

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001166	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/04/2015
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NAME OF PROVIDER OR SUPPLIER BALL OUTPATIENT SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 2401 W UNIVERSITY AVE STE 200 OMP MUNCIE, IN 47303
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Q 000 Bldg. 00	The visit was for a re-certification survey. Facility Number: 012159 Survey Date: 2-2/4-15 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor QA: claughlin 02/18/15	Q 000		
Q 041 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 center failed to assure its contracted housekeeping services were provided in a safe and effective manner for two (HK22 and HK23) of two contracted environmental services (EVS) personnel.	O 041	Responsible: The Clinical Director Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policy for Environmental Cleaning of the Surgical Suites is followed. This includes orientation and initial education, training, instruction and	03/20/2015

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>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Environmental Cleaning of Surgical Suites in the Perioperative Setting (approved 4-12) indicated the following: "Personnel cleaning peri-operative areas are to receive initial education, training, instruction and competency validation for cleaning and disinfection of the peri-operative areas." 2. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide documentation of EVS personnel orientation and training in the infection control (IC) safety standards and practices to be followed and documentation of competency for the EVS personnel performing the cleaning and disinfecting procedures (in accordance with the IC standards and practices) in the restricted surgical and other patient and public areas for two personnel (HK22 and HK23) and none was provided prior to exit. 3. In interview on 2-03-15 at 1555 hours, the offsite property manager A10 for the host hospital confirmed that no personnel files including a job description or documentation of orientation including infection control/safe practices training, 		<p>competency validation for the cleaning and disinfection of the surgery center. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. On-going compliance will be monitored via the maintenance of an up to date file for each contracted housekeeping employee. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff. Job description, competency/skills checklist, Specialized Medical Cleaning Manual, and listing of job duties are attached as Exhibit 1.</p>	

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Q 101 Bldg. 00	<p>or competency checklist for cleaning and disinfecting procedures had been prepared for the EVS personnel HK22 and HK23 currently providing housekeeping services under agreement for the surgery center.</p> <p>4. In interview on 2-04-15 at 1310 hours, the clinical nurse manager A2 confirmed that no center job description or documentation of orientation including infection control/safe practices training or competency checklist for cleaning and disinfecting procedures was available for the EVS personnel HK22 and HK23.</p> <p>416.44(a)(1) PHYSICAL ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. Based on document review and interview, the center failed to ensure that its operating rooms (OR) were maintained in accordance with national standards and that operational control records for OR ventilation were available.</p>	O 101	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that facility standards are met and maintained at the Ball Outpatient Surgery Center. The Ball Outpatient Surgery Center contracts for facility support. The contracted service provider</p>	03/24/2015	

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	<p>Findings:</p> <ol style="list-style-type: none"> 1. The American Institute of Architects (2001 edition) Guidelines for Design and Construction of Hospital and Health Care Facilities indicated the following: "Part 9.5L [Outpatient Surgery Centers] ... mechanical heating, ventilation, and air conditioning shall be as described for similar areas in Section 9.31 and Table 7.2Table 7.2: Operating Room (OR) minimum total air exchanges per hour : 15." 2. The policy/procedure Environmental Controls in the Ambulatory Surgery Center (approved 4-12) indicated the following: "The ASC will maintain a minimum of 15 ACH (air changes per hour) in the operating room, of which a minimum of 3 ACH should be fresh air ...maintenance of the environmental systems in the ASC will be coordinated with facilities management." 3. In interview on 2-02-15 at 1200 hours, the director of facilities A8 was requested to provide documentation indicating the OR air exchanges per hour for the 5 operating rooms at the center and none was provided prior to exit. 4. In interview on 2-03-15 at 1510 hours, the facilities manager A9 confirmed that no documentation of OR air exchange measurements was available. 		is required to maintain the physical plant to current standards. This includes maintenance of the minimum required air exchanges per hour and annual testing. This information shall be maintained by the clinical director and continuously monitored.	

