

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  09/10/2013
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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S000000	<p>The visit was for a licensure survey.</p> <p>Facility Number: 005399</p> <p>Survey Date: 9-09-13 to 9-10-13</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 09/16/13</p>	S000000			

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

TITLE

(X6) DATE

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

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S000226	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review, the center failed to maintain a list of all contracted services, including the scope and nature of services provided for 3 of 24 services.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of a list of contracted services provided by staff A1 failed to indicate a service provider for an ocular lens provider, a fire extinguisher service, and a microscope repair service.</li> <li>2. Review of center documentation indicated the following service providers: ocular lens provider by CS1, fire extinguisher service by CS2, and microscope repair service by CS3.</li> <li>3. During an interview on 9-10-13 at 1415 hours, staff A1 confirmed that the list of contracted services lacked the</li> </ol>	S000226	The facility already has an effective plan of monitoring contracted services on a quarterly basis. The results of this monitoring is reported to the Governing Body quarterly. The 3 services will be added to the current program. The QA manager will monitor and the report will be given to the Governing Body. The administrator will ensure the updates are completed.	10/10/2013			

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	indicated providers.			

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S000230	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based upon document review and interview, the center lacked documentation of periodic utilization review by a group of at least three licensed physicians without financial interest in the center.</p> <p>Findings:</p> <p>1. The policy/procedure Utilization Review Plan (approved 5-13) indicated the following: " ISDH requires a utilization review to be done by three (3) licensed physicians, none of whom have a financial interest in the ASC. "</p> <p>2. Documentation of utilization review dated 10-12 to 1-13 indicated only one physician was performing the review.</p>	S000230	The utilization review coordinator will ensure 3 physicians review the documents. The current policy reflects 3 physicians are to review the reports so no policy change is needed. The administrator will monitor this program. Reports are already reported to the Governing Body. The utilization review program will be conducted two times a year.	10/10/2013			

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	3. During an interview on 9-10-13 at 1330 hours, staff A1 confirmed that the utilization review documentation indicated only one physician reviewer.			

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S000334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>			

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	<p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge;</p> <p>from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p>			

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	<p>Based on document review and interview, the center lacked a process for reporting each potential reportable event occurrence at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. The policy/procedure Reporting Medical Errors to the ISDH thru their Healthnet Portal System (approved 5-13) lacked a provision for reporting potential reportable events identified by state law 410 IAC 15-2.4-2.2(a)(2).</li> <li>2. During an interview on 9-10-13 at 1350 hours, staff A1 confirmed that the policy/procedure lacked a provision for reporting potential reportable events to the ISDH.</li> </ol>	S000334	The current policy will be updated to include potential reportable events. The updated policy will be reviewed with the ASC staff by the surgery manager. The administrator will monitor the program in the event a reportable event occurs. The policy will be reviewed with the ASC staff once a year.	10/10/2013	

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S000526	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed. Based on employee file review and staff interview, the facility failed to ensure that personnel performing laboratory testing had assessed competencies documented in the employee files for 4 (staff members N1, N2, N3 and N4) of 4 RNs (registered nurses).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>at 1:25 PM on 9/9/13, review of four RN files indicated there was no documentation of competency for performing urine pregnancy testing or blood glucose testing for patients.</li> <li>interview with staff member #51, the surgery manager, at 2:15 PM on 9/9/13 indicated: <ol style="list-style-type: none"> <li>annual education is performed annually for staff related to urine pregnancy tests and glucometer testing, but staff are not assessed for competency regarding point of care testing done at the facility</li> <li>it was unknown that annual competency assessments for point of care</li> </ol> </li> </ol>	S000526	All nursing staff will have competency assessed for the performance of pregnancy testing and glucometer testing. Documentation of these skill assessments will be placed in the employee personnel file when completed each year during the annual education training. The surgery manager will be responsible for scheduling and documenting these competency checks each year. The surgery manager will also be responsible for developing the necessary form to document these competency checks.	10/10/2013			

