesia circled in the "Anesthesia Physical Exam" section of the "Pre-op Record/Patient Physical" form, and had general anesthesia documented on both the "Intra-Operative Nursing Record" form and the "Anesthesia Record" form, but had "MAC" (monitored anesthesia care" listed as the "Anesthesia" provided to the patient on the dictated operative report by the surgeon</p> <p>c. pt. N12 had an advance directive document in the chart and an "Advance Directive" sticker on the front of the chart, but had documentation by staff on the "Pre-op Record/Patient Physical" form that the patient had no Advance Directive</p> <p>d. pt. N13 had documentation by staff on the "Pre-op Record/Patient Physical" form that the patient had an Advance Directive, but lacked an "Advance Directive" sticker on the front of the chart-</p>		<p>and the importance of accuracy in documenting whether or not Advance Directives are present in patient charts. Education to the policies shall be provided to the staff at a staff/unit meeting the week of 2/20/12 and provided via email and in person to medical and AHP staff. 2. The deficiency shall be prevented in the future by performing random QA audits on charts marked Advance Directive, and of patient records to determine that ASA and anesthesia plans have been recorded consistently by different providers across several records for the same patient and encounter. Deficiencies shall be noted and corrected; individuals shall be re-educated on the policies wherever necessary. 3. The Administrator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>				

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	<p>-no Advance Directive was found in the chart, making it unknown as to whether or not the patient had an Advance Directive, or not</p> <p>3. interview with staff members NA and NH at 3:20 PM on 1/25/12 indicated:</p> <p>a. there are some inaccuracies in the medical record as stated in 2. above</p> <p>b. there is no policy and procedure related to how to document whether a patient has an Advance Directive or not</p> <p>c. the only document related to the Advance Directive stickers on the chart was a May 19, 2009 e-mail to staff by staff member NA indicating an Advance Directive sticker is to be placed on the front of the chart for each patient who, in fact, has an Advance Directive</p>				

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S0624	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(7)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure the privacy and security of individually identifiable health information.</p> <p>Findings:</p> <p>1. The policy/procedure Medical Record Content and Requirements (approved 4-10) indicated the following: " Access to medical records shall be protected from</p>	S0624	<p>1. The deficiency was corrected on 1/26/12. 2. The deficiency shall be prevented in the future by educating all Elkhart Clinic Patient Business/Billing Office staff of the requirement to ensure that unauthorized individuals cannot gain access to patient records. The ASC Supervisor shall perform random QA audits of unsecured areas throughout the facility, to check for unsecured records in conjunction with the facility walk through for safety/security/preventive maintenance purposes. Any deficiencies noted shall be corrected immediately and</p>	01/26/2012			

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	viewing by unauthorized persons ... " 2. During a tour of the facility on 1-23-12 at 1440 hours, the following condition was observed in the center basement back hall across from the exit stairwell: patient records including personal and financial identification information were contained in unsecured cardboard banker boxes on pallets. 3. On 1-23-12 at 1440 hours, staff #A3 confirmed that the observed hallway records were unprotected from viewing by unauthorized persons.		reported to the ASC Administrator. 3. The ASC Supervisor and ASC Administrator shall be responsible for 1 and 2 above. 4. The deficiency was corrected on 1/26/12.		

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to implement its policy related to legible and complete medical records for 10 of 16 charts reviewed. (pts. N1, N2, N4, N5, N6, N7, N8, N9, N13 and N16)</p> <p>Findings:</p> <p>1. at 12:15 PM on 1/25/12, review of the policy and procedure "Medical Record Content and Requirements" with a last revision date of 11/2009, indicated:</p> <p>a. under "Policy", it reads: "A medical record shall be maintained for each patient, which is accurate, legible, complete and comprehensive to ensure adequate patient care,..."</p> <p>b. under "Content", it reads: "Accurate and complete medical records are written for all patients;..."</p> <p>c. under "Legibility of Record", it reads: "...All entries in the medical record shall be legible to individuals other than the author..."</p>	S0640	<p>1. The deficiency shall be corrected by re-orienting staff and physicians to policy "Medical Record Content and Requirements," with specific attention to inaccurate documentation noted in the survey: consistent documentation of one ASA classification per patient per date of service across several patient records as documented by several healthcare providers, and; consistent documentation of the anesthesia plan across several patient records as documented by several healthcare providers. The Advance Directive policy has been updated as on 2/17/12 to reflect the approved method of marking medical records/charts containing Advance Directives, and the location/form where nursing staff records information regarding Advance Directives obtained during the preoperative assessment. Staff shall be educated on the policy changes and the importance of accuracy in documenting whether or not Advance Directives are present in patient charts. Staff shall be re-educated on the</p>	03/08/2012			

