

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  15C0001018	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  08/20/2014
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NAME OF PROVIDER OR SUPPLIER  GROSSNICKLE EYE CENTER INC	STREET ADDRESS, CITY, STATE, ZIP CODE 2251 DUBOIS DR WARSAW, IN 46580
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Q000000	The visit was for a re-certification survey.  Facility Number: 005399  Survey Date: 8-18/20-14  Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor  Linda Plummer, RN Public Health Nurse Surveyor  QA: claughlin 08/28/14	Q000000		
Q000123	416.45(c) OTHER PRACTITIONERS If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Based on review of the medical staff rules and regulations, patient medical record review, and staff interview, the medical staff failed to address medical clearance recommendations/time frames for 2 of 3 patients with medical clearance documentation requested by a guest/part time surgeon using the surgery center on an occasional basis (patients #14 and	O000123	Policy (NUR-4/15) General Policies for Anesthesia was revised by the Surgery Manager on 9-11-14 to include a physician approved time frame/limitation in regards to medical clearance for surgery patients. This policy now states that surgery must be completed within 90 days of the medical clearance report. This policy revision will ensure	09/11/2014

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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

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	<p>#16).</p> <p>Findings:</p> <p>1. Review of the Medical Staff Rules and Regulations, approved 6/18/14, indicated:</p> <p>a. Under "Article IV General Rules Regarding Surgical Care", it reads: "4.01. A history and physical is completed prior to surgery. Upon review of all information and if there is need for further evaluation, the patient is referred to their family physician for medical clearance. The medical clearance will be obtained prior to the surgical procedure, will be in writing, and placed in the surgical record."</p> <p>2. Review of patient medical records indicated:</p> <p>a. Pt. #14 was requested to have medical clearance related to: "overall health d/t (due to) heart transplant" and was signed 2/18/14 with clearance given for surgery scheduled 4/8/14, but surgery was postponed and did not occur until 7/8/14.</p> <p>b. Pt. #16 had a medical clearance from a cardiologist signed 4/14/14 for surgery which took place on 7/8/14.</p> <p>3. At 9:00 AM on 8/20/14, interview with staff member #50, the RN (registered nurse) administrator,</p>		<p>compliance with this regulation. The surgery manager will be responsible to monitor compliance of this policy.</p>				

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Q000181	<p>indicated:</p> <p>a. Patients #14 and #16 had surgical procedures that were more involved than the usual cataract surgeries performed most often at the facility, thus the requirement for medical clearance from specialty/cardiology physicians.</p> <p>b. With a 5 month space between the clearance for patient #14 and their eventual surgery 7/8/14, a change in their health could have occurred, putting them at a greater surgical risk.</p> <p>c. According to the medical staff rules and regulations, no time frame/limitation has been determined appropriate by the physicians in regard to medical clearance for patients.</p> <p>416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. Based on review of medical staff rules and regulations, review of patient medical records, and staff interview, the medical staff failed to give specific pre op orders related to heparin/saline locks for 24 of 24 patients (patients #1 through #24).</p> <p>Findings:</p>	O000181	Policy (NUR-5/10) IV access Lines and the Physician Orders for surgery patients were revised by the Surgery Manager on 9/10/14 to specifically state that when an IV is started on a surgery patient it will be started with a 22 or 24 gauge angio cath with a NS lock adapter. The old terminology "prn adapter" was replaced by NS lock adapter.	09/10/2014
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	<p>1. Review of the Medical Staff Rules and Regulations, approved 6/18/14, indicated:</p> <p>a. On page 7, under item 2.13., it read: "A physician's routine orders, when applicable to a given patient, shall be reproduced in detail on the order sheet of the patient's record..."</p> <p>2. Review of medical records #1 through #24 indicated:</p> <p>a. All pre op orders read: "...IV: Insert IV prn (as needed) - adapter access line..."</p> <p>3. At 12:45 PM on 8/19/14, interview with staff member #50, the RN (registered nurse) facility administrator, indicated:</p> <p>a. There are very few patients who do not have an IV access, per a saline/heparin lock, started in the pre op area, thus this is not prn, but routine.</p> <p>b. Most times, a 22 gauge or 24 gauge needle is used to start the IV access, and 3 cc of normal saline is used to flush this access line once started.</p> <p>c. The current standing orders do not specify a size of saline lock to use, nor is there an order related to what liquid to use for flushing, or the amount to use.</p> <p>d. The standing orders lack specificity, as is a standard of practice.</p>		This adapter will be flushed with 2-3 NS solution. These changes to the policy and orders will ensure compliance with this regulation. The surgery manager will monitor these changes to ensure compliance.	