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Q 122 Bldg. 00	<p>416.45(b) REAPPRAISALS</p> <p>Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.</p> <p>Based on document review and interview, the governing body failed to assure that medical staff reappointment included a review of the candidate's surgical case history in accordance with its medical staff bylaws for 10 of 10 (MD02, MD11, MD12, MD13, MD14, MD15, MD16, MD17, MD18 and MD19) medical staff credential files reviewed.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 1-13) indicated the following: "No physician may become or remain a member of the active staff with clinical privileges unless his or her activity in the center is sufficient to allow the center to monitor and evaluate the physician's professional performance, judgment and clinical skills..." The bylaws failed to establish a specific assessment process including the criteria and frequency for conducting the periodic evaluation of each medical staff applicant or candidate</p>	O 122	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that ongoing professional peer evaluation is included in the credentialing process for reappointments. Documentation of that evaluation will be maintained for each member of the medical staff. To monitor on-going compliance the attached peer evaluation worksheet will be included in the reappointment process and maintained in each member's file. Professional peer evaluation worksheet attached as Exhibit 3.</p>	03/24/2015

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	<p>for reappointment.</p> <p>2. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide evidence of ongoing professional peer evaluation (OPPE) with the credential files for MD02, MD11, MD12, MD13, MD14, MD15, MD16, MD17, MD18 and MD19 and no OPPE documentation was provided prior to exit.</p> <p>3. During an interview on 2-04-15 at 0900 hours, the governing board president MD01 confirmed that the medical staff bylaws lacked an assessment process with specified intervals for evaluating each medical provider including the scope and frequency of procedures, the appropriateness of a diagnosis related to a standard of care, and a clinical performance evaluation based in part on the outcome of the surgical intervention.</p> <p>4. During an interview on 2-03-15 at 1605 hours, the governing board president MD01 confirmed that the center lacks documentation of a physician performance review (OPPE) component for each credential file reviewed.</p>			

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Q 141 Bldg. 00	<p>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 nurse executive failed to ensure that nursing staff completed transfer forms, as per facility policy requirements, for 5 of 9 patients (Pts. #1, #2, #3, #13, and #20).</p> <p>Findings: 1. Review of the facility policy "Transfer of a Patient", policy number DT 10.00, with an approval and effective date of April 2012, indicated: a. In section "IV. Procedures", it reads: "...B. Complete the transfer paperwork/forms...1. The physician will need to complete the "Request to Transfer" form for all patient transfers...".</p> <p>2. Review of patient records indicated: a. Pt. #1 was transferred from the ASC (ambulatory surgery center) on 11/11/14 and lacked the transfer form required per facility policy.</p>	O 141	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that transfer forms are completed for all transfers as specified in Ball Outpatient Surgery Center policy Transfer of a Patient DT 10.00. The policy will be amended to state that "A transfer form is required for all patient's discharged to another facility require the completion of a transfer form. Patients discharged to home do not require completion of a transfer form." This policy requirement will be communicated to all staff and monitored via medical record reviews to ensure 100% compliance. Revised Transfer Policy attached as Exhibit 4.</p>	03/20/2015

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	<p>b. Pt. #2 was transferred from the ASC on 9/30/14 and lacked the transfer form required per facility policy.</p> <p>c. Pt. #3 was transferred from the ASC on 9/11/14 and lacked the transfer form required per facility policy.</p> <p>d. Pt. #13 was transferred to another facility on 2/2/15 and lacked the transfer form required per facility policy.</p> <p>e. Pt. #20 was transferred to another facility on 12/18/14 and lacked the transfer form required per facility policy.</p> <p>3. At 9:15 AM on 2/4/15, review of on line medical records with staff members #55 and #56, RN (registered nurse) informatics coordinators, indicated:</p> <p>a. Transfer forms could not be found for patients #3, #13, and #20. (Patient charts #1 and #2 were paper documents printed out by the medical records staff for review.)</p> <p>4. At 1:40 PM on 2/4/15, interview with staff member #50, the clinical nurse manager, indicated:</p> <p>a. After further review of the on line medical record for patients #1 and #2, no transfer form could be found for the patients, as required to be completed by nursing staff at the time of transfer.</p> <p>b. Pt. #13 was sent to the ED (emergency department) at the time of admission, so it was thought that a</p>			