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	<p>2. review of patient medical records through out the survey process of 1/23/12 to 1/25/12, indicated:</p> <p>a. pts. N1, N4 and N5 lacked indication that the lungs were examined as part of the "Physical Examination" performed by the surgeon on 1/14/11 on the "GI Lab Physician History & Physical/Orders" form</p> <p>b. pt. N2 had a write over in the IV (intravenous) section of the "Pre-op Record/Patient Physical" form related to the IV site</p> <p>c. pts. N5, N8 and N13 lacked documentation of a pre anesthesia evaluation with ASA (American Society of Anesthesiologists) selection prior to colonoscopy by the surgeon (on the "GI Nursing Assessment" form--bottom of page where "Anesthesia Physical Exam, ASA level and anesthesia plan" are documented with the practitioner's signature line)</p> <p>d. pt. N6:</p> <p>A. lacked documentation of the anesthesia plan selection on the "GI Nursing Assessment" form--bottom of page (a general anesthesia box was checked at the top of the "Anesthesia Record" form)</p> <p>B. lacked documentation of "machine checked" on the "Anesthesia Record" form</p> <p>e. pt. N7:</p>		<p>facility-approved method of error correction per policy. Physicians shall be re-educated on the requirement in medical staff bylaws that a physician shall perform a focused physical exam including pre-anesthetic risk assessment just prior to the scheduled procedure. The form "Anesthesia Record" has been modified to allow the user to mark that the anesthesia machine equipment is checked prior to the procedure when the procedure is being performed in OR 1 or OR 2. Education to the forms and policies shall be provided to the staff at a staff/unit meeting the week of 2/20/12 and provided via email and in person to medical and AHP staff. 2. The deficiency shall be prevented in the future by performing random QA audits on charts marked Advance Directive, and of patient records to determine that ASA and anesthesia plans have been recorded consistently by different providers across several records for the same patient and encounter. Physical exams shall be checked and anesthesia records checked to ensure it is documented that equipment is checked in OR 1 or OR 2. Deficiencies shall be noted and corrected; individuals shall be re-educated on the policies wherever necessary. 3. The Administrator shall be responsible for numbers 1 and 2 above. 4. The deficiency shall be corrected</p>				

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	<p>A. had documentation by the surgeon that the "Heart" examination was "Deferred" on the "Physician H & P /Orders" form on 11/23/11, the day of surgery for this 6 year old</p> <p>B. had 7 write overs in the "Post op Vital Signs" area, write overs in the IV section (3), 5 write overs in the "Aldrete Scoring System", and 2 write overs in the lower section of the "PACU Record" form (post anesthesia care unit = PACU)</p> <p>f. pt. N9 lacked documentation of "machine checked" on the "Anesthesia Record" form</p> <p>g. pt. N16:</p> <p>A. lacked documentation of the anesthesia plan selection on the "GI Nursing Assessment" form--bottom of page</p> <p>B. had a write over in the Fentanyl order of the "Anesthesia Pre and Post Op Orders" form</p> <p>C. had a write over in the patient's temperature documentation in the "Discharge" box at the top of the "Post-Op Record" form</p> <p>3. interview with staff member NA at 2:50 PM on 1/25/12 indicated medical records are incomplete or illegible as stated in 2. above</p>		by 3/08/12.				

