STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001097	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	X3) DATE SURVEY COMPLETED 12/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PANKRATZ EYE INSTITUTE LLC	3135 MIDDLE RD COLUMBUS, IN 47203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 0000 Bldg. 00	This visit was for recertification of an ambulatory surgery center. Facility number: 002663 Dates of survey: 12/1/15 to 12/ 3/15 QA: cjl 12/31/15	Q 0000		
Q 0041 Bldg. 00	416.41(a) CONTRACT SERVICES When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. Based on document review and interview, the Chief Executive Officer (CEO) failed to ensure implementation of policies for orientation of 3 (P1, P2 & P3) of 3 contracted employees. Findings: 1. Review of policy #3.023, titled Employee Orientation, indicated the following: New employees of the Center shall receive appropriate orientation relative to their job position. The policy further indicated the employee personnel file would include General Orientation and a Job Orientation Checklist. The	O 0041	In order to satisfy policy requirements stating that all new employees will complete an orientation program including personnel contracted by the Center, the ASC Director has generated a staff file for those contracted services which employ a consistent individual as their provider. The aforementioned criteria is applicable to the following: medical records review, pharmacy and housekeeping. Each file contains a job description and general orientation checklist which has or will be completed during the ensuing scheduled provision of service. Dates listed indicate when task achievement has/or	02/29/2016

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds 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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	policy was last reviewed 11/12/13. 2. Review of personnel files for the contracted staff P1, P2 & P3 indicated lack of documentation of a Job Orientation Checklist or any other orientation to job specific duties. 3. On 12/1/15 at 2:30pm, A1, Director, indicated evidence of training/orientation was not available for contracted staff.		will occur: Medical Records January 25, 2016, Housekeeping January 27, 2016, Pharmacy by February 29, 2016.	
Q 0081 Bldg. 00	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and			

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	problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. Based on document review and interview, the quality assurance and performance improvement program (QAPI) failed to have measurable quality indicators for 11 services/functions (biomedical engineering, biohazardous waste disposal, housekeeping, laboratory, laundry, medical records, pharmacy, transfer, infection control, medication errors and response to patient emergency). Findings: 1. Review of policy #1.07, titled Quality Assurance Plan, indicated lack of documentation of how quality indicators would be measured, tracked or analyzed. The policy was approved 3/27/13. 2. Review of documents titled Quality Assurance Committee Meeting, dated 11/16/15, 8/17/15, 5/8/15, and 2/5/15 and supporting reports, indicated lack of documentation of quality indicator measurements for the following: biomedical engineering, biohazardous waste disposal, housekeeping, laboratory, laundry, medical records, pharmacy, transfer, infection control, medication	Q 0081	Federal regulations obligate the ASC to retain an on-going, data-driven QAPI program incorporating measurable quality indicators for 11services/functions delineated within the cited deficiency. To ensure reconciliation, the Center QualityAssurance Plan will be redeveloped by the Director to meet these specifications. The process will include the following steps: 1.Assessment of the 11 services/functions listed with prioritization of performance improvement activities to be monitored in within each arena during 2016 2.Establishment of measurement standards to be defined by Center policy and/or published statistical data based upon national research and quality metrics 3.Development of tools to effectively track and record the quality indicators selected 4.Implementation of quality indicator tools and data collection 5.Assimilation and analysis of data obtained (quarterly) 6.Presentation of quality indicator findings for each service/function to the QAC and Governing Board annually (end of quarter4, 2016) for outcome	02/29/2016

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	errors and response to patient emergency. 3. On 12/2/15 at 4:30pm, A1, Clinical Manager, indicated biomedical engineering, biohazardous waste disposal, housekeeping, laboratory, laundry, medical records, pharmacy, transfer, infection control, medication errors and response to patient emergency did not have measurable standards/goals.		evaluation 7.Re-initiation of step 1 based upon QAC andGoverning Board recommendations for 2017 measurable improvement indicators to be examined The time frame for achievement of these activities is depicted below: ·February 29, 2016: completion of step #1 ·March 31, 2016: completion of step # 2 ·April 30,2016: quality indicator collection tools/methods developed for: Biomedical engineering, Biohazardous waste disposal, Housekeeping and Laboratory ·May 31, 2016: quality indicator collection tools/methods developed for: Medical records,Pharmacy, Laundry and Transfers ·June 30, 2016: quality indicator collection tools/methods developed for: Infection control, medication errors and response to patient emergencies ·July 1, 2016: completion of step #4 ·September 30 and December 30, 2016: completion of step # 5 ·Steps 6 and 7 to will be accomplished during the fourth quarter QAC and Board of Directors meetings	
Q 0083 Bldg. 00	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct			

