

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001074	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 12/05/2013
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NAME OF PROVIDER OR SUPPLIER SURGERY CENTER OF OPHTHALMOLOGY CONSULTANTS	STREET ADDRESS, CITY, STATE, ZIP CODE 7232 ENGLE RD FORT WAYNE, IN 46804
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Q000000	The visit was for a re-certification survey. Facility Number: 009567 Survey Date: 12-03-13 to 12-05-13 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor QA: cloughlin 12/18/13	O000000		
Q000141	416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. Based on policy and procedure review, medical record review, and interview, the nursing staff failed to implement facility policy to ensure the completion of a transfer form for 1 of 1 patient	O000141	1. Jackie Dayton, RN Supervisor remembers filling out this form and sending it with the paramedics when this patient was transferred to the hospital. However, when the surveyor requested those records from the	01/31/2014

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TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>transferred in the last 12 months (pt. # 15).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated a policy titled "Transfer to Lutheran Hospital", no policy number, with a date of last review of 11/2012, which indicated in item #3., "A transfer checklist will be completed by the nursing supervisor..." 2. at 9:15 AM on 12/4/13, review of the transfer medical record for pt. #15 indicated there was no transfer checklist/form present 3. interview with staff member #60, the RN (registered nurse) surgery center manager, at 12:30 PM and 2:25 PM on 12/4/13 indicated: <ol style="list-style-type: none"> a. a call was made to the receiving hospital and no transfer checklist/form could be found for pt. #15 b. this staff member thinks a checklist was completed, but is not present in the medical record here, nor at the receiving hospital 		<p>hospital, the hospital could not produce this particular form. This becomes a situation of "my word versus their word". Who is to say what happened to that form? In the future, Jackie Dayton, RN Supervisor will make sure the transfer checklist form is copied along with the other pertinent documents prior to transferring the patient to the hospital.</p>	

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Q000201	<p>416.49(a) LABORATORY SERVICES</p> <p>If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter. Based on document review and interview, the infection control committee failed to ensure the periodic evaluation of biological indicators and sterilizing processes.</p> <p>Findings:</p> <p>1. Review of the Governing Board quarterly meetings of 2/13/13, 5/15/13, 8/28/13, and 11/21/13 indicated that sterilization processes and biological indicators are not reviewed/discussed at the quarterly meetings for the group assigned to represent the infection control committee for the facility</p> <p>2. interview with staff member #60, the RN (registered nurse) and surgery center manager, at 3:00 PM on 12/4/13, indicated:</p> <p>a. if there were any errors or discrepancies with biological indicators, then these would be discussed/presented</p>	Q000201	Jackie Dayton, RN Supervisor reports quarterly on the autoclave to the medical staff. This was clearly documented in the quarterly QA table chart which the surveyor observed. However, Jackie only reports negative problems with the autoclave. She has not had any negative problems with the autoclave in years, so the quarterly QA table chart did not reflect the normal weekly biological testing. However, Jackie will add to the quarterly QA table template that normal biological testing has been reported to the medical staff.	01/31/2014			

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Q000220	<p>at quarterly meetings</p> <p>b. currently, there is no documentation of periodic evaluation of sterilization processes or biological indicators by the infection control committee/governing board</p> <p>416.50 NOTICE - POSTING ... The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable. Based on observation and interview, the posted patient rights notice lacked 4 of 14 required provisions.</p> <p>Findings:</p> <p>1. The Surgery Center of Ophthalmology Consultants Patient's Bill of Rights (approved 12-12) posted in the reception area of the center failed to indicate a provision for the following patient rights:</p> <p>a. notice of an immediate response and documented investigation for all grievances regarding mistreatment, neglect, verbal, mental, sexual and/or physical abuse and reporting of substantiated allegations to a State or local authority</p> <p>b. notice of the right to exercise his or her rights without discrimination or reprisal</p> <p>c. notice of the right to receive care in a safe setting</p> <p>d. notice of the right to be free from all forms of</p>	Q000220	<p>Douglas Miller, Practice Administrator will make the necessary additions to our patient rights declaration posted in our reception area. The added statements will include: a. notice of an immediate response and documented investigation for all grievances regarding mistreatment, neglect, verbal, mental, sexual and/or physical abuse and reporting of substantiated allegations to a State or local authority</p> <p>b. notice of the right to exercise his or her rights without discrimination or reprisal</p> <p>c. notice of the right to receive care in a safe setting</p> <p>d. notice of the right to be free from all forms of abuse, neglect or harassment from staff, other</p>	01/31/2014			

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Q000221	<p>abuse, neglect or harassment from staff, other patients, or visitors</p> <p>2. During an interview on 12-04-13 at 1610 hours, staff A1 confirmed the posted Patient Bill of Rights lacked notice of the 4 patient rights provisions.</p> <p>416.50(a) NOTICE OF RIGHTS An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>Based on document review and interview, the center failed to ensure that the patient rights information given to a patient, patient representative or surrogate prior to the procedure included 4 of 14 required elements.</p> <p>Findings:</p> <p>1. The Surgery Center of Ophthalmology Consultants Patient's Bill of Rights (approved 12-12) failed to indicate a provision for the following patient rights:</p> <p>a. notice of the physicians who have financial interest or ownership in the ASC center</p>	O000221	<p>patients, or visitors</p> <p>Upon reading our patient rights document, the first finding " notice of the physicians who have financial interest or ownership in the ASC center" has been present since 2009. Our patients sign a document that remains a part of their medical record that discloses the physicians ownership of the ASC. It is unclear why the surveyors did not see this. However, Douglas Miller, Practice Administrator will add the other 3 findings to our patient rights form. b. notice of an immediate response and documented investigation for all grievances regarding</p>	01/31/2014			