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Q 162 Bldg. 00	<p>transfer form was not indicated. (The pre op nurse had documented the patient's arrival to the ASC.)</p> <p>5. At 9:35 AM on 2/4/15, interview with PACU (post anesthesia care unit) nurse #54, indicated:</p> <p>a. Some of the patients who were transferred had their surgery canceled due to complications noted in the pre op area.</p> <p>b. It was thought that if a case was canceled, and the surgery did not take place, a transfer form was not needed.</p> <p>416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:</p> <p>(1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia</p>			

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	<p>administration.</p> <p>(7) Documentation of properly executed informed patient consent.</p> <p>(8) Discharge diagnosis.</p> <p>Based on policy and procedure review, medical record review, and interview, the facility failed to ensure that medical records were legible and complete for 9 of 28 records reviewed (Pts. #1, #2, #5, #7, #8, #9, #10, #11, and #25).</p> <p>Findings:</p> <p>1. Review of the policy "Content of Medical Records", policy number CLR 6.00, with an effective date of July 2012, indicated:</p> <p>a. On page 3, in item C., it reads: "The following apply to all entries in the Medical Record: 1. All entries must be legible and complete,...".</p> <p>b. On page 7, in item 7. d., it reads: "A post-operative progress note must be present in the medical record immediately after surgery to provide pertinent information until the complete operative report is available...".</p> <p>2. Review of the policy "File No: NSP-152-P, with a revision date of 6/6/13 and titled "Indiana University Health Medical Staff", indicated: "I. GENERAL DOCUMENTATION STANDARDS A. The following practice standards define the MINIMUM expectations for documentation...C. All</p>	O 162	<p>Responsible: The Clinical Director is responsible to ensure that Ball Outpatient Surgery Center's Content of the Medical Record policy is followed. Corrective Action: Ball Outpatient Surgery Center Policy CLR 6.00 Content of the Medical Record requires that each medical record be complete and legible. CLR 6.00 also requires: 1. the presence of a post-operative progress note be present in the medical record until the complete report is available. 2. All medical record entries whether electronic or paper be dated, timed and signed. 3. Documentation of an advanced directive. The Ball Outpatient Surgery Center shall ensure that medical records are complete and accurate. This will be accomplished by: 1. assigning staff daily to review the days medical records, 2. performing internal medical record audits at periodic intervals and 3. employing the services of a contracted medical record consultant to perform medical record audits which will be shared with Ball Outpatient Surgery Center Employees and with the medical staff.</p>	03/20/2015

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	<p>medical record entries whether electronic or on paper must be legible, complete, dated, timed and signed with name and credentials...".</p> <p>3. Review of medical records indicated:</p> <p>a. Pt. #1 had:</p> <p>A. No documentation as to whether or not the patient had an advanced directive on the "Pre-op Phone Call Record", document number 11978.</p> <p>A. No brief operative note in either the paper chart, or the EMR (electronic medical record).</p> <p>B. No date and time of authentication of orders (document #10437).</p> <p>C. Illegible orders written on the order document form #10437.</p> <p>D. Illegible notation by the surgeon on the History and Physical.</p> <p>b. Pt. #2 had:</p> <p>A. No physician authentication, date, and time on the pre op orders on document #10447.</p> <p>B. No date and time with authentication of orders on the form #11895.</p> <p>C. Illegible notations by the surgeon on the document "Consent to Surgery/Procedure".</p> <p>c. Pt. #5 had the area crossed out where staff was to document whether or not the</p>			

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	<p>patient had an advanced directive on the "Pre-op Phone Call Record" form. (The information was also absent in the EMR in the "Pre-procedure checklist" section.)</p> <p>d. Pt. #7 lacked documentation on the "Pre-op Phone Call Record" as to whether or not the patient had an advanced directive.</p> <p>e. Pt. #8 lacked a date and time with the physician authentication of orders on the form #10414.</p> <p>f. Pt. #9 lacked a date and time with the physician authentication of orders on the form #11975, for the dosing of Acetaminophen.</p> <p>g. Pt. #10 lacked a date and time with the physician authentication of orders on the forms #10419 (2 forms), 10447, and 10437.</p> <p>h. Pt. #11 lacked a date and time with the physician authentication of orders on the forms #10419 and 11895.</p> <p>i. Pt. #25 lacked documentation on the form "Patient Transfer Note" as to the patient's "Condition on transfer".</p> <p>4. At 10:00 AM on 2/4/15, interview with staff member #55, a registered nurse</p>			