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S0862	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(C)</p> <p>Requirement for surgical services include:</p> <p>(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:</p> <p>(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:</p> <p>(i) Emergency call system. (ii) Oxygen. (iii) Resuscitation equipment. (iv) Defibrillator. (v) Cardiac monitors. (vi) Tracheostomy set. (vii) Oximeter. (viii) Suction equipment. (ix) Other supplies and equipment specified by the medical staff.</p> <p>Based on document review, observation and interview, the center failed to ensure that required emergency equipment was available if needed for 1 of 9 required emergency equipment.</p> <p>Findings: 1. The policy/procedure Emergency Crash Cart Security and Accountability (approved 4-10) and Code Blue Plan</p>	S0862	<p>1. The deficiency has been corrected through a policy update as of 2/17/12 to "Emergency Crash Cart Security and Accountability," which is now titled Emergency Cart Contents, Security, and Accountability. The policy states an oximeter is kept on the Crash Cart. A finger pulse oximeter was purchased and has been placed on the Crash Cart on 2/17/12 and is reflected on the Cart contents list. The updated</p>	02/17/2012			

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	<p>(approved 4-10) failed to indicate that an oximeter was listed as available for use in the event of an emergency.</p> <p>During an center tour on 12-25-12 at 1030 hours, no oximeter was observed on or around where the crash cart was located in the pre and post-op area.</p> <p>3. During an interview on 1-25-12 at 1030 hours, staff #A3 confirmed that the policy/procedures failed to indicate a location or provision for the required equipment if needed.</p>		<p>policy shall be provided to staff for education at the staff/unit meeting which will be held the week of 2/20/12. The policy will be reviewed and the oximeter provided for staff to recognize it and learn how to use it. 2. We shall prevent the deficiency in the future asking nursing staff to complete the daily check of the crash cart to check for the presence of the pulse oximeter. Random QA checks of the cart and documentation of Crash Cart checks shall be performed by the ASC Supervisor to ensure the oximeter's presence on the cart. Any absence of the oximeter shall be corrected immediately and reported to the ASC Administrator. 3. The ASC Supervisor shall be responsible for 1 and 2 above. 4. The deficiency was corrected on 2/17/12.</p>		

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S0888	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(F)</p> <p>Requirement for surgical services include:</p> <p>(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:</p> <p>(F) A requirement for an operative report describing techniques, findings, and tissue removed or altered to be written or dictated immediately following surgery and authenticated by the surgeon in accordance with center policy and governing body approval.</p> <p>Based on review of medical staff rules and regulations, patient medical record review, and staff interview, the facility failed to ensure that operative notes were completed immediately following the surgical procedure for 2 of 2 patients with services by Dr. L. (pts. N8 and N13)</p> <p>Findings: 1. at 10:25 AM on 1/25/12, review of the Medical Staff Rules and Regulations indicated in Section 11 "Medical Record Requirements" that in item "D.", it reads: "The patient's medical record shall also contain an operative summary with a</p>	S0888	<p>1. The deficiency has been corrected through a policy update as of 2/17/12 to "Medical Staff Rules and Regulations" stating that operative reports shall be dictated within 24 hours of the procedure, as this is reflective of what "immediately following the surgical procedure" is for staff at this facility. The policy update shall be provided to staff at the staff/unit meeting during the week of 2/20/12 and provided to the active medical staff via email and in person by 3/08/12. 2. The deficiency shall be prevented in the future through education of staff and physicians on the policy update. Random QA audits on</p>	03/08/2012			

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	<p>complete description of the operative procedure, including any complications, indications for surgery, name and signature of primary surgeon and assistant, findings, technical procedures used, specimens removed and postoperative diagnosis with the surgeon's signature."</p> <p>2. review of patient medical records through out the survey process of 1/23/12 to 1/25/12 indicated:</p> <p>a. pt. N8 had surgery performed on 12/6/11 by Dr. L that began at 11:45 AM, and had an operative report dictated on 12/8/11 at 11:54 AM</p> <p>b. pt. N13 had surgery performed on 11/15/11 by Dr. L, with the patient going to OR at 1:13 PM, and had an operative report dictated on 12/16/11 at 6:26 PM</p> <p>3. interview with staff member NA at 12:20 PM on 1/25/12, indicated:</p> <p>a. it was thought that the requirement for operative reports was addressed in the medical staff rules and regulations and that they were to be dictated within 24 hours of the procedure</p> <p>b. there is no other facility policy that addresses any indication of what "immediately following the surgical procedure" is for the staff at this facility</p> <p>c. Dr. L is "new" to the facility and may not know that the expectation for</p>		<p>medical records shall be performed to ensure physicians are achieving this standard. Physicians not adhering to the facility policy shall be informed of the need for correction to comply with policy; the ASC Medical Director, MAC, and Board shall be informed of QA audit results.</p> <p>3. The ASC Administrator shall be responsible for 1 and 2. 4. The deficiency shall be corrected by 3/08/12.</p>				