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Q000242	<p>b. notice of an immediate response and documented investigation for all grievances regarding mistreatment, neglect, verbal, mental, sexual and/or physical abuse and reporting of substantiated allegations to a State or local authority</p> <p>c. notice of the right to receive care in a safe setting</p> <p>d. notice of the right to be free from all forms of abuse, neglect or harassment from staff, other patients, or visitors</p> <p>2. During an interview on 12-04-13 at 1610 hours, staff A1 confirmed the Patient Bill of Rights lacked notice of the 4 patient rights provisions.</p> <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 policy and procedure review, personnel health file review, and staff interview, the infection control committee failed to ensure an effective employee health program related to immune status and TB (tuberculosis) monitoring.</p> <p>Findings: 1. at 10:45 AM on 12/3/13, review of the policy and procedure manual</p>	0000242	<p>mistreatment, neglect, verbal, mental, sexual and/or physical abuse and reporting of substantiated allegations to a State or local authority c. notice of the right to receive care in a safe setting d. notice of the right to be free from all forms of abuse, neglect or harassment from staff, other patients, or visitors</p> <p>Jackie Dayton, RN Supervisor completed the CDC Appendix B Risk Assessment document prior to the surveyor leaving, however the surveyor would not accept it's authenticity. The risk assessment document will be brought to the infection control committee for approval and ultimately the governing board for approval, tentatively for 2/26/14. The assessment shows that our facility is at a low risk and annual TB testing is not required.</p>	02/28/2014

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	<p>indicated:</p> <p>a. an infection control plan that reads that the committee had determined they were "low risk" for TB and did not need to do annual TB testing, but lacked the CDC (centers for disease control and prevention) Appendix B Risk assessment worksheet required to make this determination</p> <p>b. a policy titled "Titers Post-Vaccine" (no policy number) with a last reviewed date of 11/2012, that reads: "...the CDC's Advisory Committee on Immunization Practices (ACIP) say "not" to do titers on employees several years after they were vaccinated because antibody concentrations decline over time, but healthcare workers (HCWs) remain protected...The best course of action to obtain absolute proof of immunization is to vaccinate again. Of course, the employee may decline the re-administration of the vaccine. If this is the case have them sign a declination form."</p> <p>2. review of personnel files indicated:</p> <p>a. staff members N1 and N2 were hired in December 2012 and lacked new hire two step TB tests, as required by CDC</p> <p>b. staff member N2 is non immune to Rubeola</p> <p>c. staff members N3 and N4 are</p>		<p>However, the 2 newly hired employees will be given the intradermal PPD test to check for exposure, administered by Jackie Dayton, RN Supervisor. Jackie will make sure that all future employees will have the intradermal PPD test administered upon hiring. The 3 employees that show negative immune status to MMR will have a declination for a booster signed and placed in their files. It will also be added to our policy that these 3 employees will be exempt from working if ever an outbreak of measles, mumps, or rubella occur.</p>				

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	<p>"negative" (non immune) to Mumps</p> <p>3. interview with staff member #60, the RN (registered nurse) and surgery center manager, at 1:45 PM on 12/4/13 and 9:40 AM on 12/5/13, indicated:</p> <p>a. it was unknown that there was a CDC TB risk assessment worksheet, the facility had just checked locally in regards to TB risk</p> <p>b. no TB testing was performed with the newly hired staff in December 2012, no TB history was requested at the time of hire, either</p> <p>c. there is no documentation for staff members N2, N3 or N4 of when immunizations for Rubeola or mumps was performed for them previously</p> <p>d. it was thought that there was "latent" immunity, based on reading CDC ACIP data as stated in 1. b. above</p> <p>e. there was no documentation that indicated these staff members (N2, N3, N4) signed declination forms and refused boosters for the non immune Rubeola and mumps</p> <p>f. the infection control plan/employee health policies do not state that non immune staff would not be allowed to work in the event of an outbreak due to the uncertainty of immunity to either Rubeola or mumps</p>						

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Q000245	<p>416.51(b)(3) INFECTION CONTROL PROGRAM 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, infection control plan review, observation, and interview, the infection control committee failed to ensure that medical staff removed their surgical masks before leaving the area in which they were used, failed to ensure that earrings were covered by surgical/bouffant hats, and failed to ensure that outside clothing was covered by surgical scrubs or cover up jackets, and failed to ensure that surgical attire was worn outside of the pre and post op areas, as required per facility policy. Also, based on policy and procedure review, manufacturer's booklet review/recommendations, observation, and interview, the facility failed to ensure that the glucometer was cleaned per manufacturer's recommendations and that it was cleaned after each patient use.</p> <p>Findings: 1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated: a. one policy titled "Dress Code" (no policy number), with the most recent review date of 11/2012, indicated: "...Surgical attire is worn to promote healthcare personnel safety and a high level of cleanliness and hygiene...6. Jewelry should be contained and confined within the surgical attire a. Earrings are contained within the caps...3. Personnel working beyond the doorways of pre-op and post-op require surgical scrubs, hair covers and shoe covers...8. Masks</p>	Q000245	Jackie Dayton, RN Supervisor has already begun staff training in the areas described to be faulty in regards to surgical attire. The staff have been re-educated to change masks with every case and to discard them immediately upon leaving the operating room. They are not to dangle around the neck. Jackie reminded the staff that earrings must be enclosed underneath the bouffant cap. Any clothing worn underneath surgical scrubs must be completely covered including long sleeves. Jackie will also enforce more strictly the restricted areas where surgical attire must be worn. Non-surgical personnel are not allowed into this area. Jackie also reminded the technician that does the glucometer testing to discard the control solutions after 90 days. An "open" date must be legible on the bottle of control solution. Jackie also re-educated the staff in the glucometer cleaning procedures. This will be addressed annually during competency testing for CLIA waived tests.	01/31/2014			

