

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001066	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/05/2012
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NAME OF PROVIDER OR SUPPLIER AESTHETIC SURGERY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 13590 N MERIDIAN ST CARMEL, IN 46032
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S0000	<p>The visit was for a licensure survey.</p> <p>Facility Number: 009563</p> <p>Survey Date: 1-04-12 to 1-05-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Karilyn Tretter, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 01/20/12</p>	S0000	<p>All policy and procedure updates, modifications, clarifications, or changes have [as per your directions on 2/20/12] been made retroactive to 2/5/12 and form changes made as directed. All of the above have been communicated to all staff either by verbal, written, or electronic communication by medical director who is responsible for notification and compliance of above. Thank you for your assistance.</p>	

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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S0166	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based upon document review and interview, the center failed to maintain and update its policies/procedures in accordance with center policy.</p> <p>Findings:</p> <p>1. Minutes of the Annual Meeting dated 4-15-2011 indicated the following: " All policies and procedures utilized at the center were reviewed in January by the governing body and were reaffirmed. "</p> <p>2. The policy/procedure Patient Records, Access To (approved 4-11) indicated the following: " Any medical records involved in potential or actual litigation shall be given immediately to the <u>Facility Manager</u>. "</p> <p>3. The policy/procedure Medical Record Department Quality Improvement Participation (approved 4-11) indicated the following: " The medical records clerk performs daily chart analysis documenting repeated omissions, errors, etc., for referral to the <u>Facility Manager</u>... "</p> <p>4. The policy/procedure Security, Surgery Center (approved 4-11) indicated multiple references to</p>	S0166	<p>(1 & 2) Organization is a small facility with threefull time staff. Because of the sizethere is not a problem in delineating who are administrative personnel. Facility manager is a term that was used inthe 1st years of operation and was felt to be obvious in the managementstructure to be consistent with the term administrator used in subsequentyears. Since the same person is head ofthe governing body; CEO of organization; medical director; and administratorand since the staff a small confusion on difference in terminology of"facility manager" vs. "administrator" has not been aproblem.</p> <p>(3 & 4) In order to clarify and eliminate potential confusion, the organization hasadopted the following policy for clarification of terminology used fordemonstrated positions: "For purposes of clarification, in</p>	02/05/2012			

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	<p>the "<u>Facility Manager</u> ."</p> <p>5. The policy/procedure Pharmacy Policies and Procedures (approved 4-11) indicated multiple references to the "<u>Facility Manager</u> ."</p> <p>6. The policy/procedure Fire Plan (approved 4-11) indicated a reference to the "<u>Facility Manager</u>."</p> <p>7. On 1-05-12 at 1135 hours, staff #A4 was requested to provide a job description for a Facility Manager and none was provided prior to exit.</p> <p>8. During an interview on 1-05-12 at 1700 hours, staff #A1 confirmed that the position Facility Manager was not a current position and confirmed that the policy/procedures failed to indicate the responsible person.</p> <p>9. The policy/procedure Guidelines for Maintaining the Medical Record as a Medicolegal Document (approved 4-11) indicated the following: " When medical records are filed incomplete ... attach a statement about the incomplete status to the medical record signed by the <u>Medical Record Chairman of the Governing Body</u> ."</p> <p>10. During an interview on 1-05-12 at 1700 hours, staff #A1 confirmed that the policy/procedure had not been properly maintained and needed revision.</p>		<p>all policies, procedures, and organization minutes and communications, the terms "facility manager", "administrator", "businessmanager" and "manager" will be considered synonymous with "administrator". The position of administrator, chief executive officer [CEO], and medical director may be held by the same individual."</p> <p>The medical director is in charge of compliance.</p>		

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S0300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</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 discrete, specific, objective standards for contracted services provided at the facility.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 4-11) indicated the following: " The Quality Assurance Committee shall ... adopt and submit for approval of the governing body a Quality Assurance Plan that provides for specific rules, methods, and procedures for reviewing, evaluating, and maintaining the quality and efficiency of patient care within the center, including ... establishing objective criteria, establishing objectives and measuring</p>	S0300	<p>(1 & 2) Facility does feel that it does have an effective, ongoing quality assurance program which does identify trends and does benchmark against national standards from accrediting organizations and/or peer reviewed medical literature. Program is multifaceted and consists of multiple review instruments. QA Grid was developed in response to previous surveyor comments and includes identifiable tasks be completed if problems identified and identifies individual responsible. This and other trend instruments are completed on a monthly basis, reviewed at the quality assurance meetings held as a component of the monthly staff meetings. Copies of the specific monthly reports are contained in computer sub-vials in either the quality assurance section or the monthly meeting section of surgery center record forms.</p> <p>Quality assurance plan is supported by monitoring key</p>	02/05/2012			