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	operative reports is that they are dictated within 24 hours of a surgical procedure			

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S0906	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)(2)</p> <p>(a) Patient care services must require the following:</p> <p>(2) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.</p> <p>Based on policy and procedure review, personnel file review, and staff interview, the facility failed to ensure that personnel with appropriate training, related to PALS (pediatric advanced life support) certification and care of pediatric patients, was lacking for 2 of 3 RNs (registered nurses). (P4 and P6)</p> <p>Findings:</p> <p>1. at 1:00 PM on 1/24/12, review of the "Job description: Pre/postoperative registered nurse" indicated under "Requirements": "...Preferred 1. PALS certification...</p> <p>2. review of personnel files during the 1/23/12 to 1/25/12 survey process, indicated there was no documentation of PALS certification for RNs P4 and P6</p> <p>3. interview with staff member NA at 1:00 PM on 1/24/12 indicated:</p> <p>a. only pre/post op nurses are required to have PALS</p>	S0906	<p>1. The deficiency has been corrected through policy update on 2/17/12 of policy "New Employee Orientation," which specifies nursing staff new to the center shall have 9 months from the date of hire to complete ACLS and PALS certification. During this time, certified nursing staff (in PALS and ACLS) shall be present in the center whenever patients are present. The two nurses uncertified in PALS shall become certified. The updated policy shall be provided to staff at the staff/unit meeting the week of 2/20/12. 2. The deficiency shall be prevented in the future through compliance with the updated policy. The ASC Supervisor shall track completion of ACLS and PALS within the specified time frame for new RN employees. QA audits of new RN employee personnel files shall be performed; any nurse lacking PALS or ACLS certification 9 months from date of hire shall be required to become certified as soon as possible. 3. The ASC Supervisor and ASC</p>	03/08/2012			

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	<p>b. both P4 and P6 work in the pre/post op areas at times (staff are "cross trained")</p> <p>4. interview with staff member NA at 3:20 PM on 1/25/12 indicated:</p> <p>a. pediatric surgical patients could be at risk for safety with the lack of PALS certified nursing staff</p> <p>b. the RN job description should have PALS certification as a required skill, and not a "preferred" skill</p>		<p>Administrator shall be responsible for 1 and 2 above. 4. The deficiency shall be completed by 3/08/12.</p>	

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S1146	<p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on document review, observation and interview, the center failed to ensure that blanket warmers were safely maintained for patients at the facility.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-24-12 at 1620 hours, staff #A1 was requested to provide a policy/procedure or manufacturer 's recommendation for blanket warmer temperature settings and none was provided prior to exit. During a tour on 1-24-12 at 1545 hours, a blanket warmer was observed in the surgery hallway near endoscopy decontamination with an indicated temperature of 158 degrees Fahrenheit. During a tour on 1-25-12 at 1040 hours, a blanket warmer was observed in 	S1146	<ol style="list-style-type: none"> The deficiency is corrected through a new policy approved 2/17/12 titled "Blanket Warmer," which provides for the safe operation/use of the blanket warmers. The policy shall be provided to staff at the staff/unit meeting to be held the week of 2/20/12. Staff shall begin daily logs of temperature checks on the warmers, not to be set higher than 130 degrees F. 2. The deficiency shall be prevented in the future through compliance with the new policy. Staff shall record blanket warmer temperatures daily, and report and correct temperatures greater than 130 degrees F. QA audits of records and of the warmer shall be performed by the ASC Supervisor to ensure staff are complying with policy and making corrections as needed. Non-compliance with policy shall be corrected immediately and 	03/08/2012

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	<p>the surgery hallway near surgical suite #2 with an indicated temperature of 150 degrees Fahrenheit.</p> <p>4. During a tour on 1-25-12 at 1145 hours, a blanket warmer was observed in the pre and post-op area with an indicated temperature of 158 degrees Fahrenheit.</p> <p>5. Center documentation of monthly blanket warmer safety checks failed to indicate what temperature was observed by staff and failed to indicate what temperature was acceptable for the equipment.</p> <p>6. During an interview on 1-25-12 at 1200 hours, staff #A1 confirmed that the center lacked a policy/procedure indicating a temperature recommended for safely maintaining the blanket warmers.</p>		<p>reported to the ASC Administrator. 3. The ASC Supervisor shall be responsible for 1 and 2 above. 4. The deficiency shall be corrected by 3/08/12.</p>		