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	<p>should be worn for all surgical and invasive procedures..."</p> <p>b. the infection control plan, with a review date of 11/2012, which reads on page 2 under "Personal Protective Equipment (PPE): Gowns, Gloves, Masks, Eyewear: Remove all PPE before leaving the area where used..."</p> <p>2. It was observed at 9:50 AM on 12/4/13, in the pre operative area, that staff member #65, the CMA-certified medical assistant, had a surgical mask dangling about the neck and was in and out of the pre op area and the operating rooms with the same surgical mask (at 9:55 AM, this same staff member returned to the pre op area with the same mask down about the neck)</p> <p>3. at 10:04 AM on 12/4/13, it was observed in the pre op area that the surgery RN (registered nurse), #64, entered the pre op area from the surgery rooms with their surgical mask down about the neck</p> <p>4. at 10:09 AM on 12/4/13, staff members #64 and #65 entered the pre op area with masks down about the neck, took pt. in bay #2 to the operating room and pulled the masks up and tied them for repeat use</p> <p>5. at 10:15 AM on 12/4/13, it was observed that surgeon #63 entered the pre op area from the surgery rooms with their surgical mask down and dangling about the neck</p> <p>6. at 10:33 AM on 12/4/13, it was observed in the surgical suite that staff member #65 had earrings not covered by the surgical/bouffant cap/hat</p> <p>7. at 10:45 AM and 10:57 AM on 12/4/13, staff member #60 the RN, surgery center manager,</p>			

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	<p>entered the surgical suite, while surgery was in progress, with earrings not covered by the bouffant head cover and with a long sleeved shirt exposed under the short sleeved surgical scrub top</p> <p>8. at 11:00 AM on 12/4/13, it was observed that staff member #61, the administrator, entered the scrub area outside the operating rooms (beyond the pre and post op areas) in street clothes and without a bouffant hat and shoe covers</p> <p>9. interview with staff member #60 at 12:30 PM on 12/4/13 and 10:00 AM on 12/5/13 indicated:</p> <ul style="list-style-type: none"> a. it was unknown that staff members were not removing surgical masks when exiting the operating rooms, as per the infection control plan requirement b. the administrator did enter the scrub sink area just outside the operating rooms without wearing appropriate PPE, as noted in 8. above c. it was thought that it would be OK not to cover earrings and to have long sleeved shirts exposed if not "scrubbed in" <p>10. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated a policy titled "Blood Glucose Monitoring System", (no policy number), with a last review date of 11/2012, that indicated:</p> <ul style="list-style-type: none"> a. item #9. reads: "Clean the meter according to manufacturer's recommendations." b. the policy lacks instruction to the staff as to when to clean the glucometer (after each patient use) <p>11. at 2:55 PM on 12/4/13, review of the True Track glucometer owner's booklet indicated on page 30:</p> <ul style="list-style-type: none"> a. under the title "Caring for True Track", it reads: "...Meter care Wipe Meter with clean, 			

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S000000	<p>lint-free cloth dampened with mild detergent/soap or 10% household bleach and water. Do not use alcohol to clean Meter. Cleaning Meter with alcohol WILL cause damage...Glucose Control Care Write date opened on Control label. Discard 3 months after opening..."</p> <p>12. interview with staff member #60, the RN (registered nurse) surgery center manager, at 9:40 AM on 12/5/13 indicated:</p> <p>a. currently, staff are to clean the glucometer with a Q tip with alcohol on the tip (this is not per the manufacturer's recommendations)</p> <p>b. it was thought that it was OK to clean the glucometer at the end of the day, not necessarily after each patient use</p> <p>The visit was for a licensure survey.</p> <p>Facility Number: 009567</p> <p>Survey Date: 12-03-13 to 12-05-13</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 12/18/13</p>	S000000		

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S000442	<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 policy and procedure review, personnel health file review, and staff interview, the infection control committee failed to ensure an effective employee health program related to immune status and TB (tuberculosis) monitoring.</p> <p>Findings:</p> <p>1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated:</p> <p>a. an infection control plan that reads that the committee had determined they were "low risk" for TB and did not need to do annual TB testing, but lacked the</p>	S000442	<p>Jackie Dayton, RN Supervisor completed the CDC Appendix B Risk Assessment document prior to the surveyor leaving, however the surveyor would not accept it's authenticity. The risk assessment document will be brought to the infection control committee for approval and ultimately the governing board for approval, tentatively for 2/26/14. The assessment shows that our facility is at a low risk and annual TB testing is not required. However, the 2 newly hired employees will be given the intradermal PPD test to check for exposure, administered by Jackie Dayton, RN Supervisor. Jackie will make sure that all</p>	02/28/2014
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	<p>CDC (centers for disease control and prevention) Appendix B Risk assessment worksheet required to make this determination</p> <p>b. a policy titled "Titers Post-Vaccine" (no policy number) with a last reviewed date of 11/2012, that reads: "...the CDC's Advisory Committee on Immunization Practices (ACIP) say "not" to do titers on employees several years after they were vaccinated because antibody concentrations decline over time, but healthcare workers (HCWs) remain protected...The best course of action to obtain absolute proof of immunization is to vaccinate again. Of course, the employee may decline the re-administration of the vaccine. If this is the case have them sign a declination form."</p> <p>2. review of personnel files indicated:</p> <p>a. staff members N1 and N2 were hired in December 2012 and lacked new hire two step TB tests, as required by CDC</p> <p>b. staff member N2 is non immune to Rubeola</p> <p>c. staff members N3 and N4 are "negative" (non immune) to Mumps</p> <p>3. interview with staff member #60, the RN (registered nurse) and surgery center manager, at 1:45 PM on 12/4/13 and</p>		<p>future employees will have the intradermal PPD test administered upon hiring. The 3 employees that show negative immune status to MMR will have a declination for a booster signed and placed in their files. It will also be added to our policy that these 3 employees will be exempt from working if ever an outbreak of measles, mumps, or rubella occur.</p>				