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	improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results Based on document review and interview, the Center failed to undertake at least one specific quality improvement project in 2014 or 2015. Findings: 1. Review of policy #1.07, titled Quality Assurance Plan, indicated lack of documentation of a plan for to undertake specific projects. The policy was approved 3/27/13. 2. On 12/2/15 at 4:30pm, A1, Director, indicated the Center did not complete or initiate a specific/distinct improvement project in 2014 or 2015.	O 0083	To ensure adherence to performance enhancement standards requiring the ASC to conduct a minimum of one improvement project per year, the Director will select and initiate a distinctive QAPI project annually to reflect the ASC's services and scope of operations. In 2016, this project will be dedicated to cataract surgery quality of care as evidenced by post-operative patient visual outcomes. The VF-8R questionnaire will be employed to survey a randomly selected percentage of patients during their pre-surgical exam and 90 days post cataract extraction commencing April 1, 2016 with data collection parameters to be established prior to this date. Results will be assimilated and communicated to the QAC and Governing Board during this year's fourth quarter meetings. Recommendations for forthcoming undertakings will be based upon conclusions ascertained and quality improvement priorities for the Center. The Director will be responsible for initiating a new project(s) in January of each	02/02/2016

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			succeeding year.	
Q 0084 Bldg. 00	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. Based on document review and interview, the governing body failed to ensure sufficient staff, time, information systems and training were adequately allocated to implement the QAPI (quality assurance performance improvement) program, and failed to ensure that the QAPI program described in detail, indicator data to be collected, how it would be collected or the frequency of data collection for the past 4 quarters. Findings: 1. Review of policy #1.07, titled Quality Assurance Plan, indicated the following: A. The Board of Directors...retains oversight responsibility which entails direct involvement in the program.	O 0084	To maintain the Governing Board's responsibility for oversight of and continued adherence to federal regulation expectations pertaining to the functionality and efficacy of the Center QAPI program via the allocation of sufficient time, staff and financial resources; restructuring of current roles and responsibilities for ASC staff and leadership has been initiated. The Director will be relinquishing selected day to day operational functions thus providing the necessary time essential for the integration of ongoing QA activities/studies as delineated in compliance response Q081. The Director will begin this transition immediately permitting a three day per week QAPI time dedication to transpire upon completion of successor training	02/02/2016

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	B Program Reappraisal would occur at least annually to assure that the program was achieving objectives, is effective, is cost efficient and consistent with external requirements; taking into account the following: 1. Evidence of impact 2. Resources expended in carrying out program activities 3. Other external and internal information reflecting the program effectiveness. C. The policy lacked documentation of detailed quality indicator data to be collected, how data would be collected, or the frequency of data collection. The policy was approved 3/27/13. 2. Review of documents titled Quality Assurance Committee Meeting, dated 11/16/15, 8/17/15, 5/8/15, and 2/5/15 and supporting reports, lacked documentation of detailed indicator data with frequency and method of collection. 3. On 12/2/15 at 4:30pm, A1, Director, indicated the following A. MD#3 was the only member of the QAC and that A1 & A2 sat in on meetings as liaisons. B. That A1 was the primary person responsible for all QAPI activity. C. That A1 was able to spend approximately 6 hours per month on QAPI as available.		on or before March 31, 2016.	

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	D. That the Center did not keep a written budget designating allocation of funds/resources, but instead had individual requests approved or denied per MD#3 (owner). E. A1 indicated QAPI training may be approved for on-line training when time permits or one may attend training on own time with own funding.			
Q 0121 Bldg. 00	416.45(a) MEMBERSHIP AND CLINICAL PRIVILEGES Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel. Based on document review and interview, the Governing Body (GB) failed to ensure granting of privileges for 3 of 3 medical staff (MS) members (MD#1, MD#2 and MD#3) was documented in writing for appointments between 7/28/14 and 10/29/15. Findings:	Q 0121	To ensure Center privileges granted practitioners by the governing body are: consistent with their training, experience and other qualifications, communicated to the practitioner and documented within each medical staff file; the Credentialing Committee, at their quarterly meeting January25, 2016, reviewed the request for privileges submitted by each Center physician during their	02/08/2016