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	<p>actual practice against the criteria ...taking appropriate action to correct identified problems [and] following up on action taken. "</p> <p>2. On 1-04-12 at 1030 hours, staff #A4 was requested to provide a copy of the center QA plan and none was provided prior to exit.</p> <p>3. Review of the Contract Services Quarterly Monitoring Evaluation Form failed to indicate specific, individualized and objective standards for evaluating each service and failed to indicate how the standards could be reviewed over multiple periods for ongoing monitoring of each service.</p> <p>4. The Combined Medical Staff-Governing body monthly meeting minutes failed to incorporate identified QA grids and reports as exhibits with the monthly committee meetings. The documentation failed to ensure QA program elements could be reviewed against criteria and standards and compared with outcomes for effectiveness separately from unrelated content presented in the combined monthly meeting reports.</p> <p>5. QA Committee Meeting Minutes dated 5-6-11, 7-1-11, and 12-3-11 indicated the following: "Continue to work to obtain more information regarding patient's satisfaction. [Staff #A1] noted that we still are having a small percent of patients who response [respond]. However [it] is noted there are no problems or complaints. Patient comments the [has] been extremely satisfactory. [Staff #A6] related report on quality assurance patient satisfaction study done for BASI patients which are the ASC patients also. No complaints</p>		<p>events on a monthly basis and comparing these tonationally accepted standards as noted above. This allows identification of outliers and identification of any aberrant trends. Reports are reviewed and discussed at the monthly meetings. Various check lists and report forms [copies of monthly for forms attached] are reviewed to verify compliance. Background support information is also obtained in monthly record box contained at the surgery center nurses' station or are scanned in and contained in ASC computer record keeping files.</p> <p>Vendor evaluations are done on a monthly basis [C quality assurance grid] and expanded quality reviews are performed on a quarterly basis on criteria est. by the governing body [see attached policy] and on a specific report form which monitors the specific criteria [see copy of report form attached]. The organization feels the program is effective based on the fact that in the past twelve months to vendors were terminated based on performance evaluations [carbon dioxide laser vendor and lawn maintenance-irrigation vendor].</p> <p>Patient's satisfaction is monitored through a written evaluation questionnaire which is presented to each patient on discharge. Responses and complaints are</p>				

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	<p>were noted. All responses rated high-quality and gave highest quality rating." The minutes failed to indicate an action in response to the identified concern if the study reported was ongoing.</p> <p>6. Center documentation QA/PI Monitors Monthly Review duplicated information reported through other documentation including the monthly Medical Staff-Governing body meeting minutes. The narrative standards following each service area heading failed to indicate specific, meaningful, measurable criteria or frequency of sampling methods. The Review tool monitors failed to reflect ongoing review for effectiveness of evaluative criteria. The narrative format failed to ensure data obtained over successive months could be reviewed for trending and response to action taken as required by the Medical Staff Bylaws Quality Assurance Committee standards.</p> <p>7. During an interview on 1-05-12 at 1715 hours, staff #A1 confirmed that the current QA standards applied to the contracted services failed to objectively evaluate each service. Staff #A1 confirmed that the QA committee minutes failed to ensure the ongoing review and revision of the standards for evaluation and failed to indicate ongoing program evaluation and revision using the current format.</p>		<p>monitored as part of the general quality assurance program and discussed on a monthly basis. Minutes of review that response rate to questionnaires is low. However, patient satisfaction is gauge to be high based upon verbal comments made by patients, lack of receiving any complaints or grievances, and patients returning for additional treatments. Discussions in the quality assurance minutes reflect discussions on ways to improve response. However, no "problem" regarding patient satisfaction or quality of care was identified, so no specific tracking action or task was necessary. It should be noted, however, that the organization has been active in evaluating more refined instruments to monitor outcomes and patient satisfaction. Attached find copies of information distributed to staff and discussed in regard to improving patient satisfaction surveys. It should be noted, however that such information discussions may not be identified in monthly meeting minutes. Because the staff is small and the entire governing body is present at all of the staff meetings. This information is communicated affectively to all parties.</p> <p>(3) Organization has revised quality assurance policy to more</p>		

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			<p>clearly delineate expanded scope of activities and review formsutilized for quality monitoring and trend monitoring. Reporting forms and minutes more clearly reflect any problem areasidentified, task assigned, and individuals responsible for taskcompletion. Medical director will beresponsible for insuring completion.</p> <p>(4) Followup—ongoing – continuous via governingbody on monthly or quarterly basis</p> <p>References(attachment supplied via CD): Monthlyquality assurance forms Qualityassurance studies for continues quality improvement 2011 Monthlytrend monitoring forms [examples [Vendor/contractorpolicy and evaluation form Patientsatisfaction monitoring form development file—informational/work in progress</p>		

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S0414	<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 policy/procedure review, staff interview, and facility documentation review, the facility failed to ensure that the Infection Control Committee met on a quarterly basis and failed to ensure the appropriate membership on the Infection Control Committee.</p> <p>Findings included: 1. On 1-4-2012 at 1300, during review of the ASC's Infection Control manual "Infection Prevention Manual for Ambulatory Care -</p>	S0414	<p>Organization has an infection control committee whose chairman isa board certified infectious disease specialist who is also the chairman ofinfection control at Indiana University Health North. He has assisted us in obtaining the servicesof an infection control nurse who assists in infection control activities and providesconsultative services. The infectiousdisease specialist is available for telephone</p>	02/05/2012