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Q 181 Bldg. 00	<p>and clinical informatics coordinator, indicated:</p> <p>a. Review of the paper charts and EMRs for the patients listed in 3. above, indicated lack of documentation and illegibility was acknowledged.</p> <p>5. At 1:40 PM on 2/4/15, interview with staff member #50, the clinical nurse manager, indicated:</p> <p>a. A re-review of paper charts and EMRs for the patients listed in 3. above indicated lack of documentation and illegibility was acknowledged.</p> <p>b. The policy listed in 2. above is a requirement for all physicians in an agreement with the local hospital, who also is a co-owner of the surgery center.</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 policy and procedure review, observation, and interview, the facility failed to ensure the implementation of its policy related to multi dose vials in one</p>	O 181	<p>Responsible: Clinical Director & Medical Director Corrective Action: Ball Outpatient Surgery Center policy PM 11.07 requires that when using multi-dose vials,</p>	03/20/2015

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	<p>anesthesia cart observed.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of the policy "Medication Use Policy, policy number PMM 11.07, with an effective date of July 2012, indicated: <ol style="list-style-type: none"> On page 4 under "Administration", in section D., it reads: "...When utilizing multi-dose vials, the vial with the unused portion must be dated to indicate expiration within 28 days." While on tour of operating room #1 at 2:05 PM on 2/2/15, in the company of staff member #50, the clinical nurse manager, it was observed in the anesthesia cart that one multi dose vial of Zofran 40 mg/20 ml and one multi dose vial of Neostigmine 10 mg/ml were opened, but not dated with a 28 day expiration date. Interview with two of the RNs (registered nurses) cleaning the surgery suite at 2:10 PM on 2/2/15 indicated they check the anesthesia care each day and throw away the multi dose vials that anesthesiologists fail to date when opened with the 28 day expiration date. At 2:10 PM on 2/2/15, interview with staff member #50 indicated that the destruction of opened multi dose vials, due the the lack of dating by anesthesia, 		<p>the vial with the unused portion must be dated to indicate expiration within 28 days. The clinical director and medical director will send notice to all staff and physicians of this requirement. On-going compliance will be monitored by routine monitoring of the clinical areas.</p>	

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Q 242 Bldg. 00	<p>is wasteful to the surgery center.</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, other document review, observation, and interview, the infection control committee failed to ensure an effective infection control program in relation to: physician response to the monthly request of patient post op infections; follow up to employee verbal self reporting history of Varicella; the hole observed in the wall outside operating room #5; and dusty blanket warmers in the restricted hallway outside operating room suites.</p> <p>Findings: 1. Review of the "Infection Prevention and Control Program", chapter 7 - Infection Prevention & Control", "policy number" IPC 7.02, with an effective date of April 2013, indicated: a. On page 4, in section "4) Reporting and Surveillance", it reads: "A. The</p>	O 242	<p>Responsible: Clinical Director, Infection Control Committee, Medical Staff, Board of Managers Corrective Action: To improve on the efficiency of the Ball Outpatient Surgery Center Infection Control Program the following actions will be taken.1.) The Ball Outpatient Surgery Center will make multiple attempts to follow-up with physicians who fail to respond to requests of possible infections for their surgery patients. The medical director will follow-up with physicians who do not respond to requests for gaining information regarding possible post op infections of surgery patients.2.) Ball Outpatient Surgery Center employees are leased from IU Health Ball Memorial Hospital. IU Health Ball Memorial Hospital currently has a plan in place to address changes in CDC requirements in regards to Varicella. The plan initially called</p>	03/20/2015			