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S1154	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(C)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.</p> <p>Based on document review and interview, the center failed to ensure that a triennial analysis was performed on operational and maintenance records for the mechanical and physical plant equipment at the facility.</p> <p>Findings: 1. On 1-23-12 at 1130 hours, staff #A1 was requested to provide documentation indicating a triennial analysis of operational and maintenance control records for heating, ventilation, air conditioning, fire alarm and/or smoke</p>	S1154	<p>1. The deficiency was corrected on 2/8/12. Environmental Services Manager Mike Poole completed the triennial review of the physical plant mechanicals on 2/8 and provided documentation to support this. The policy Preventive Maintenance was updated 2/17/12 to include the provision for the triennial review of physical plant mechanicals. Staff shall be educated on the policy the week of 2/20/12.2. The deficiency shall be prevented in the future through compliance with the updated Preventive Maintenance policy. The ASC Administrator shall continue to report the date of the triennial</p>	02/17/2012			

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	<p>detector system was performed and none was provided prior to exit.</p> <p>2. The policy/procedure Preventive Maintenance (approved 4-10) lacked a provision for performing a triennial review of the PM records at the center.</p> <p>3. Review of the maintenance schedules and equipment maintenance records failed to indicate that the center records were analyzed at least triennially.</p> <p>4. During an interview on 1-25-12 at 1520 hours, staff #A1 confirmed that the center lacked documentation of a triennial analysis of the mechanical systems and equipment records.</p>		<p>review just performed on future QA Services dashboards and shall set a reminder for the next review.3. The ASC Administrator and the ES Manager shall be responsible for 1 and 2.4. The deficiency was corrected on 2/17/12.</p>		

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S1164	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(i)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the center failed to ensure that preventive maintenance (PM) was provided to all patient care equipment for its call light/code system. Findings: 1. On 1-23-12 at 1130 hours, staff #A1 was requested to provide documentation of PM for the TekTone nurse emergency call (code) system and none was provided prior to exit. 2. During an interview on 1-25-11at 1515</p>	S1164	<p>S1164</p> <p>1. The deficiency has been corrected on 2/14/12. Our contracted Biomedical Engineer was on site to provide PM on the nurse call system as per manufacturer's guidelines. A sticker was placed on the main unit to show the unit was checked and the date the unit is scheduled to be checked again in the future. The ASC Supervisor shall continue to perform monthly checks of the nurse call system as before and document said checks on the</p>	02/14/2012			

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	hours, staff #A1 confirmed that the center lacked documentation of PM for the nurse code call system.		<p>monthly Preventive Maintenance checklist.</p> <p>2. The deficiency shall be prevented from recurring in the future by adding the system to the list of items the Biomed Engineer routinely checks. The ASC Administrator shall check the Engineer's records to ensure that the system is added to the master list of facility equipment and that the PM of the call system is completed as required. The Supervisor's monthly PM check of the call system shall be reviewed monthly as before to ensure it is being completed.</p> <p>3. The ASC Supervisor and ASC Administrator shall be responsible for 1 and 2.</p> <p>4. The deficiency was corrected on 2/14/12.</p>		

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S1168	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iii)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.</p> <p>Based on document review and interview, the center failed to ensure that a triennial analysis was performed on all patient care equipment at the center.</p> <p>Findings:</p> <p>1. On 1-23-12 at 1130 hours, staff #A1 was requested to provide documentation indicating that a triennial analysis of patient care equipment preventive maintenance (PM) records was performed</p>	S1168	<p>S1168 1. The deficiency has been corrected on 2/14/12 by the contracted Biomedical Engineer from Memorial Health System. The triennial analysis of the patient care equipment was completed per Terry Starlin; we met and discussed the results on 2/14 and Terry stated a printed report and letter would be forthcoming as documentation that the review was complete. Documentation shall be on file at the center by 3/08/12. The policy Preventive Maintenance was updated and approved 2/17/12.</p> <p>2. The deficiency shall be prevented in the future by</p>	03/08/2012			