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	<p>2009 Edition", Page 9, I. Responsibility, included "The Infection Prevention Committee meets on a regular basis."</p> <p>2. On 1-4-2012 at 1300, the ASC's Infection Control manual "Infection Prevention Manual for Ambulatory Care - 2009 Edition", Page 9, under V, included "The Infection Prevention Committee is composed of the following: Medical Director, Nursing Director, Infection Preventionist, Infectious Disease (ID) Physician Consultant, Member(s) of the active medical staff, and CEO."</p> <p>3. On 1-5-2012 at 0915, the names of the ASC's Infection Prevention Committee were provided, including the ID Physician Consultant.</p> <p>4. On 1-5-2012 at 1000, during review of the Infection Control Committee meetings, it was noted that the ID Physician Consultant was not listed as being present at any of the Infection Control Committee meetings in 2011.</p> <p>5. On 1-5-2012 at 1015, during review of the Infection Control Committee meetings in 2011, it was found that the Infection Control Committee met on 2/26/2011 and on November 4, 2011. An Annual Review of Infection Control was held on April 9, 2011.</p>		<p>consultation and on site review evaluation whenever necessary. The medical director frequently consults with the infectious disease specialist via telephoneregarding various issues. Annually theinfection disease specialist reviews all infection control protocols, policies,procedures and conducts a thorough evaluation and in-service with staff. The medical director and nursing directorhave undergone additional training in infection control activities [seeattached list of educational activities] which have been reviewed and approvedby infection control consultants and felt to be appropriate and services qualifyingeducational activities qualify the medical director nursing director forconducting infection control activities within organization. Monthly infection committee meetings are heldin conjunction with monthly staff meetings [see attached meeting minutesexample of monthly staff meetings]. Additional separate infection committee meetings have been conductedquarterly all which have been attended by the infection control nurse and theinfection disease specialist and chair of committee conducted the annualinfection control review on 4-9-11. Thisreview and oversight is felt to be appropriate by the organization and by theconsultant infection control specialist given the fact that our</p>		

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			<p>patient volume is small. This means that either the infection control nurse or the infection disease specialist was present at the facility for review for every 12 - 20 surgical patients encounters. Since no infections or quality control problems have occurred [so infection control quality assurance -total quality improvement evaluation for first 6 months of 2011 documenting no quality control issues - attached], it is felt to be appropriate. Consultants are available to review and consultation immediately if needed.</p>	

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S0620	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(5)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the center policies.</p> <p>Based upon document review and interview, the center lacked a policy/procedure for including plain paper facsimile documents in the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation indicating that plain paper facsimile documents were approved for inclusion in the MR and none was provided prior to exit. On 1-05-12 at 1030 hours, staff #A4 indicated that the center lacked a policy/procedure that allowed plain paper facsimile documents to be entered in the patient record. On 1-05-12 at 1655 hours, staff #A1 confirmed that the center failed to 	S0620	<p>(1 & 2) Organization has the attached policy on faxdocuments which was adopted 1997 [see attached]</p> <p>“Dictated reports should be ready within 24 – 48 hours. In no case should they take more than one week to be placed on the chart. Authentication by the author needs to be made as soon as possible after transcription. It cannot be made with a hand stamp, but must be a signature. At the present time records must be signed in the facility. It is anticipated in the future that facsimile copies may be used as an original. When that becomes the case, by state regulation, dictated material would be faxed to the author for their authentication</p>	02/05/2012			

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	ensure that plain paper facsimile documents may be entered in the MR.		<p>by signature and then re-faxed to the Surgery Center to be incorporated into the chart. “</p> <p>(3) Organization has adopted a revised policy regarding including fax documents in medical records .</p> <p>“</p> <p>“Dictated reports should be ready within 24 – 48 hours. In no case should they take more than one week to be placed on the chart. Authentication by the author needs to be made as soon as possible after transcription. If physician is not available in facility to authenticate, the medical director may execute authentication on their behalf. It cannot be made with a hand stamp, but must be a signature or electronic signature which includes date and time of authentication. Facsimile copies may be used as an original. Materials dictated at the facility may be faxed to the author for their authentication by signature and then re-faxed to Aesthetic Surgery Center</p>	

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			<p>to be incorporated into the chart. Faxed documents received which provide pertinent information for patient care may be incorporated into the medical record at the discretion of the medical director, nursing director, administrator, or the patient's physician."</p> <p>. Medical director is implementation.</p> <p>(4) N/A</p> <p>Attachment: Med record policy adopted 1997</p>		

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based upon document review and interview, the center lacked a policy/procedure ensuring that all entries in the medical record (MR) were legible for 2 of 6 records.</p> <p>Findings:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was requested to provide a policy/procedure for verifying entries of questionable legibility and none was provided prior to exit.</p> <p>2. Center document titled AAAHC Clinical Record Worksheet (dated July 2011) indicated under the category <u>The record is legible to clinical personnel with or without assistance</u> that 2 of 6 MR reviewed (MR 3011 and MR 3010) were inadequate. The documentation lacked an indication for follow-up to ensure that the entries were clarified.</p> <p>3. On 1-05-12 at 1655 hours, staff #A1 confirmed the center lacked a policy/procedure for verifying illegible</p>	S0640	<p>(1&2) Organization does have policy for legibility of medical record and for resolution of problem [see attached policy 2009]. If this illegibility was noted on a AAAHC form chart review, it was being conducted by consultant or review physicians for peer review and was not noted to be a problem by clinical staff at time of service or policy protocol would have been utilized. Follow up review with staff involved on care of patient s identified on records for number listed revealed no interpretation problems or care issues noted by staff caring for patient. Because of small staff, members are familiar with hand writing and legibility is not issue, if is – policy followed. Organization is moving toward implementation of electronic clinical record which will further reduce legibility problems.</p> <p>(3 & 4) Organization has reviewed and reaffirmed its policies and protocols regarding legibility of medical record and clarification of entries. Organization will conduct quality assurance study for legibility and quality of medical</p>	02/05/2012			

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	information in the patient record.		records entries regarding completeness, accuracy, and legibility. Review will be conducted quarterly for the next six months with results being presented to quality assurance committee and governing body for an appropriate as necessary. If legibility completeness and accuracy are in the 95th percentile after six months, quality assurance studies will be discontinued. Medical director will be responsible for compliance.		