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	1. Review of policy #2.01, titled By-Laws of the Medical Staff, indicated the following: The term "clinical privileges" means the permission granted to a practitioner to render specific diagnostic, therapeutic, medical or surgical services. The By-Laws further indicated: A practitioner providing direct clinical services at this surgery center by virtue of medical staff membership shall be entitled to exercise only those clinical privileges or specified services specifically granted to him/her by the governing body. The By-Laws were approved by the GB 2/16/15. 2. Review of appointment letter documents addressed to MD#1, MD#2 and MD#3 dated 10/30/15, 7/28/14, and 7/28/14 respectively, lacked documentation of privileges granted. 3. On 12/2/15 at 3:45pm, A1, Director, indicated the credential files of MD#1, MD#2 and MD#3 lacked written documentation of privileges having been granted.		appointment/reappointment process as documented in their medical staff files. Committee findings indicated that only one physician had modified his request listing privileges which were not supported by evidence of supplementary training or experience. This practitioner was notified of this deficiency by the ASC Director. The physician subsequently revised his previous request to include only those procedures sustained by his documented level of training and experience. The Credentialing Committee reconvened for a special meeting on January 29, 2016 to review and subsequently approved his request. These findings will be presented to the Boardof Directors during their quarterly meeting scheduled February 8, 2016. Following approval, a letter of confirmation with delineation of privileges will be drafted by the ASC Director, distributed to each practitioner and placed within each of their medical staff files.	
Q 0241 Bldg. 00	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to			

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	professionally acceptable standards of practice. Based on policy review and observation, the facility failed to ensure an environment which minimizes infection exposure regarding operating room attire. Findings: 1. Facility policy Dress Requirements, reviewed 4/18/2014, indicated: A. Procedures; 7. Face masks are to be changed between cases, or more frequently when necessary. 2. During the observation of a patient ophthalmology procedure on 12/02/2015 between 1300 and 1400 hours, it was noted that healthcare staff members #4 (circulating registered nurse) and #5 (physician) went from one operating room (OR) to the other without changing masks. Staff member #4 came out into PACU (post-anesthesia care unit) and untied the top tie on the mask and then retied mask when going into the OR for another case.	O 0241	To ensure adherence to Center policy asserting that surgical masks are to be changed between each case, the Director will conduct a policy review in-service for all Center staff as part of the monthly staff meeting February 3, 2016 to verify understanding and future compliance. The Director will also incorporate this identified problem-prone area into the QAPI program as a performance indicator metric for infection control.	02/03/2016

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S 0000 Bldg. 00	This visit was for State licensure survey. Facility Number: 002663 Dates: 12/1/15 to 12/3/15 QA: cjl 12/31/15	S 0000		
S 0116 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(2)(A-D) The governing body shall do the following: (2) Ensure the following: (A) The requests of practitioners, for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff. (B) Reappointments are acted upon at least biennially. (C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications. (D) This process occurs within a reasonable period of time as specified by the medical staff bylaws. Based on document review and interview, the Governing Body (GB) failed to ensure 3 of 3 Medical Staff	S 0116	To ensure Center privileges granted practitioners by the governing body are: consistent with their training, experience and	02/08/2016

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	(MS) members were granted privileges according to MS By-Laws. Findings: 1. Review of policy #2.01, titled By-Laws of the Medical Staff, indicated the following: The term "clinical privileges" means the permission granted to a practitioner to render specific diagnostic, therapeutic, medical or surgical services. The By-Laws further indicated: A practitioner providing direct clinical services at this surgery center by virtue of medical staff membership shall be entitled to exercise only those clinical privileges or specified services specifically granted to him/her by the governing body. Section B of the document indicated a request by a staff member for a modification of privileges must be supported by documentation of additional training and/or experience. The By-Laws were approved by the GB 2/16/15. 2. Review of appointment letter documents addressed to MD#1, MD#2, and MD#3 dated 10/30/15, 7/28/14, and 7/28/14 respectively, lacked documentation of privileges granted. 3. Review of the credential file of MD#2 indicated a modification to his/her		other qualifications, communicated to the practitioner and documented within each medical staff file; the Credentialing Committee, at their quarterly meeting January25, 2016, reviewed the request for privileges submitted by each Center physician during their appointment/reappointment process as documented in their medical staff files. Committee findings indicatedthat only one physician had modified his request listing privileges which were not supported by evidence of supplementary training or experience. This practitioner was notified of this deficiency by the ASC Director. The physician subsequently revised his previous request to include only those procedures sustained by his documented level of training and experience. The Credentialing Committee reconvened for a special meeting on January 29, 2016 to review and subsequently approved his request. These findings will be presented to the Boardof Directors during their quarterly meeting scheduled February 8, 2016. Following approval, a letter of confirmation with delineation of privileges will be drafted by the ASC Director, distributed to each practitioner and placed within each of their medical staff files.	