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Q000220	<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 center failed to ensure that the posted patient rights notice included 5 of 14 required elements.</p> <p>Findings:</p> <p>1. The patient rights document posted in the reception area failed to indicate the following:</p> <ul style="list-style-type: none"> <li>a. notice of the physicians with a financial interest or ownership in the ASC center.</li> <li>b. notice of the center policy on advance directives in the event of a patient emergency and notice of the availability of a copy of the State advanced directive forms upon request.</li> <li>c. notice that patients may exercise their rights without being subjected to discrimination or reprisal</li> <li>d. notice of the right to receive care in a safe setting</li> <li>e. notice of the right to be free of all forms of abuse, neglect, or harassment</li> </ul> <p>2. During an interview on 8-21-14 at 1020 hours, administrator A1 confirmed that the posted information lacked the indicated requirements.</p>	O000220	<p>The CQI manager updated the posted patient rights on 9-10-14. The updated information will address advanced directives, exercising rights without being subjected to discrimination or reprisal, receiving care in a safe setting and free of abuse, neglect and harassment. The surgery patients already receive notice of physician ownership in their surgical packets before surgery. A notice will also be posted in the lobby. The administrator will be responsible to ensure compliance of this policy.</p>	09/10/2014
Q000221	<p>416.50(a) NOTICE OF RIGHTS An ASC must, prior to the start of the</p>			

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Q000234	<p>416.50(g)</p> <p>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> <ol style="list-style-type: none"> <li>The patient rights notice provided to patients failed to indicate the following: <ol style="list-style-type: none"> <li>notice of the grievance process including how to file a grievance</li> <li>notice that patients may exercise their rights without being subjected to discrimination or reprisal</li> <li>notice of the right to receive care in a safe setting</li> <li>notice of the right to be free of all forms of abuse, neglect, or harassment</li> </ol> </li> <li>During an interview on 8-21-14 at 1020 hours, administrator A1 confirmed that the posted information lacked the indicated requirements.</li> </ol>	0000221	The patient rights notice given to the patient, representative or surrogate was updated by the CQI manager on 9-10-14. The revision will include information on filing a grievance, exercising rights without being subjected to discrimination or reprisal, receiving care in a safe setting, free of abuse, neglect or harassment. The administrator will be responsible to ensure ongoing compliance of this policy.	09/10/2014

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	<p><b>CONFIDENTIALITY OF CLINICAL RECORDS</b></p> <p>The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.</p> <p>Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure the privacy and security of individually identifiable health information.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>The Medical Staff Rules and Regulations (approved 6-14) indicated the following: "Unauthorized individuals cannot gain access to patient records."</li> <li>The policy/procedure Confidentiality (approved 3-14) indicated the following: "...[the center] realizes its obligation to safeguard health records against unauthorized or inadvertent disclosures, uses, loss, tampering, alteration, or destruction."</li> <li>During a tour of the center on 8-19-14 at 1440 hours, the following condition was observed in the office space immediately behind the reception and information desk of the waiting room area: unsecured patient records including personal information were filed in an</li> </ol>	0000234	<p>The Medical Records area is currently locked when staff leaves for the day, but housekeeping does have access to this area for cleaning purposes. This will no longer be the case starting on 9/15/14. This area will be securely locked at the end of business hours and cleaned by Medical Records Staff as needed.</p> <p>The Surgery Manager or Administrator will be responsible for implementing this change in procedure that will ensure compliance with this regulation.</p> <p>Policy (MR-5) General Policies of the Medical Records Department was revised by the Surgery Manager on 9-10-14 to reflect this change. The surgery manager will evaluate these changes and monitor compliance.</p>	09/10/2014	

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Q000242	<p>open shelving unit.</p> <p>4. During an interview on 8-19-14 at 1440 hours, medical records staff A5 indicated that the medical records (MR) are the prepped and ready charts for patients scheduled for procedures. The staff A5 confirmed that the environmental services personnel clean the room after the MR staff have gone for the day and confirmed that the records are not secured to prevent access to the MR information.</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, employee health file review, and staff interview, the infection control committee failed to ensure the immunization status for 2 of 3 nursing staff (staff members N2 and N3).</p> <p>Findings:</p>	0000242	Policy (INF 1/4) Employee Health Program was revised by the Surgery Manager on 9/10/14 to state that if "physician authenticated" documentation is not available for the recommended vaccines, a titer will be drawn to determine the level of immunity. This change to facility policy will ensure compliance with regulation. The	09/10/2014