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S0644	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(2)</p> <p>All entries in the medical record must be as follows:</p> <p>(2) Made only by authorized individuals as specified in center and medical staff policies.</p> <p>Based on document review and interview, the center lacked a policy/procedure specifying which individuals, staff members and medical professionals are permitted to make entries in the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation indicating which individuals are authorized to make entries in the MR and none was provided prior to exit. The policy/procedure Guidelines for Maintaining the Medical Record as a Medicolegal Document (approved 4-11) failed to indicate what individuals were authorized to make entries in the MR. During an interview on 1-05-12 at 1650 hours, staff #A1 confirmed that the policy/procedure lacked a provision indicating which individuals and medical 	S0644	<p>((1&2) the organization employees only registered nurses and one administrative/surgical technician. Only nurses are allowed to make notes in the medical record along with physicians. Organization has policy against using LPNs or nursing aids. Credentialing process acknowledges and delineates ability to make medications in medical records for nursing staff under the direction of the supervising physician which in all cases in this facility is the medical director. [attachment - #5 on credentialing application] Medical records policy states nurses will make progress note entries and verify entries of other support personnel [see highlighted area of attached policy]. However, medical record policy could be more definitive in this regard.</p> <p>(3) Organization has amended policies to clarify who can make entries in medical record and take verbal orders. Medical director responsible for completion and implementation.</p>	02/05/2012	

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	professionals were authorized to make MR entries.		(4) N/A		

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S0772	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based on document review, the center failed to ensure all preoperative History and Physical (H&P) examinations done prior to the date of the procedure are updated on the day of surgery and documented in the patient record.</p>	S0772	No policy is utilized for documentation of no change in physical exam because it is not necessary. All patients have an examination by the surgeon on the day of surgery. A prior physical and history conducted previously may be attached and included in the	02/05/2012			

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	<p>Findings:</p> <ol style="list-style-type: none"> On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation indicating that a medical H&P exam performed prior to the date of surgery shall have an update on the day of admission and none was provided prior to exit. The policy/procedure Preoperative History and Physical (approved 4-11) lacked a provision for documenting an update in the patient record on admission for all H&P examinations performed prior to the date of the procedure. The sample H&P form included in the policy/procedure lacked a provision for indicating the H&P was updated on the day of surgery or reviewed with no changes by the attending surgeon. 		<p>medical record in which case the physician would note the present date and fact that there was no change in the attached exam. However, the physical exam form that is part of the ASC medical record would also need to be completed that day (day of surgery) by the surgeon and signed. [see copies of clinical records]. The organization has adopted a policy clarifying that an examination must be provided by the physician on the day of surgery. A prior physical and history previously performed by the physician within two weeks prior to surgery will be recognized as a valid exam for this purpose and included in the patient's medical record provide the physician signs, dates, times the re-exam "update" attesting that there is no change from the attached examination or history except for those changes noted.</p>	

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S0780	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based upon document review and interview, the center lacked a uniform policy/procedure for authenticating verbal orders in the medical record (MR) and lacked a provision ensuring authentication was performed in compliance with center policy.</p> <p>Findings:</p> <p>1. The policy/procedure Guidelines for Maintaining the Medical Record as a Medicolegal Document (approved 4-11) indicated the following: " All telephone orders should be signed by the appropriate authorized personnel to whom dictated with the name of the practitioner per his or her own name. " The policy/procedure</p>	S0780	((1 &2) Organization does have the following policy regarding noting time and dateof verbal order adopted in 2009 [see attachment], but does not have writtenpolicy on the current policy in practice of nurse being only individual who canreceive verbal orders. "All verbal orders will beauthenticated by the ordering physician as soon as possible. Medication will beby signature with date and time of signature. In the event that the physicianplacing the order is not readily available, the medical record can beauthenticated by the medical director." (3) Organization hasadopted a new policy to clarify nurses ability to take verbal orders : "Use of verbal orders should be	02/05/2012			

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	<p>failed to indicate what individuals were authorized to take verbal orders and failed to indicate the requirement to date and time the entry when the order was received.</p> <p>2. The policy/procedure Verbal Orders (approved 4-11) indicated the following: "...verbal orders should be signed by the physician on the day of surgery ..[and] ...verbal orders should be signed prior to the physician leaving the facility. " The policy/procedure lacked the requirement to date the entry when authenticated by the physician ensuring compliance with the policy.</p> <p>3. During an interview on 1-05-12 at 1655 hours, staff #A1 confirmed that the policy/procedures were not uniform and lacked the indicated provisions.</p>		<p>kept to a minimum. Registered nurses have the authority to take verbal orders. Verbal orders may be taken by other individuals only if they have been granted specific authority(privilege) to do so by the Governing Body as part of the credentialing process. When verbal orders are given,individual taking the verbal order should write the order down and then repeatback the verbal order for confirmation by the ordering physician. Verbal orders should be cosigned by the ordering physician as soon as possible. In the event that the physician making the original verbal order is notavailable, the verbal order can be reviewed and co-signed by the medicaldirector, which will be viewed as sufficient authorization” Medicaldirector is responsible for compliance.</p> <p>(4) N/A</p> <p>Attachment: Medrecord policy adopted 2009</p>		