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	<p>9:40 AM on 12/5/13, indicated:</p> <ul style="list-style-type: none"> a. it was unknown that there was a CDC TB risk assessment worksheet, the facility had just checked locally in regards to TB risk b. no TB testing was performed with the newly hired staff in December 2012, no TB history was requested at the time of hire, either c. there is no documentation for staff members N2, N3 or N4 of when immunizations for Rubeola or mumps was performed for them previously d. it was thought that there was "latent" immunity, based on reading CDC ACIP data as stated in 1. b. above e. there was no documentation that indicated these staff members (N2, N3, N4) signed declination forms and refused boosters for the non immune Rubeola and mumps f. the infection control plan/employee health policies do not state that non immune staff would not be allowed to work in the event of an outbreak due to the uncertainty of immunity to either Rubeola or mumps 						

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S000444	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(ix)</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>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>Based on policy and procedure review, infection control plan review, observation, and interview, the infection control committee failed to ensure that medical staff removed their surgical masks before leaving the area in which they were used, failed to ensure that earrings were covered by surgical/bouffant hats, and failed to ensure that outside clothing was covered by surgical scrubs or cover up jackets, and failed to ensure that surgical attire was worn outside of the pre and post op areas, as required per facility policy.</p> <p>Findings: 1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated: a. one policy titled "Dress Code" (no</p>	S000444	Jackie Dayton, RN Supervisor has already begun staff training in the areas described to be faulty in regards to surgical attire. The staff have been re-educated to change masks with every case and to discard them immediately upon leaving the operating room. They are not to dangle around the neck. Jackie reminded the staff that earrings must be enclosed underneath the bouffant cap. Any clothing worn underneath surgical scrubs must be completely covered including long sleeves. Jackie will also enforce more strictly the restricted areas where surgical attire must be worn. Non-surgical personnel are not allowed into this area. Jackie also reminded the technician that does the glucometer testing to discard the control solutions after 90 days. An "open" date must be legible on the bottle of control	01/31/2014			

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	<p>policy number), with the most recent review date of 11/2012, indicated: "..Surgical attire is worn to promote healthcare personnel safety and a high level of cleanliness and hygiene...6. Jewelry should be contained and confined within the surgical attire a. Earrings are contained within the caps...3. Personnel working beyond the doorways of pre-op and post-op require surgical scrubs, hair covers and shoe covers...8. Masks should be worn for all surgical and invasive procedures..."</p> <p>b. the infection control plan, with a review date of 11/2012, which reads on page 2 under "Personal Protective Equipment (PPE): Gowns, Gloves, Masks, Eyewear: Remove all PPE before leaving the area where used..."</p> <p>2. It was observed at 9:50 AM on 12/4/13, in the pre operative area, that staff member #65, the CMA-certified medical assistant, had a surgical mask dangling about the neck and was in and out of the pre op area and the operating rooms with the same surgical mask (at 9:55 AM, this same staff member returned to the pre op area with the same mask down about the neck)</p> <p>3. at 10:04 AM on 12/4/13, it was observed in the pre op area that the surgery RN (registered nurse), #64,</p>		<p>solution. Jackie also re-educated the staff in the glucometer cleaning procedures. This will be addressed annually during competency testing for CLIA waived tests.</p>				

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	<p>entered the pre op area from the surgery rooms with their surgical mask down about the neck</p> <p>4. at 10:09 AM on 12/4/13, staff members #64 and #65 entered the pre op area with masks down about the neck, took pt. in bay #2 to the operating room and pulled the masks up and tied them for repeat use</p> <p>5. at 10:15 AM on 12/4/13, it was observed that surgeon #63 entered the pre op area from the surgery rooms with their surgical mask down and dangling about the neck</p> <p>6. at 10:33 AM on 12/4/13, it was observed in the surgical suite that staff member #65 had earrings not covered by the surgical/bouffant cap/hat</p> <p>7. at 10:45 AM and 10:57 AM on 12/4/13, staff member #60 the RN, surgery center manager, entered the surgical suite, while surgery was in progress, with earrings not covered by the bouffant head cover and with a long sleeved shirt exposed under the short sleeved surgical scrub top</p> <p>8. at 11:00 AM on 12/4/13, it was observed that staff member #61, the administrator, entered the scrub area</p>						

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	<p>outside the operating rooms (beyond the pre and post op areas) in street clothes and without a bouffant hat and shoe covers</p> <p>9. interview with staff member #60 at 12:30 PM on 12/4/13 and 10:00 AM on 12/5/13 indicated:</p> <p>a. it was unknown that staff members were not removing surgical masks when exiting the operating rooms, as per the infection control plan requirement</p> <p>b. the administrator did enter the scrub sink area just outside the operating rooms without wearing appropriate PPE, as noted in 8. above</p> <p>c. it was thought that it would be OK not to cover earrings and to have long sleeved shirts exposed if not "scrubbed in"</p>			

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S000466	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(3)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not limited to, the following:</p> <p>(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.</p> <p>(B) Results of biological indicators used in testing the sterilizing processes.</p> <p>Based on document review and interview, the infection control committee failed to ensure the periodic evaluation of biological indicators and sterilizing processes.</p> <p>Findings: 1. Review of the Governing Board quarterly meetings of 2/13/13, 5/15/13, 8/28/13, and 11/21/13 indicated that sterilization processes and biological indicators are not reviewed/discussed at the quarterly meetings for the group assigned to represent the infection control committee for the facility</p>	S000466	Jackie Dayton, RN Supervisor reports quarterly on the autoclave to the medical staff. This was clearly documented in the quarterly QA table chart which the surveyor observed. However, Jackie only reports negative problems with the autoclave. She has not had any negative problems with the autoclave in years, so the quarterly QA table chart did not reflect the normal weekly biological testing. However, Jackie will add to the quarterly QA table template that normal biological testing has been reported to the medical staff.	01/31/2014			