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	<p>1. Review of the policy and procedure "Employee Health Program All Sites", policy number "Code: INF-1/4", with a last date of approval 6/4/14, indicated:</p> <p>a. Under "Procedure", it read: "A. New Employee Health Program Includes:...2. Documentation of current immunization status; i.e., MMR (measles, mumps, rubella) (x2) and varicella. If documentation is not available or the recommended vaccines have not been obtained, a titer will be drawn to determine the level of immunity...".</p> <p>2. Review of employee health files indicated:</p> <p>a. RN (registered nurse) N2 had a self reported history of varicella noted as 1997 on a State Department of Health immunization record form.</p> <p>b. RN N3 had a self reported "Rosie Ola", for May 1961, noted on their childhood immunization document.</p> <p>3. At 10:50 AM on 8/20/14, interview with staff member #52, the infection control practitioner, indicated:</p> <p>a. A physician has not authenticated the communicable disease history for Staff members N2 and N3 related to the diseases listed in 2. above.</p> <p>b. It was thought that roseola and rubeola were the same communicable</p>		<p>surgery manager will monitor compliance of these changes when new hires start employment.</p>				

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S000000	disease, but with research it was found to not be the same, so that staff member N3 lacks immunization status for rubeola.  The visit was for a State survey.  Facility Number: 005399  Survey Date: 8-18/20-14  Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor  Linda Plummer, RN Public Health Nurse Surveyor  QA: claughlin 08/28/14	S000000		
S000442	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)  The infection control committee responsibilities must include, but are not limited to:  (E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to			

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	<p>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, employee health file review, and staff interview, the infection control committee failed to ensure the immunization status for 2 of 3 nursing staff (staff members N2 and N3).</p> <p>Findings:</p> <p>1. Review of the policy and procedure "Employee Health Program All Sites", policy number "Code: INF-1/4", with a last date of approval 6/4/14, indicated:</p> <p>a. Under "Procedure", it read: "A. New Employee Health Program Includes:...2. Documentation of current immunization status; i.e., MMR (measles, mumps, rubella) (x2) and varicella. If documentation is not available or the recommended vaccines have not been obtained, a titer will be drawn to determine the level of immunity...".</p> <p>2. Review of employee health files indicated:</p> <p>a. RN (registered nurse) N2 had a self reported history of varicella noted as</p>	S000442	S 0442 Policy (INF 1/4) Employee Health Program was revised by the Surgery Manager on 9/10/14 to state that if "physician authenticated" documentation is not available for the recommended vaccines, a titer will be drawn to determine the level of immunity. This change to facility policy will ensure compliance with regulation. The surgery manager will ensure compliance with these changes when new hires begin employment.	09/10/2014

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S000624	<p>1997 on a State Department of Health immunization record form.</p> <p>b. RN N3 had a self reported "Rosie Ola", for May 1961, noted on their childhood immunization document.</p> <p>3. At 10:50 AM on 8/20/14, interview with staff member #52, the infection control practitioner, indicated:</p> <p>a. A physician has not authenticated the communicable disease history for Staff members N2 and N3 related to the diseases listed in 2. above.</p> <p>b. It was thought that roseola and rubeola were the same communicable disease, but with research it was found to not be the same, so that staff member N3 lacks immunization status for rubeola.</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</p>				

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	<p>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. Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure the privacy and security of individually identifiable health information.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>The Medical Staff Rules and Regulations (approved 6-14) indicated the following: "Unauthorized individuals cannot gain access to patient records."</li> <li>The policy/procedure Confidentiality (approved 3-14) indicated the following: "...[the center] realizes its obligation to safeguard health records against unauthorized or inadvertent disclosures, uses, loss, tampering, alteration, or destruction."</li> <li>During a tour of the center on 8-19-14 at 1440 hours, the following condition was observed in the office space immediately behind the reception and information desk of the waiting room area: unsecured patient records including</li> </ol>	S000624	<p>S 0624 The Medical Records area is currently locked when staff leaves for the day, but housekeeping does have access to this area for cleaning purposes. This will no longer be the case starting on 9/15/14. This area will be securely locked at the end of business hours and cleaned by Medical Records Staff as needed. The Surgery Manager or Administrator will be responsible for implementing this change in procedure that will ensure compliance with this regulation. Policy (MR-5) General Policies of the Medical Records Department was revised by the Surgery Manager on 9-10-14 to reflect this change. The Surgery Manager will monitor the changes are followed and the process is working.</p>	09/10/2014