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S0784	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(P)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.</p> <p>Based on document review, the center lacked the requirement for documenting a final diagnosis along with the completion of the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation indicating that the final diagnosis shall be documented in the MR along with the timeframe for completion and none was provided prior to exit. The policy/procedure Medical Records Procedures (approved 4-11) and Discharge Record Processing (approved 4-11) failed to indicate a provision for documenting a final diagnosis in the MR. The MR auditing tool AAAHC Clinical Record Worksheet (2005) lacked the provision for ensuring that a final 	S0784	<p>((1 & 2) Organization utilizes medical record forms which haveplaced a designate postop diagnosis and condition [see copies of attachedsurgical records]. Post surgerydiagnosis and condition are recorded on medical record on all patients and a summariesheet is completed at the time of release summarizing care.</p> <p>(3 & 4) position hasadopted policy clarifying need to complete post surgery diagnosis and conditionsection of medical record form as well as completing discharge sheet that timeof release Medical director will be responsible for clients. Because postoperative diagnosis and conditionare currently being recorded on all patients and because medical records areall reviewed as part of ongoing quality assurance program, compliance with thisprovisional would be</p>	02/05/2012			

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	diagnosis was documented on the MR when the records were reviewed each month by the Nursing Director.		incorporated automatically into the aforementioned ongoing reviews.		

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S1010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on document review and interview, the center failed to maintain its policy/procedures regarding pharmacy multi-dose vials in accordance with acceptable standards of practice at the facility.</p> <p>Findings:</p> <p>1. The United States Pharmacopeia (USP) General Chapter 797 [16] indicated the following for multi-dose vials of sterile pharmaceuticals: " If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. "</p> <p>2. The policy/procedure Pharmacy Policies and Procedures (approved 4-11)</p>	S1010	<p>((1 & 2) Organizationhas had policy regarding use of multidose vials noting that they had to be usedwithin twenty-eight days of opening [see attached policy]. However, in 2008 the organization adopted apolicy of single use of all multidose vials as part of its continuing qualityassurance program. Attached documentsindicate that this policy was accepted verbally and would be memorialized inwriting. Attached quality assureddocuments in December 2008 indicate 100% compliance with this policy. However it appears that formal written policywas never put in place.</p> <p>(3) Organization hasadopted a written policy memorializing the practice in effect since 2008 of single patient use of all multi-dose medication vials. Medical director is responsible forcompliance.</p>	02/05/2012	

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	lacked a provision for dating a multi-dose vial when opened and discarding within 28 days or requiring the vial to be used with one patient and disposed of on the same day. 3. During an interview on 01-05-12 at 1430 hours, staff #A2 confirmed the policy/procedure lacked the requirement to date the multi-dose vial when a medication was opened and lacked the requirement to discard the opened vial within 28 days.		(4) N/A Attachment: QAstudy regarding single use of multi-dose vials		

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S1020	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(D)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(D) Reporting of adverse reactions and medication errors to the practitioner responsible for the patient and the appropriate committee, and documented in the patient's record.</p> <p>Based on document review and interview, the center failed to ensure a policy/procedure ensuring medication errors would be documented in the patient record.</p> <p>Findings:</p> <p>1. The policy/procedure Pharmacy Policies and Procedures (approved 4-11) failed to indicate that the error will be documented <u>in the patient record</u> when a medication was administered to the wrong patient or incorrect medication was administered to a patient.</p> <p>3. During an interview on 01-05-12 at 1710 hours, staff #A1 confirmed that the policy/procedure lacked the requirement to document the error in the patient</p>	S1020	<p>The organization has a policy that calls for: "Any reaction to medications will result in a report being made to the pharmacy committee and to the medical director. An incident report can be utilized for this purpose." This would ensure that medication errors and reactions would be appropriately reviewed and corrective measures taken. Incident reports are required in any event that could adversely affect the patient, so even if there was a medication error which did not cause a reaction, it would result in triggering an incident report and subsequent review. Medical ethics and the Indiana medical licensure statute would</p>	02/05/2012

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	record.		dictate the physician would have to note medicationerror or adverse reaction in the patient's medical record. For that reason it would appear that theaforenoted policy suffices and that no additional policy is necessary. However, the organization has adopted policywhich states that any medication and/ormedical error as well as any adverse reactions will be appropriately documentedin patient's medical record, in addition to the above noted policy and procedure. Medical director is responsible for compliance		

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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, the center failed to ensure refrigerated medications were safely maintained for patients at the center.</p> <p>Findings:</p> <p>1. The policy/procedure Pharmacy Policies and Procedures (approved 4-11) failed to indicate what temperature range (2 to 8 degrees Centigrade) was specified by the manufacturer for ensuring the safe refrigerated storage of medications, failed to indicate a provision for documenting the observed temperature to validate compliance with the acceptable temperature range, and failed to indicate an action for staff to perform if the observed value was not within the " accurate " temperature range.</p>	S1146	(1 & 2) Organization has the attached policy regarding refrigeration which is in compliance with regulations. Attached policy and records are contained in nurses log book kept in nurses station for recording temperatures. [See attached policy and records showing compliance] (3&4) N/A – continues to be a part of monthly QA monitoring program – see QA plan and monthly reports!	02/05/2012			

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	2. Center documentation of daily checks failed to indicate what temperature was observed by staff, failed to indicate what temperature range was acceptable, and failed to indicate what response staff should perform if the observed temperature was not within the acceptable temperature range.			