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S000526	<p>2. interview with staff member #60, the RN (registered nurse) and surgery center manager, at 3:00 PM on 12/4/13, indicated:</p> <p>a. if there were any errors or discrepancies with biological indicators, then these would be discussed/presented at quarterly meetings</p> <p>b. currently, there is no documentation of periodic evaluation of sterilization processes or biological indicators by the infection control committee/governing board</p> <p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.</p> <p>Based on personnel file review and interview, the facility failed to document the skills competencies for waived lab testing performed by nursing staff.</p> <p>Findings:</p> <p>1. review of personnel files indicated that annual evaluations have a statement that reads: "Ability to perform CLIA waived testing (glucose and urine pregnancy)", but lack any documentation</p>	S000526	Jackie Dayton, RN Supervisor performs annual competency skill checks for all nursing staff. However, the competency skill check list will contain more details how these skills are monitored. For example, in performing a glucometer check off, the list would contain detailed steps in performing the test. 1. Wash hands and gather supplies needed. 2. Explain to patient what you are about to do Jackie will observe each step during the	01/31/2014			

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S000624	<p>of what those skills entail and how/when these were observed by the nursing manager</p> <p>2. interview with staff member #60, the RN (registered nurse) surgery center manager, at 9:40 AM on 12/5/13, indicated there is no actual observation/checklist of each RN with relation to skills competencies of glucometer checks and pregnancy test performance</p> <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 upon document review and interview, the center failed to develop a</p>	S000624	<p>competency check off and keep this competency checklist in the employee file. These skill check offs will be performed annually.</p> <p>These polices specific for "indicating a set of qualifying</p>	01/31/2014			

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S000672	<p>policy/procedure for releasing medical records (MR) or information to authorized individuals in accordance with federal and state laws.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Medical Records (approved 12-12) and Custody of Official Documentation (approved 12-12) failed to indicate a set of qualifying conditions or individuals authorized to receive patient records and failed to indicate a process for requesting and releasing information or copies of medical records. During an interview on 12-5-13 at 1335 hours, staff A2 confirmed that the center lacked a policy/procedure indicating the conditions and process for releasing MR. <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(f)(13)</p> <p>All patient records must document and contain, at a minimum, the following:</p> <p>(13) A copy of the transfer form, if the patient is referred to a hospital or other facility.</p> <p>Based on policy and procedure review,</p>			S000672	<p>conditions or individuals authorized to receive patient records and for indicating a process for requesting and releasing information or copies of medical records" were present in our HIPAA/Privacy Manual. It is unclear why the surveyors cited us for these deficiencies when the policies were present. Jackie Dayton, RN Supervisor will include the policies from the HIPAA manual into the Policy Manual Medical Records section, so these policies will not be overlooked in the future.</p>		01/31/2014

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	<p>medical record review, and interview, the nursing staff failed to ensure the completion of a transfer form for 1 of 1 patient transferred in the last 12 months (pt. # 15).</p> <p>Findings:</p> <p>1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated a policy titled "Transfer to Lutheran Hospital", no policy number, with a date of last review of 11/2012, which indicated in item #3., "A transfer checklist will be completed by the nursing supervisor..."</p> <p>2. at 9:15 AM on 12/4/13, review of the transfer medical record for pt. #15 indicated there was no transfer checklist/form present</p> <p>3. interview with staff member #60, the RN (registered nurse) surgery center manager, at 12:30 PM and 2:25 PM on 12/4/13 indicated:</p> <p>a. a call was made to the receiving hospital and no transfer checklist/form could be found for pt. #15</p> <p>b. this staff member thinks a checklist was completed, but is not present in the medical record here, nor at the receiving hospital</p>		<p>and sending it with the paramedics when this patient was transferred to the hospital. However, when the surveyor requested those records from the hospital, the hospital could not produce this particular form. This becomes a situation of "my word versus their word". Who is to say what happened to that form? In the future, Jackie Dayton, RN Supervisor will make sure the transfer checklist form is copied along with the other pertinent documents prior to transferring the patient to the hospital.</p>				

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

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	<p>(iv) Documentation of experience in the practice of medicine.</p> <p>(v) Documentation of specialty board certification as applicable.</p> <p>(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).</p> <p>(D) Category of medical staff appointment and delineation of privileges approved.</p> <p>(E) A signed statement to abide by the rules of the center.</p> <p>(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.</p> <p>(G) Other items specified by the center and medical staff.</p> <p>Based on document review and interview, the governing body failed to ensure that the medical staff credential files included a complete application with current health status for 3 of 4 credentialed staff and included a signed statement to abide by the rules of the center for 4 of 4 credentialed staff at the center.</p> <p>Findings:</p> <p>1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval</p>	S000710	Douglas Miller, Practice Administrator will make corrections to the current re-application process to include a signed statement indicating that the applicant has read and agrees to abide by the Medical Staff bylaws, rules, regulations and policies of the center and a biannual physical exam will completed on each MD to reflect their current health status upon re-appointment.	01/31/2014	

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	<p>date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate a provision ensuring that each medical staff application for appointment or re-appointment contains a signed statement indicating that the applicant has read and agrees to abide by the Medical Staff bylaws, rules, regulations and policies of the center.</p> <p>2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating a bylaws provision for each medical staff applicant to provide a statement of current health status and a signed statement to abide by the Medical Staff bylaws, rules, regulations and policies and none was provided prior to exit.</p> <p>3. Review of 3 credential files (MD01, MD02 and MD03) failed to indicate a current (2013) document titled Application for Professional Staff Membership observed with the 2011 credentialing documents for the 3 practitioners and the 2013 credentialing documentation for MD04.</p> <p>4. Review of the (4) credential files for MD01, MD02, MD03 and MD04 failed to indicate a signed statement to abide</p>			