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	<p>Infection Control Practitioner (ICP) will monitor and track infections...i. Physician Communication - The ICP or contracted designee will provide patient lists to each physician working in the ASC (ambulatory surgery center) monthly. The responsible physician is expected to confirm the details of any reported infection to the ICP...".</p> <p>2. Review of the ASC "...4th Quarter 2013 News Letter", sent from the physician board chair to all physicians, indicated:</p> <p>a. At the bottom of page one, the last paragraph reads: "Of interest, we are now sending E-mails to each surgeon for post-operative infection surveillance. Due to changes in hospital epidemiology staff, they are no longer able to include our outpatient cases with review of our inpatient cases. Please respond in a timely as fashion as possible to these E-mails!!!".</p> <p>3. Review of the physician response lists (for reporting patient infections from the list sent by the ASC department secretary on behalf of the ICP) indicated:</p> <p>a. 18 of 38 physicians failed to respond to the request for July and August 2014.</p> <p>b. 15 of 35 surgeons failed to respond to the request, with a total of 455 surgery patients, in September and October 2014.</p>		<p>for employees to be drawn over three years. 2015 is the final year of that plan and all employees leased to the Ball Outpatient Surgery Center will be completed by June 30, 2015.3.) It is the expectation of the Ball Outpatient Surgery Center that the physical plant be properly maintained. Repairs to the facility are performed at BOSC's request by the building landlord IU Health Ball Memorial Hospital. A work order was entered for the referenced wall penetration and succesfully completed by 03/03/2015.4.) Cleanliness is a key component of the Ball Outpatient Surgery Center Infection control plan. Accumulation of dust on the blanket warmers will be addressed by adding a date to the Cleaning/Expiration Log. Staff are reminded to monitor the dust level in their assigned areas and adjust cleaning schedules as needed. Ongoing compliance will be monitored during the facility walkthroughs performed by the EOC committee.</p>	

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	<p>(The July/August list did not include surgery totals/physician as the September/October list did.)</p> <p>c. 9 physicians failed to respond to both the July/August request and the September/October request.</p> <p>4. At 2:50 PM on 2/4/15, interview with staff member #63, the ASC department secretary, indicated:</p> <p>a. There is no follow up when physicians fail to respond to requests of possible infections for their surgery patients.</p> <p>5. At 2:55 PM on 2/4/15, interview with staff member #64, the ICP, indicated:</p> <p>a. There is no reporting to medical staff, or the infection control committee, regarding the percent of physicians reporting, or not responding, to a request regarding patient infections.</p> <p>b. There is no encouragement by the medical director, or board, in gaining information regarding possible post op infections of surgery patients.</p> <p>c. The ICP "mostly relies on the 30 day admits" to the local hospital, but may be missing patients who are given antibiotics for post op infections at follow up post op visits, and don't require a hospital admission.</p> <p>6. Review of the contracted/partial</p>			

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	<p>owner hospital policy "Immunizations", policy number "File No: EHS-7-P, with a revision date of 6/4/12, indicated:</p> <p>a. On page 3, it reads: "VARICELLA: All health care personnel should have documentation of two varicella (chickenpox) vaccines or a titer that shows immunity. Any health care personnel that is not immune and does not have a medical contraindication should receive the two doses 4 weeks apart. EHS (employee health services) can administer the vaccines...EHS is drawing blood on current employees to check for varicella immunity. This is a three year plan to get everyone completed...".</p> <p>7. Review of employee health files indicated:</p> <p>a. 1 of two MHTs (multi task technicians) had a self reported history of having had varicella as a child.</p> <p>b. 1 of 4 CSTs (certified surgical techs) had a self reported history of having had varicella as a child.</p> <p>8. Review the list of ASC staff indicating those who have unknown immunity to varicella, based on self reported history of disease at the time of hire, indicated that 29 of 59 employees are of unknown communicable disease status.</p>			

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	<p>9. At 3:40 PM on 2/3/15 and 9:00 AM on 2/4/15, interview with staff member #65, the employee health nurse (at the hospital), indicated:</p> <p>a. Per the hospital policy, employees with only verbal confirmation of varicella or non-immune status are required to wear a mask when caring for a patient in precautions for Varicella, or if exposed to varicella, they are to have a titer drawn.</p> <p>b. The current IC plan is ineffective as those who are non-immune, or of unknown immune status, may be exposed in the community, and not just when caring for a patient with varicella, which would be a rare occurrence in the ASC. And, the non-immune staff member could be incubating for 14 to 21 days and infecting other staff, patients, and/or their family members.</p> <p>c. The three year plan to draw titers is in effect at the hospital. The ASC will be the last to have titers drawn after all hospital employees have been drawn.</p> <p>10. While on tour of the surgery center, in the company of staff member #50, the clinical nurse manager, at 2:50 PM on 2/2/15, it was observed that:</p> <p>a. A hole was noted in the hallway wall, just above the handrail, across from OR (operating room) #5.</p> <p>b. The hole was noted to be at least 3</p>			