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S001010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on policy and procedure review, observation, and staff interview, the facility failed to ensure that multidose vials were labeled when opened, and discarded after 28 days as required by policy, in one area observed.</p> <p>Findings</p> <p>1. at 11:40 AM on 9/9/13, review of the facility policy and procedure manual indicated a policy titled: "Medication Guidelines", policy number NUR-4/4, which indicated:</p> <p>a. under "Procedure", it reads: "...2. Injectable medications shall be purchased...When only multiple dose vials (MDV) are available, the vials shall be refrigerated (if required) and discarded after 28 days of opening..."</p> <p>2. at 8:57 AM on 9/10/13, while on tour of the facility in the company of staff</p>	S001010	The Medication Guidelines policy will be reviewed with the nursing staff at the October 1, 2013 staff meeting. All multi-dose injectable vials will be labeled with an open date and an expiration date of 28 days. The pharmacy nurse will continue to monitor outdates with her monthly medication audit checks. The safety officer will also complete periodic spot checks during the quarterly hazard/safety assessments of the facility. The surgery manager will be responsible for monitoring these checks and for modifying the facility's hazard/safety checklist to include the quarterly spot checks of multi-dose vials.	10/10/2013			

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	<p>member #51, the surgery manager, it was observed in the post op medication area that one opened 5 ml vial of Flumazenil was dated 8/7/13</p> <p>3. at 9:00 AM on 9/10/13, interview with staff member #51, the surgery manager, it was indicated:</p> <p>a. it is unclear if the dated Flumazenil was opened on 8/7/13 or expired on 8/7/13, either way, it was beyond 28 days and should have been discarded either on 8/7/13, or 9/4/13 (if opened on 8/7/13)</p> <p>b. staff have been reminded to mark open dates and discard dates on multi dose vials when opening, but apparently need more education</p>				

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S001146	<p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on policy and procedure review, manufacturer's packing list/package insert review, observation, and staff interview, the facility failed to ensure that no condition was maintained that might cause a hazard to patients, related to the possibility of an incorrect blood sugar level.</p> <p>Findings:</p> <p>1. at 11:40 AM on 9/9/13, review of the policy and procedure manual indicated a policy titled: "Blood Glucose Testing", policy number NUR-5/13, which indicated:</p> <p>a. on page 6, it reads: "...One Touch Test Strips have a 6 month (120 day) DISCARD date once opened..."</p> <p>2. at 3:00 PM in 9/10/13, review of the package insert for the One Touch Ultra</p>	S001146	The Glucometer policy will be reviewed with the nursing staff at the October 1, 2013 staff meeting. The discard date will be marked on the glucometer test strip bottle each time a new bottle is opened. The facility's Infection Control CQI Monitor checklist will now include checking the multi-dose vials for proper outdate labeling on a monthly basis. The surgery manager will be responsible for revising the checklist to include the monthly checks of the glucometer test strips and a nursing staff member will be responsible for completing the monthly checks	10/10/2013			

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	<p>Blue test strips indicated:</p> <p>a. under the section "Storage and Handling", it reads: "...Write the discard date (date opened plus 6 months) on the vial label when you first open it..."</p> <p>3. at 9:05 AM on 9/10/13, while on tour of the pre op area of the facility in the company of staff member #51, the surgery manager, it was observed that the one touch test strips were not dated when opened, or when the 6 month expiration date is/was</p> <p>4. at 9:10 AM on 9/10/13, interview with staff member #51, the surgery manager, indicated:</p> <p>a. the policy is incorrect in stating that 120 days is the 6 month expiration date for opened test strips, it should read 180 days</p> <p>b. the bottle of test strips found in the pre op area was not dated with an opened and expiration date, making it impossible to tell when the 6 month discard date is, or was</p> <p>c. staff have been reminded to follow the facility policy in dating test strips when opening them</p>				