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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, 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:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was asked 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>The organization conducts annual review of physical plant and systems including review of preventive maintenance—see attached copy of March 2011 review. Although this is performed annually, the organization has no policy requiring a triennial review.</p> <p>While it should be noted that the organization is in compliance with having aforementioned reviews performed on annual basis, the organization has adopted a policy that operational and maintenance control records will be analyzed and approved by the governing body at least triennially. Medical director responsible for</p>	02/05/2012			

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	<p>detector system and none was provided prior to exit.</p> <p>2. Review of the maintenance schedules and equipment maintenance records failed to indicate that the center records are analyzed at least triennially.</p> <p>3. During an interview on 1-05-12 at 1720 hours, staff #A1 confirmed that the center lacked documentation of a triennial analysis of the mechanical systems and equipment in use at the center.</p>		compliance.		

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S1162	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(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: Based on document review, observation, and interview, the center failed to ensure that the facility defibrillator was maintained in good working order as recommended by the manufacturer. Findings: 1. On 1-04-12 at 1030 hours, staff #A4 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. 2. The center document Crash Cart Weekly Check dated January 2012 lacked a description of the process for checking the defibrillator according to the</p>	S1162	<p>Organization has policy [attached] on maintenance and checking of equipment based on manufacturers' recommendations. A binder containing all manufacture recommendations is maintained at nurses' station. Defibrillator is checked by bio technical contractor as part of preventive maintenance program. Defibrillator is checked per shift by staff according to manufacturer's recommendations which include rotation of battery and charge and discharging at sequential level verifying charge calibration [see daily log check--attached]. While staff discharge at each level, there is no policy describing this function other than reference to adhering to manufacturer's recommended practices. Staff</p>	02/05/2012			

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	<p>manufacturer ' s recommendations.</p> <p>3. The Datascope Defibrillator service manual (1995) indicated the following under the heading Preventive MAINTENANCE: " The Datascope Defibrillator Battery Packs have an expiration date on them. Replace the Battery Pack on or before the expiration date. "</p> <p>4. During a tour on 1-04-12 at 1600 hours, the following condition was observed: (2) Datascope Defibrillator battery packs with an expiration date 8-2006.</p> <p>5. During an interview on 1-04-12 at 1630 hours, staff #A1 confirmed that the center defibrillator batteries needed replacement to ensure its availability for use if needed.</p>		<p>has developed policy to check defibrillator according to manufacturer's recommendations. It should be noted that battery expiration date was missed by staff and prior and current bio technical vendors. It should be noted that checks on each shift verified that battery was functioning appropriately and equipment was able to produce appropriate charge levels despite age. When expiration was noted, backup defibrillator unit was immediately obtained for emergency use until replacement batteries could be obtained. Organization has taken corrective action by changing defibrillator check sheet to provide area to indicate equipment checked at each energy level and has worked with biotechnical consultant to review manufacturer's preventive maintenance and testing requirements for equipment to insure recommendations are being followed. Where applicable, policies or stepwise procedure guidance are posted along with the equipment check list to facilitate compliance with recommendations. Staff have demonstrated competency with policies and procedures as applied to defibrillator testing and maintenance. Organization is currently using an AED and is in the process of upgrading to new defibrillator at which time above</p>	

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			noted polices and orientation will be revised. Medical director will be responsible for completing policy review and updates. Nursing director will be responsible for ensuring all staff are trained and demonstrate competency with new policies including importance of checking for and verifying expiration dates on all equipment and components.		

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S1168	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iii)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.</p> <p>Based on document review and interview, the center failed to ensure that a triennial analysis was performed on all patient care equipment in use at the center.</p> <p>Findings:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was asked to provide documentation indicating triennial analysis of patient care equipment preventive maintenance (PM) records and none was provided</p>	S1168	<p>The organization conducts annual review of patient care equipment and safety systems including review of preventive maintenance—see attached copy of BioHelp reviews and policy calling for annual review. Although this is performed annually, the organization has no policy requiring a triennial review.</p> <p>While it should be noted that the organization is in compliance with having aforementioned reviews performed on annual basis, the organization has adopted a policy calling for at least triennial review and approval</p>	02/05/2012			

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	<p>prior to exit.</p> <p>2. PM records for patient care equipment failed to indicate triennial analysis by either the biomedical engineering services provider for patient care equipment or the center.</p> <p>3. During an interview on 1-05-12 at 1720 hours, staff #A1 confirmed that the center lacked documentation of a triennial analysis of the mechanical systems and equipment in use at the center.</p>		<p>bygoverning body of equipment maintenance,repairs, and electrical current leakage checks. Medical director is responsible for compliance.</p>		