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	<p>inches long, 2 inches wide and 2 1/2 to 3 inches deep to the insulation.</p> <p>c. A work order, sent to the hospital, was dated 1/20/15 and taped to the handrail to alert staff that a request for repair had been made.</p> <p>11. At 3:00 PM on 2/2/15, interview with staff member #51, the facility administrator, indicated:</p> <p>a. No response was received from the plant operations staff at the host hospital/partial owner of the ASC, to report that they had received the work order.</p> <p>b. There has been no communication, regarding the work order, with the ASC.</p> <p>12. At 3:01 PM on 2/2/15, staff member #51 e-mailed plant operations (staff member #60) to ask what the progress was on "fixing this hole in the drywall". (e-mail provided) The responding e-mail was at 5:05 PM on 2/2/15 and stated "I will check with my team. Do you know when the original request was submitted?".</p> <p>13. At 12:55 PM on 2/3/15, interview with staff member #60, the director of plant operations at the hospital, indicated:</p> <p>a. He had received an e-mail from staff member #51 on 2/2/15 notifying their department regarding the hole and asking</p>			

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	<p>what the status of progress in fixing it was, as surveyors were interested in knowing the status of repair.</p> <p>b. This staff member had "just begun to address the issue this AM" and that their staff "prioritizes work orders", but that this staff member, nor their supervisor, had ever seen this work order.</p> <p>c. Since the hole is in the restricted corridor outside OR #5, it presents an infection control issue as it cannot be cleaned/disinfected appropriately.</p> <p>14. Review of the policy and procedure "Blanket and Fluid Warmers", policy number PSF 10.19, with an approval and effective date of April 2013, indicated:</p> <p>a. On page 2 under "VI. Procedures A. Warming Cabinets Used for Blankets Only...2. Cleaning: to reduce the spread of infectious agents, the interior of the warmer will be wiped down by staff members monthly and when visibly soiled...C. Warming Cabinets Used for Blankets and Fluids Simultaneously...2. Cleaning: to reduce the spread of infectious agents, the interior of the Warmer will be wiped down by staff members monthly and when visibly soiled...".</p> <p>15. At 2:30 PM on 2/2/15, while on tour of the restricted area back hallway outside the OR suites, it was observed</p>			

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Q 245 Bldg. 00	<p>that two blanket warmers had an accumulation of dust present between the bottom shelf (plenum) and base of the interior of the blanket warmers.</p> <p>16. Review of the January 2015 "Monthly Cleaning/Expiration Date Log", indicated the Blanket warmer was cleaned (and fluid dates checked) during that month by nursing staff. (No specific date of cleaning was noted, just nursing initials for the person who cleaned the warmers.)</p> <p>17. Interview with the clinical nurse manager, staff member #50, at 2:30 PM on 2/2/15, indicated:</p> <p>a. It is thought that perhaps the nursing staff was only wiping down the walls of the warmers and forgetting to clean the bottom shelf.</p> <p>b. If monthly cleaning of the warmers is not sufficient to reduce the dust build up, a bimonthly cleaning may need to take place.</p> <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</p>						

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	<p>improvement. Based on policy and procedure review, document review, observation and interview, the facility failed to: ensure that environmental services staff provided cleanliness to guard against the transmission of disease in four areas toured; failed to ensure that the contracted environmental services staff follow cleaning processes and policies; failed to establish a policy regarding compliance with the State's reportable disease requirements; and failed to update their TB (tuberculosis) policy when it was determined they were a low risk facility, and failed to provide a 2 step TB test for 1 of 3 staff newly hired in 2014 (Staff member N3).</p> <p>Findings: 1. Review of the policy "Bloodborne Pathogens Exposure Control Plan", policy number IPC 7.10, with an effective date of July 2012, indicated: a. On page 8, in section "11. Housekeeping", it reads: "a. All work areas shall be maintained in a clean and sanitary condition...d. Follow manufacturer recommendations for environmental surface and equipment disinfection...".</p> <p>2. Review of the policy "Environmental Cleaning of Surgical Suites in</p>	O 245	<p>Responsible: The Clinical Director Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policy for Environmental Cleaning of the Surgical Suites is followed. This includes orientation and initial education, training, instruction and competency validation for the cleaning and disinfection of the surgery center. The Special Medical Cleaning Manual revised to remove language referring to micro fiber flat mops. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. On-going compliance will be monitored via the maintenance of an up to date file for each contracted housekeeping employee. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff. Job description, competency/skills checklist, Specialized Medical Cleaning Manual, and listing of job duties are attached as Exhibit 1.</p>	03/20/2015	