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S000732	<p>by the rules and bylaws of the center for the current credentialing period effective 8-28-13.</p> <p>5. During an interview on 12-05-13 at 1210 hours, staff A2 confirmed that the medical staff bylaws failed to indicate the requirements to obtain and maintain a completed, signed application including current health status and a statement to abide by the rules of the center.</p> <p>6. During an interview on 12-06-13 at 1330 hours, staff A2 confirmed that the 3 credential files (MD01, MD02 and MD03) lacked a current application for medical staff membership including current health status and confirmed that the 4 credential files lacked a signed agreement to follow the medical staff bylaws and rules of the center.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p> <p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially. Based upon document review and interview, the medical staff failed to follow its policy/procedure and review its bylaws, rules and regulations at least</p>	S000732	This was cited in last year's survey (2012). Included in my POC, I stated that an emergency meeting of the governing board was called to order on 12/13/12 to	02/28/2014			

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	<p>biennially.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure ASC Committees and Their Functions (reviewed 12-12) indicated the following: " The duties of the Credentials Committee shall be: To review at least biennially the Medical Staff Bylaws, Rules and Regulations and/or Policies of the ASC ... " On 12-3-13 at 1030 hours, staff A2 was requested to provide documentation indicating that the medical staff had reviewed its medical staff bylaws, rules and regulations within the past 2 years and none was provided prior to exit. No documentation indicated that the medical staff bylaws had been reviewed and approved by the medical staff or credentials committee prior to a special governing board meeting convened 12-13-12 and the 12-13-12 governing board minutes failed to indicate which bylaws (governing board bylaws or medical staff bylaws) were reviewed and approved by the governing board. During an interview on 12-04-13 at 1605 hours, staff A1 confirmed that no documentation was available to indicate 		<p>approve and accept the Policy/Procedure Manual and the By-Laws. This correction was approved as acceptable by you, the ISDH. Now currently, for 2013, the surveyors are saying this is not acceptable. They are saying it must go before the credentials committee prior to the governing board. In our facility, the credentials committee and the governing board are one and the same. The Credentials Committee will meet on 2/26/14 followed by the Governing Board to approve the ByLaws.</p>				

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S000744	<p>the required approval of the medical staff bylaws, rules and regulations by the medical staff or credentials committee prior to the governing board meeting on 12-13-12.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(D)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(D) A procedure for designating an individual practitioner with current privileges as chief, president, or chairperson of the staff.</p> <p>Based on document review and interview, the governing body failed to ensure that the medical staff bylaws included a process for appointing or electing a physician with current privileges to the position of medical staff chairman, chief, or president.</p> <p>Findings:</p> <p>1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate a provision or process for appointment or election of medical staff</p>	S000744	Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.	02/28/2014			

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S000746	<p>chairman, chief, or president.</p> <p>2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating an approved process for appointing or electing a medical staff chairman and none was provided prior to exit.</p> <p>3. During an interview on 12-04-13 at 1220 hours, administrator A2 confirmed that no documentation indicating a process for appointing or electing a medical staff chairman was available and confirmed that the medical staff bylaws lacked the requirement.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(E)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(E) A statement of duties and privileges for each category of the medical staff.</p> <p>Based on document review and interview, the medical staff bylaws failed to indicate the categories for medical staff appointment including a description of duties, privileges and</p>	S000746	Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in	02/28/2014			

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	<p>responsibilities for each category.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate the categories of medical staff appointment including a description of privileges and duties for each category. 2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating the medical staff appointment categories with duties, privileges and responsibilities and none was provided prior to exit. 3. The document Recommendation for Privileges observed in the initial credential file for MD04 and in the re-credentialing files for MD01, MD02, MD03 indicated that all 4 practitioners were Provisionally Appointed in 2013. 4. During an interview on 12-04-13 at 1220 hours, administrator A2 confirmed that no documentation indicating the categories of medical staff appointment was available and confirmed that the 		<p>place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.</p>		

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S000748	<p>medical staff bylaws lacked the requirement.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(F) These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(F) A description of the medical staff applicant qualifications. Based on document review and interview, the governing body failed to ensure that the medical staff bylaws included a description of medical staff applicant qualifications to be met for appointment or reappointment to the medical staff at the center.</p> <p>Findings:</p> <p>1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate the applicant qualifications to be met by the candidate including a provision for hospital admitting and surgical privileges.</p> <p>2. On 12-04-13 at 1125 hours, administrator A2 was requested to</p>	S000748	<p>Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.</p>	02/28/2014

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S000750	<p>identify or provide documentation indicating the medical staff applicant qualifications and standards for (re)-appointment at the center and none was provided prior to exit.</p> <p>3. During an interview on 12-04-13 at 1220 hours, administrator A2 confirmed that no documentation indicating the qualifications for medical staff appointment or reappointment was available and confirmed that the medical staff bylaws lacked the requirement.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(G)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.</p> <p>Based on document review and interview, the medical staff bylaws failed to indicate the criteria for granting, withdrawing, and modifying the privileges to be granted for each category of medical staff appointment and failed to indicate a center process or procedure for applying the criteria to</p>	S000750	Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed.	02/28/2014			

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	<p>each medical staff candidate.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate the categories of medical staff appointment including the criteria for granting, modifying or withdrawing privileges for each category and failed to indicate a procedure for applying the criteria to applicants requesting medical staff privileges. 2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating the appointment categories with corresponding criteria for privileging and a procedure for applying the criteria to medical staff candidates and none was provided prior to exit. 3. During an interview on 12-04-13 at 1220 hours, administrator A2 confirmed that no documentation indicating the medical staff appointment categories with criteria for privileging or procedure for applying the privileging criteria to candidates was available and confirmed that the medical staff bylaws lacked the 		Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.				