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	<p>and none was provided prior to exit.</p> <p>2. The policy/procedure Preventive Maintenance (approved 4-10) lacked a provision for performing a triennial review of the PM records at the center.</p> <p>3. PM records failed to indicate that a triennial analysis was performed by either center staff or the biomedical engineering services provider for patient care equipment.</p> <p>4. During an interview on 1-25-12 at 1520 hours, staff #A1 confirmed that the center lacked documentation of triennial analysis for the patient care equipment PM records.</p>		<p>continuing to report the date of the triennial review just performed on future QA Services dashboards and setting reminders for the next future review. The ASC Administrator shall follow up after the next triennial review is complete to ensure documentation is received and kept on file at the Center.</p> <p>3. The ASC Administrator is responsible for 1 and 2. 4. The deficiency shall be corrected by 3/08/12.</p>		

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S1170	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iv)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p> <p>Based on document review, observation and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer.</p> <p>Findings:</p> <p>1. On 1-23-12 at 1130 hours, staff #A1 was requested to provide a policy/procedure indicating a description of the process for checking the defibrillator according to the manufacturer's recommendations and none was provided prior to exit.</p>	S1170	<p>S11701. The deficiency has been corrected through a policy update as of 2/17/12 to "Emergency Crash Cart Security and Accountability," which is now titled Emergency Cart Contents, Security, and Accountability. The policy describes the process for checking the defibrillator according to manufacturer's recommendations and states the defibrillator is to be discharged per recommendations. The policy lists specific tests and inspections to be performed daily by staff. The policy shall be rolled out to staff at the staff/unit meeting the week of 2/20/12.</p>	03/08/2012			

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	<p>2. The center document Crash Cart Checklist dated January 2012 failed to indicate the process for checking the defibrillator or discharge according to the manufacturer's recommendations or refer to the operators manual for the specific tests and inspections to be performed daily by staff.</p> <p>3. During a facility tour on 1-25-12 at 1030 hours, it was observed that the center copy of the Physio-Control LifePak 9 Operating Instructions (1993 edition) available on the top of the Crash Cart failed to include Section 6 Maintaining the Equipment where Table 6-1 <u>Recommended maintenance and testing for clinical personnel</u> is found.</p> <p>4. During an interview on 1-25-12 at 1030 hours, staff #A3 confirmed that the daily defibrillator checks were not being performed according to the manufacturer's recommendations.</p>		<p>The Center will have all staff educated and compliant with the policy by 3/08/12.2. The deficiency shall be prevented in the future through compliance with the policy updates. The ASC Supervisor shall perform QA audits of staff performing the daily check to ensure staff compliance with the policy. The Supervisor shall audit the daily checks log to ensure documentation is reflective of policy compliance. Corrections to practice or documentation shall occur, with re-education wherever needed.</p> <p>3. The ASC Supervisor shall be responsible for 1 and 2.4. The deficiency shall be corrected by 3/08/12.</p>		

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S1198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the center lacked documentation of participation with community, state and/or federal emergency disaster preparedness agencies.</p> <p>Findings:</p> <p>1) On 1-23-12 at 1130 hours, staff #A1 was requested to provide documentation of participation with local, state, and/or federal emergency disaster preparedness exercises and none was provided prior to exit.</p> <p>2) During an interview on 1-25-12 at 1130 hours, staff #A1 indicated that the center lacked documentation of participation, coordination or contacts with a local, state or federal disaster services agency and failed to participate in an inter-agency training exercise or</p>	S1198	<p>S11981. The deficiency has been corrected on 2/2/12. The ASC Administrator and Supervisor attended an Emergency Preparedness and Planning Meeting at the EMA site. The meeting was provided by: Whitney Pierle, Public Health Coordinator from the Elkhart County Health Department; Jenn Tobey, EMA Director; and Michael Pennington, Deputy EMA Director. On this date, the ASC Administrator also provided the EMA and Health Department with letters listing ASC assets, and provided the EMA Director with the ASC's most recent Disaster Plan for review.2. The deficiency shall be prevented in the future by the Administrator and Supervisor attending future meetings with the Health Department and EMA, and through attending the biannual MEPCO meeting (Elkhart County's Medical Emergency Planning Committee). The Administrator and Supervisor shall attempt to coordinate an</p>	02/02/2012	

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	related activity since the final months of 2009.		inter-agency training exercise or related activity with one of these groups or with the local hospital.3. The ASC Administrator shall be responsible for 1 and 2.4. The deficiency is corrected as of 2/2/12.		