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S1170	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iv)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p> <p>Based on document review and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer.</p> <p>Findings: 1. On 1-04-12 at 1030 hours, staff #A4 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>Defibrillator is checked per shift by staff according to manufacturer's recommendations which include rotation of battery and charge and discharging at sequential level verifying charge calibration[see daily log check-attached]. While staff discharge at each level, there is no policy describing this function other than reference to adhering to manufacturer's recommended practices. Staff has developed policy to check defibrillator according to manufacturer's recommendations. It should be noted that battery expiration date</p>	02/05/2012

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	<p>2. The center document Crash Cart Weekly Check dated January 2012 lacked a description of the process for checking the defibrillator or discharge according to the manufacturer ' s recommendations.</p> <p>3. The Datascope Defibrillator service manual (1995) indicated the following under the heading Preventive Maintenance: " To ensure the readiness of your Datascope Defibrillator ...Datascope has provided the following OPERATOR ' S SHIFT CHECK LIST....Perform the OPERATOR'S SHIFT CHECK LIST located in section 8.9 of this manual, every shift. "</p> <p>4. The Datascope Defibrillator service manual (1995) indicated the following under the heading OPERATOR ' S SHIFT CHECK LIST: "Charge to manufacturer's recommended test energy level ...[and]... discharge per manufacturer's instructions."</p> <p>4. During an interview on 1-05-12 at 1710 hours, staff #A1 confirmed that the center lacked a policy/procedure and the Crash Cart checklist lacked a process or reference guide for daily defibrillator checks or discharge based on the manufacturer ' s recommendations.</p>		<p>was missed by staff and prior and current bio technical vendors. It should be noted that checks on each shiftverified that battery was functioning appropriately in equipment was able toproduce appropriate charge levels despite age. When expiration was noted, backup defibrillator unit was immediatelyobtained for emergency use until replacement batteries could be obtained. Organization has taken corrective action byworking with biotechnical consultant to re–review all manufacturer's preventivemaintenance and testing requirements to ensure recommendations are beingfollowed. Policies or stepwise procedureguidance will be posted along with the equipment check list to facilitatecompliance where applicable. AED hasbeen obtained until upgraded defibrillator can be obtained. Staff have demonstratedcompetency with policies and procedures as applied to equipment testing and maintenance of AED and will do samewhen upgrade defibrillator obtained. Medical director responsible for policy review and updates. Nursing director responsible for insuring all staff aretrained and demonstrate competency with new equipment including importance of checking for and verifying expiration dates on all equipmentand components –</p>				

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S1180	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.</p> <p>Based on document review and interview, the center failed to establish a safety management program that included a review of safety functions by a committee appointed by the chief executive officer and included representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation of a safety management program including committee minutes and a designated safety officer and none was provided prior to exit.</p> <p>2. Review of information provided for survey review failed to indicate a policy/procedure or center-wide plan for safety management or risk management.</p> <p>3. During an interview on 1-05-12 at 1710 hours, staff #A1 indicated that the safety management functions were integrated in the Quality Assurance Program at the center.</p> <p>4 The Medical Staff Bylaws Quality Assurance Committee (approved 4-11) failed to indicate a safety function, provision or reference to a safety management</p>	S1180	(1 & 2) Organization does have an active and ongoing risk management-patient safety program which it feels is in compliance with standards. Program is incorporated into overall quality assurance program [see attached quality assurance outline]. Patient safety and risk management would be incorporated into parts of infection control and drug monitoring aspects of quality assurance plan and are directly applicable to section 8 of QA plan-"analysis of injury"; section 9-"surveillance and maintenance of equipment and environment" and section 11 "disaster drills and emergencies". A specific risk management section is outlined in policies [see attached risk management policy] as a part of the overall quality assurance program. In addition the highlighted sections of the monthly QA Grid [see attached] highlights	02/05/2012			

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	<p>committee process or risk management review process and failed to indicate a process to designate the safety officer.</p> <p>5. The Combined Medical Staff - Governing Body Meeting minutes dated 9-02-11, 10-03-11, and 11-02-11 indicated the following: "Voting Members Present: (Staff #A1) Non-voting Members Present: (staff #A2), (staff #A4), (staff #A5), (staff #A6)." The minutes failed to indicate a committee process that demonstrated how staff #A2 and staff #A5 were contributing to the functions of a safety management program. The minutes failed to indicate a distinct heading including the words Safety Management for evaluating safety functions separate from the listed headings.</p> <p>6. During an interview on 1-05-12 at 1707 hours, staff #A1 confirmed that the Quality Assurance Committee Bylaws lacked a safety management provision, the center failed to develop a written safety management plan and that the center meeting minutes failed to document an organized process for reviewing safety functions to comply with State requirements.</p>		<p>areas that would be considered in the patient safety risk management arena. In addition, the facilities had ongoing quality assurance- total quality improvement studies in 2011 which are applicable to these areas. Studies were conducted on Prevention of Sharps Injuries and evaluation and risk assessment for patient falls [see quality assurance studies attached]. In addition, quality assurance benchmarking study to the National Patient Safety Goals and Sentinel Events was conducted in December 2011 [see attached quality assurance study]. Also, the facility does a monthly risk review assessment and compares this to prior months to identify any trends- [see attached] In addition OSHA activities would be consistent with patient safety and risk management activities as would disaster planning [see attached]</p> <p>(3 & 4) Organization has modified quality assurance, risk management, and patient safety activities and revise policies and procedures so that the patient safety and risk management components of the overall quality assurance activities are more transparent. Medical director is responsible for ongoing compliance..</p>		