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S000752	<p>requirement.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(H)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing body.</p> <p>Based on document review and interview, the medical staff bylaws failed to indicate a center process for reviewing applications for appointment or reappointment including the delineation of privileges based on applicant competence and submission of appointment recommendations to the governing board.</p> <p>Findings:</p> <p>1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate a process for reviewing medical staff applications including the</p>	S000752	Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.	02/28/2014			

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	<p>delineation of privileges and recommendations for appointment to the governing board.</p> <p>2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating a process for reviewing applications for appointment leading to a recommendation for appointment and none was provided prior to exit.</p> <p>3. During an interview on 12-04-13 at 1220 hours, administrator A2 indicated that no documentation indicating a process for reviewing applications for medical staff appointment including the delineation of privileges and recommendations for appointment was available and confirmed that the medical staff bylaws lacked the requirement.</p>						

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S000754	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(I)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(I) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting enforcement actions against practitioners who fail to comply with the center and medical staff bylaws and rules.</p> <p>Based on document review and interview, the medical staff bylaws failed to indicate a process for reporting practitioners who fail to comply with State licensing requirements as described in IC 25-22.5 and failed to indicate a process for documenting sanctions against medical staff who fail to comply with the medical staff bylaws and center rules.</p> <p>Findings:</p> <p>1. The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate a process for documenting</p>	S000754	<p>Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.</p>	02/28/2014			

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	<p>sanctions against medical staff who fail to comply with the medical staff bylaws and center rules and failed to indicate a process for reporting practitioners who fail to comply with State licensing requirements as described in IC 25-22.5.</p> <p>2. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating a process for addressing violations of medical staff bylaws and center rules by a practitioner and indicating a process for reporting a violation of State licensing requirements by a practitioner and none was provided prior to exit.</p> <p>3. During an interview on 12-04-13 at 1220 hours, administrator A2 indicated that no documentation indicating a process for addressing violations of medical staff bylaws, rules and regulations or a process for reporting violations of State licensing requirements by a practitioner was available and confirmed that the medical staff bylaws lacked the requirements.</p>			

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S000764	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(K)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(K) A process for appeals of decisions regarding medical staff membership and privileges. Based on document review and interview, the governing body failed to ensure that the medical staff bylaws included a process for appealing an adverse decision regarding medical staff membership and privileges at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> The Bylaws of Ophthalmology Consultants of Fort Wayne (no approval date) provided on 12-03-13 at 1130 hours and identified by administrator A2 as the center medical staff bylaws failed to indicate a process for practitioner appeals of medical staff and governing board decisions regarding medical staff membership and privileges. On 12-04-13 at 1125 hours, administrator A2 was requested to identify or provide documentation indicating a medical staff appeals process and none was provided prior to exit. During an interview on 12-04-13 at 1220 hours, administrator A2 indicated that no documentation indicating a process for practitioner appeals of adverse decisions regarding privileges or membership was available and confirmed that the medical staff 	S000764	<p>Our By-Laws have been sent to our attorney for review. The citations specific to our By-Laws have been sent to the attorney as well. She has been asked to have a rough draft returned to us within 30 days with all the corrections in place. After a final draft has been submitted, the Governing Board will be called to order on Wed. Feb. 26, 2014 to approve the final draft of the By-Laws. Doug Miller, Practice Administrator will oversee this task.</p>	02/28/2014

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S000862	<p>bylaws lacked the requirement. 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 maintained per manufacturer ' s recommendations and available if needed for 2 of 9 emergency equipment and supplies.</p> <p>Findings: 1. The 2006 Welch Allyn AED 10</p>	S000862	Jackie Dayton, RN Supervisor has already replaced the expired AED pads. There are currently 2 sets of pads within expiration dates inside the unit. As for the expired Atropine, I explained to Brian Montgomery, RN, that currently Atropine is on a manufacturer backorder and I cannot get any from my suppliers. I have documentation from my pharmacy consultant that it is	01/31/2014			

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	<p>(Automatic External Defibrillator) manufacturer ' s recommendations indicated the following: " Supplies - a. Two sets of pads in sealed packages within expiration date ... "</p> <p>2. The document Crash Cart Inventory indicated the following: " The crash cart should be checked for the following: ...All medications should be within their expiration date ... The defibrillator should be checked in the following manner: ...Two sets of pads in sealed packages within expiration date ... "</p> <p>3. During a tour on 12-04-13 at 1430 hours, in the pre-surgical patient care area, the following condition was observed: a set of expired Welch Allyn AED10 defibrillator pads with an expiration date of 10-13.</p> <p>4. During an interview on 12-04-13 at 1440 hours, staff A1 confirmed that the set of defibrillator pads were expired.</p> <p>5. During a tour on 12-04-13 at 1435 hours, in the pre-surgical patient care area, the following condition was observed: (4) four 0.4 milligram / 1.0 milliliter vials of Atropine medication with an expiration date of 11-13.</p>		<p>wise and prudent to keep expired emergency drugs rather than having none at all. My Atropine was only a week expired during the ISDH surveyor visit. I placed a noticeable sticker on the crash cart inventory that Atropine is expired and on manufacturer backorder. In the event of an emergency where Atropine is needed, the MD can make a decision at the moment to use the expired Atropine or not.</p>				

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S001146	<p>6. During an interview on 12-04-13 at 1440 hours, staff A1 confirmed that the (4) four vials of medication were expired.</p> <p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on policy and procedure review, manufacturer's booklet review/recommendations, observation, and interview, the facility failed to ensure that no condition was created that might create a hazard to patients in regards to the possibility of incorrect blood sugar checks.</p> <p>Findings: 1. at 10:45 AM on 12/3/13, review of the policy and procedure manual indicated a policy titled "Blood Glucose Monitoring System", (no policy number), with a last review date of 11/2012, that indicated:</p>	S001146	Jackie Dayton, RN Supervisor re-educated the technician that does the glucometer testing to discard the control solutions after 90 days. An "open" date must be legible on the bottle of control solution. Jackie also re-educated all staff in the glucometer cleaning procedures. This will be addressed annually during competency testing for CLIA waived tests.	01/31/2014