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S000780	<p>personal information were filed in an open shelving unit.</p> <p>4. During an interview on 8-19-14 at 1440 hours, medical records staff A5 indicated that the medical records (MR) are the prepped and ready charts for patients scheduled for procedures. The staff A5 confirmed that the environmental services personnel clean the room after the MR staff have gone for the day and confirmed that the records are not secured to prevent access to the MR information.</p> <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 on review of medical staff rules and regulations, review of patient</p>	S000780	S 0780 Policy (NUR-5/10) IV access Lines and the Physician Orders for surgery patients were	09/10/2014			

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	<p>medical records, and staff interview, the medical staff failed to give specific pre op orders related to heparin/saline locks for 24 of 24 patients (patients #1 through #24).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Review of the Medical Staff Rules and Regulations, approved 6/18/14, indicated: <ol style="list-style-type: none"> <li>On page 7, under item 2.13., it read: "A physician's routine orders, when applicable to a given patient, shall be reproduced in detail on the order sheet of the patient's record..."</li> </ol> </li> <li>Review of medical records #1 through #24 indicated: <ol style="list-style-type: none"> <li>All pre op orders read: "...IV: Insert IV prn (as needed) - adapter access line..."</li> </ol> </li> <li>At 12:45 PM on 8/19/14, interview with staff member #50, the RN (registered nurse) facility administrator, indicated: <ol style="list-style-type: none"> <li>There are very few patients who do not have an IV access, per a saline/heparin lock, started in the pre op area, thus this is not prn, but routine.</li> <li>Most times, a 22 gauge or 24 gauge needle is used to start the IV access, and 3 cc of normal saline is used to flush this access line once started.</li> </ol> </li> </ol>		<p>revised by the Surgery Manager on 9/10/14 to specifically state that when an IV is started on a surgery patient it will be started with a 22 or 24 gauge angio cath with a NS lock adapter. The old terminology "prn adapter" was replaced by NS lock adapter. This adapter will be flushed with 2-3 NS solution. These changes to the policy and orders will ensure compliance with this regulation. The Surgery Manager will monitor these changes.</p>	

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S000854	<p>c. The current standing orders do not specify a size of saline lock to use, nor is there an order related to what liquid to use for flushing, or the amount to use.</p> <p>d. The standing orders lack specificity, as is a standard of practice.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)</p> <p>Requirements 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: Based on review of the medical staff rules and regulations, patient medical record review, and staff interview, the medical staff failed to address medical clearance recommendations/time frames for 2 of 2 patients with medical clearance documentation (patients #14 and #16).</p> <p>Findings: 1. Review of the Medical Staff Rules and Regulations, approved 6/18/14, indicated: a. Under "Article IV General Rules Regarding Surgical Care", it read: "4.01. A history and physical is completed prior</p>	S000854	S 0854 Policy (NUR-4/15) General Policies for Anesthesia was revised by the Surgery Manager on 9-11-14 to include a physician approved time frame/limitation in regards to medical clearance for surgery patients. This policy now states that surgery must be completed within 90 days of the medical clearance report. This policy revision will ensure compliance with this regulation. The Surgery Manager will monitor compliance of these changes.	09/11/2014

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	<p>to surgery. Upon review of all information and if there is need for further evaluation, the patient is referred to their family physician for medical clearance. The medical clearance will be obtained prior to the surgical procedure, will be in writing, and placed in the surgical record."</p> <p>2. Review of patient medical records indicated:</p> <p>a. Pt. #14 was requested to have medical clearance related to: "overall health d/t (due to) heart transplant" and was signed 2/18/14 with clearance given for surgery scheduled 4/8/14, but surgery was postponed and did not occur until 7/8/14.</p> <p>b. Pt. #16 had a medical clearance from a cardiologist signed 4/14/14 for surgery which took place on 7/8/14.</p> <p>3. At 9:00 AM on 8/20/14, interview with staff member #50, the RN (registered nurse) administrator, indicated:</p> <p>a. Patients #14 and #16 had surgical procedures that were more involved than the usual cataract surgeries performed most often at the facility, thus the requirement for medical clearance from specialty/cardiology physicians.</p> <p>b. With a 5 month space between the clearance for patient #14 and their</p>						

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	<p>eventual surgery 7/8/14, a change in their health could have occurred, putting them at a greater surgical risk.</p> <p>c. According to the medical staff rules and regulations, no time frame/limitation has been determined appropriate by the physicians in regards to medical clearance for patients.</p>				