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	request for privileges in the Center. The file lacked documentation of supporting documentation of additional training and/or experience for the specifically requested procedures. 4. On 12/2/15 at 3:45pm, A1, Director, indicated the credential files of MD#1, MD#2, and MD#3 lacked documentation of privileges having been granted and that the file of MD#2 lacked supporting documentation for his/her modification to privileges request.			
S 0153 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C) Require that the chief executive officer develop and implement policies and programs for the following: (C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies. Based on document review and interview, the Chief Executive Officer (CEO) failed to implement policies for orientation of 3 contracted employees and 1 direct employee. Findings:	S 0153	In order to satisfy policy requirements stating that all new employees will complete an orientation program including personnel contracted by the Center, the ASC Director has generated a staff file for those contracted services which employ a consistent individual as their	02/29/2016

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	1. Review of policy #3.023, titled Employee Orientation, indicated the following: New employees of the Center shall receive appropriate orientation relative to their job position. The policy further indicated the employee personnel file would include General Orientation and a Job Orientation Checklist. The policy was last reviewed 11/12/13. 2. Review of personnel files for the contracted staff P1, P2, & P3 lacked documentation of a Job Orientation Checklist or any other orientation to job specific duties. No personnel file was available for the direct employee (receptionist) P4. 3. On 12/1/15 at 2:30pm, A1, Director, indicated documentation of orientation for contracted staff was not available and that employee P4 is shared with the office side of the practice and personnel files or documentation of orientation is not kept for those employees.		provider. The aforementioned criteria is applicable to the following: medical records review,pharmacy and housekeeping. Each file contains a job description and general orientation checklist which has or will be completed during the ensuing scheduled provision of service. Dates listed indicate when task achievement has/or will occur: Medical Records January 25, 2016, Housekeeping January 27, 2016, Pharmacy by February 29, 2016. An additional delinquency sited pertains to the absence of staff file creation and maintenance for the ASC receptionist. The Director will develop a file for this individual by February 29, 2016 with inclusions satisfying Center policy and procedure prerequisites for all employees.	
S 0400 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(a) (a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001097	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED 12/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PANKRATZ EYE INSTITUTE LLC	3135 MIDDLE RD COLUMBUS, IN 47203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	visitors. Based on policy review and observation, the facility failed to ensure an environment which minimizes infection exposure regarding operating room attire. Findings: 1. Facility policy Dress Requirements, reviewed 4/18/2014, indicated: A. Procedures; 7. Face masks are to be changed between cases, or more frequently when necessary. 2. During the observation of a patient ophthalmology procedure on 12/02/2015 between 1300 and 1400 hours, it was noted that healthcare staff members #4 (circulating registered nurse) and #5 (physician) went from one operating room (OR) to the other without changing masks. Staff member #4 came out into PACU (post-anesthesia care unit) and untied the top tie on the mask and then retied mask when going into the OR for another case.	S 0400	To ensure adherence to Center policy asserting that surgical masks are to be changed between each case, the Director will conduct a policy review in-service for all Center staff as part of the monthly staff meeting February 3, 2016 to verify understanding and future compliance. The Director will also incorporate this identified problem-prone area into the QAPI program as a performance indicator metric for infection control.	02/03/2016
S 0728 Bldg. 00	410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)			

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	(b) The medical staff shall adopt and enforce bylaws to carry out its responsibilities. These bylaws and rules must be as follows: Based on document review and interview, the medical staff (MS) failed to enforce bylaws and rules for the Quality Assurance Committee in the past year. Findings: 1. Review of policy #2.01, titled By-Laws of the Medical Staff; Section C. Quality Assurance Committee (QAC), indicated the QAC shall consist of a chairperson and one or two members who shall be appointed from the MS. This committee shall also have as members the following non-medical staff members: The Executive Director and the Director. The By-Laws were approved by the MS on 2/6/15 and approved by the governing body on 2/16/15. 2. Review of documents titled Quality Assurance Committee Meeting, dated 11/16/15, 8/17/15, 5/8/15 and 2/5/15, each indicated the "Committee member in attendance" was MD#3. "Also in attendance" was A1 and A2. The documents lacked documentation of any other MS member.	S 0728	Medical staff bylaws and rules pertaining to the Center Quality Assurance Committee (QAC) stipulate that committee membership must include a chairperson, minimum of one member from the medical staff, the Executive Director and Director. Failure to meet this regulation was reconciled during the quarterly Medical Staff meeting held January 25, 2016, during which Dr. Pankratz requested and was granted approval to chair the QAC. He subsequently appointed Dr. Klass (medical staff), Larry Gardner and Brenda Richardson (Executive Director and Director) to attend as members in accordance with the previously referenced Medical Staff bylaws.	01/25/2016

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	3. Review of MS meeting minutes dated 11/11/15, 8/14/15, 5/7/15 and 2/6/15 lacked documentation of who was the QAC chairperson and lacked documentation of the MS having appointed any member to the QAC. 4. On 12/2/15 at 4:30pm, A1, Director, indicated MD#3 was the only member of the QAC and that A1 & A2 sat in on meetings as liaisons.			