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	<p>a. item #9. reads: "Clean the meter according to manufacturer's recommendations."</p> <p>b. the policy lacks a requirement to date and discard control solutions after they have been opened for 90 days</p> <p>2. at 2:55 PM on 12/4/13, review of the True Track glucometer owner's booklet indicated on page 30:</p> <p>a. under the title "Caring for True Track", it reads: "...Meter care Wipe Meter with clean, lint-free cloth dampened with mild detergent/soap or 10% household bleach and water. Do not use alcohol to clean Meter. Cleaning Meter with alcohol WILL cause damage...Glucose Control Care Write date opened on Control label. Discard 3 months after opening..."</p> <p>3. while on tour of the facility at 2:45 PM on 12/4/13, it was observed in the pre op area that control solutions 0 (zero), 1 and 2 all lacked the marking/noting of a date when they were opened, and lacked notation of a 90 day (3 months) expiration date (based on the opening date)</p> <p>4. interview with staff member #60, the RN (registered nurse) surgery center manager, at 9:40 AM on 12/5/13 indicated:</p>			

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S001180	<p>a. the CMA (certified medical assistant) knew there was a 90 day expiration date for the control solutions, but failed to write this on the three control solution bottles</p> <p>b. the policy does not list the 90 day requirement for control solutions</p> <p>c. currently, staff are to clean the glucometer with a Q tip with alcohol on the tip (this is not per the manufacturer's recommendations)</p> <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 lacked documentation of a functioning safety management program that included a review of safety functions by a committee with representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. The policy/procedure ASC</p>	S001180	Jackie Dayton, RN Supervisor will make sure the Safety Committee is added to the meeting agenda template so the committee is not overlooked for the future. The committee is new as of last year and Jackie failed to include the committee functions in the minutes. Jackie developed the Safety Manual last year through the aid of a website. Jackie will review the manual again and pay stricter attention to the	01/31/2014

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	<p>Committees and their Functions (approved 12-12) and Safety Officer/Safety Program (approved 12-12) failed to indicate a provision for a Safety Committee/Safety Program including committee membership and the safety functions to be reviewed by the committee.</p> <p>2. The Policy/procedure Organizational Chart (approved 12-12) failed to indicate a Safety Program function.</p> <p>3. The policy/procedure Safety and Health Plan (approved 12-12) indicated the following: "...[page 3] ...Frequency of Safety Meetings: Annually ...[page 8] ...Safety and Health Committee will be composed of the following individuals: not applicable ...Our Safety and Health Committee will meet regularly but not less than Not Applicable ..."</p> <p>4. Center staff meeting minutes dated 2-20-13, 8-01-13 and 11-21-13 or Quality Improvement (QI) Committee meeting minutes dated 2-13-13, 5-15-13, 8-28-13 or 11-21-13 failed to indicate a safety committee function, section heading or safety committee discussion or action.</p> <p>5. During an interview on 12-04-13 at 1230 hours, administrator A2 confirmed</p>		customizable features so they reflect more accurately the functions of our safety committee.				

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S001188	<p>that the safety program documentation lacked a defined constituency and safety functions to be reviewed and confirmed that the QI committee minutes lacked documentation of a review of safety functions by the committee.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(4) A written fire control plan that contains provisions for the following:</p> <p>(A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of patients, personnel, and guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills.</p> <p>Based on document review and interview, the center failed to follow its policy/procedure for conducting quarterly fire drills for 2 of 4 required drills.</p> <p>Findings:</p> <p>1. The policy/procedure Steri-Safe OSHA Emergency Preparedness Plan titled Emergency Action Plan - Fire</p>	S001188	Jackie Dayton, RN Supervisor will make sure quarterly fire drills are performed throughout 2014. They were overlooked in 2013 due to the institution of electronic medical records. The EMR process took the place of 2 quarterly staff meetings thus the fire drills were overlooked.	01/31/2014

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S001198	<p>(approved 12-12) indicated that fire drills will be conducted on a quarterly basis at the center.</p> <p>2. Fire drill documentation dated 8-01-13 and 11-21-13 indicated that only two quarterly drills were performed in 2013.</p> <p>3. During an interview on 12-04-13 at 1600 hours, staff A1 confirmed that the center failed to conduct a fire drill for the 1st and 2nd quarters in 2013.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the center failed to maintain and follow its emergency and disaster plan and conduct an annual drill for each emergency response plan.</p> <p>Findings:</p> <p>1. The policy/procedure Emergency</p>	S001198	This citation reflects the previous citation S1180 due to the fact our safety manual was developed through a web site and was not proof-read carefully. Several customizable features did not adequately describe the functions of our safety committee. Jackie Dayton, RN will revise the safety manual and review it carefully before presenting to the governing board for approval.	01/31/2014

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	<p>Preparedness Plan (approved 12-12) indicated the following: " Power Outage ...how frequently will drills be performed for all the above procedures? Annually ...[and] ...Tornado ...how frequently will drills be performed for all the above procedures? Semi-annually ...[and] ... Winter Storms ... how frequently will drills be performed for all the above procedures? Annually ...[and] ...Workplace Violence ...how frequently will drills be performed for all the above procedures? Annually ...[and] ...BloodOPIMSpill (blood other potentially infectious material spill) ... how frequently will drills be performed for all the above procedures? Annually ...[and] ...Bomb Threat ... how frequently will drills be performed for all the above procedures? Annually ...[and] ...Civil Disturbance ... how frequently will drills be performed for all the above procedures? Annually ...[and] ...Earthquake ... how frequently will drills be performed for all the above procedures? Annually ... "</p> <p>2. Disaster drill documentation indicated that one tornado drill was performed 8-01-13 and no other additional emergency drill documentation was provided prior to exit.</p>			

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	3. During an interview on 12-04-13 at 1600 hours, staff A1 confirmed that the emergency preparedness policy/procedures indicated each one to be done annually and confirmed that the center had only performed one tornado drill inservice in 2013.			