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S1182	<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 upon document review and interview, the center failed to develop a written safety management program that indicated an ongoing, center wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Findings:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation of a safety management program indicating the process to collect and evaluate information about safety practices and hazards and none was provided prior to exit.</p> <p>2. Information provided for survey review failed to indicate a safety program, process, or center-wide plan for evaluating safety practices and hazards by committee. The center failed to establish a formal framework for integrating several center practices into an organized process.</p> <p>3. During an interview on 1-05-12 at 1707 hours, staff #A1 confirmed that the center failed to develop a written safety management program that demonstrated an ongoing, organized process for evaluating safety issues and problems to ensure a safe environment for patients, staff members, and the public.</p>	S1182	((1 & 2) Organization does have an active and ongoing risk management-patient safety program which it feels is in compliance with standards. Program is incorporated into overall quality assurance program [see attached quality assurance outline]. Patient safety and risk management would be incorporated into parts of infection control and drug monitoring aspects of quality assurance plan and are directly applicable to section 8 of QA plan-"analysis of injury"; section 9-"surveillance and maintenance of equipment and environment" and section 11 "disaster drills and emergencies". A specific risk management section is outlined in policies [see attached risk management policy] as a part of the overall quality assurance program. In addition the highlighted sections of the monthly QA Grid [see attached] highlights areas that would be considered	02/05/2012			

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			<p>in the patient safetyrisk management arena. In addition, thefacilities had ongoing quality assurance- total quality improvement studies in2011 which are applicable to these areas. Studies were conducted on Prevention of Sharps Injuries and evaluationand risk assessment for patient falls [see quality assurance studiesattached]. In addition, quality assurancebenchmarking study to the National Patient Safety Goals and Sentinel Events wasconducted in December 2011[see attached quality assurance study]. Also, the facility does a monthly risk reviewassessment and compares this to prior months to identify any trends-[seeattached]</p> <p>(3 & 4) Organizationhas reviewed quality assurance, risk management, and patient safety activitiesand revise policies and procedures sothat the patient safety and risk management components of the overall qualityassurance activities are more transparent. Medical director is responsible for risk management-patient safety .</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001066		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/05/2012	
NAME OF PROVIDER OR SUPPLIER AESTHETIC SURGERY CENTER LLC				STREET ADDRESS, CITY, STATE, ZIP CODE 13590 N MERIDIAN ST 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			
S1184	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 2.5-7(c)(3)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(3) The safety program includes, but is not limited to, the following:</p> <p>(A) Patient safety. (B) Health care worker safety. (C) Public and visitor safety.</p> <p>Based on document review and interview, the center failed to establish a safety management program that included provisions for patient, public, visitor, and health care worker safety.</p> <p>Findings:</p> <p>1. On 1-04-12 at 1030 hours, staff #A4 was requested to provide documentation of a safety management program that included provisions for patient, public, visitor and health care worker safety and none was provided prior to exit.</p> <p>2. Information provided for survey review failed to indicate a safety program or committee with specific provisions for patient safety, public and visitor safety, and health care worker safety.</p> <p>3. During an interview on 1-05-12 at 1710 hours, staff #A1 indicated that the safety management functions were integrated in the Quality Assurance Program at the center.</p> <p>4. The Medical Staff Bylaws Quality Assurance Committee (approved 4-11) failed to indicate a provision for a safety management program with accountability for patient, public, visitor and</p>	S1184	(1 & 2) Organization does have an active and ongoing risk management-patient safety-visitor safety program which it feels is in compliance with standards. Program is incorporated into overall quality assurance program [see attached quality assurance outline]. Patient safety and risk management would be incorporated into parts of infection control and drug monitoring aspects of quality assurance plan and are directly applicable to section 8 of QApn-"analysis of injury"; section 9-"surveillance and maintenance of equipment and environment" and section 11 "disaster drills and emergencies". A specific risk management section is outlined in policies [see attached risk management policy] as a part of the overall quality assurance program. In addition the highlighted sections of the	02/05/2012			

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	health care worker safety issues and problems. 5. During an interview on 1-05-12 at 1707 hours, staff #A1 confirmed that the center failed to develop a written safety management plan with specific provisions for patient safety, public and visitor safety, and health care worker safety to comply with state requirements.		monthly QA Grid [see attached] highlights areas that would be considered in the patient safety risk management arena. In addition, the facilities had ongoing quality assurance- total quality improvement studies in 2011 which are applicable to these areas. Studies were conducted on Prevention of Sharps Injuries and evaluation and risk assessment for patient falls [see quality assurance studies attached]. In addition, quality assurance benchmarking study to the National Patient Safety Goals and Sentinel Events was conducted in December 2011 [see attached quality assurance study]. Also, the facility does a monthly risk review assessment and compares this to prior months to identify any trends-[see attached]. The Security and environmental monthly facility check list are examples of both patient, staff and visitor safety measures. And the OSHA program is also applicable to all groups [see attachments] (3 & 4) Medical director will work with consultants and review quality assurance, risk management, and patient safety activities and revise policies and procedures so that the patient safety and risk management components of the overall quality assurance activities are more transparent. Medical director will be responsible for		

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