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	<p>Perioperative Settings", policy number IPC 7.18, with an effective date of July 2012, indicated:</p> <p>a. Under "I. Purpose", it reads: "To establish and reestablish safe, clean environment after each surgical and invasive procedure and to provide guidance for the environmental cleaning and disinfection in the peri-operative setting. Application of these practices should result in a clean environment for patients and minimize the exposure risk of health care personnel and patients to potentially infectious microorganisms."</p> <p>3. At 1:55 PM on 2/2/15, it was observed in the women's locker room that an accumulation of dust was present on the top of women's lockers.</p> <p>4. At 2:40 PM on 2/2/15, while on tour of the surgery center in the company of staff member #50, the clinical nurse manager, it was observed in the decontamination room that an accumulation of dust was on the ceiling air vent and a ceiling mounted speaker.</p> <p>5. Interview with staff member #50, the clinical nurse manager, at 2:40 PM on 2/2/15, indicated acknowledgement that there was:</p> <p>a. Dust on the tops of the women's lockers.</p>			

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	<p>b A large accumulation of dust on the air vent and speaker in the ceiling of the decontamination room indicating these were not cleaned as expected by environmental cleaning staff.</p> <p>6. At 2:45 PM on 2/2/15, while on tour of the surgery center in the company of staff member #50, the clinical nurse manager, it was observed that the "Laser Sonics #7113" machine and the "Breast Analyzer" machine had accumulations of dust on the side edges and lower edges of the machines.</p> <p>7. Interview with staff member #50, the clinical nurse manager, on 2/2/15 at 2:45 PM, indicated agreement that the two machines (listed in 6. above) were not cleaned/disinfected appropriately, to reduce the possible transmission of disease, or that may cause infection.</p> <p>8. At 2:10 PM on 2/3/15, while observing a patient in pre op, it was observed that the tops of the suction canisters in pre op bays #2, #3, and #4 had dust on the tops of the canisters.</p> <p>9. At 3:30 PM on 2/3/15, while observing a patient in the PACU (post anesthesia care unit), it was observed that the top of the code cart was dusty and with debris, especially behind the</p>			

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	<p>defibrillator.</p> <p>10. Review of the EVS (environmental services) housekeeping processes binder, from the housekeeping closet in the surgery suite area of the ASC, indicated:</p> <p>a. On the page "Cleaning Methods for Sterile Areas", it reads: "...Micro fiber flat mops and cleaning cloths are used for cleaning all surfaces..One mop head and three (3) cleaning cloths are used for each operating room...".</p> <p>b. On the page titled; "Operating Room-Equipment, Tools, Products, and Supplies", it reads: "Supplies Micro fiber cloths Tools Micro fiber flat mop head...".</p> <p>c. On the page titled: "Sterile Hallways", it reads: "Procedures: 1. Using a micro fiber flat mop, wipe down all walls and ceiling surfaces...".</p> <p>11. Review of the policy "Environmental Cleaning of Surgical Suites in Perioperative Settings", policy number IPC 7.18, with an effective date of July 2012, indicated:</p> <p>a. On page 4, under "AFTERCARE", it reads: "...Wet Vac Care Titan Wet Vac: This Wet Vac can only hold 8 gallons...At the end of the day after all rooms have been terminally cleaned, the (Titan) Wet Vac will need to be decontaminated. Follow these steps:</p>			

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	<p>Vacuum up 1 gallon of clean water to rinse debris from the hose, then vacuum up a gallon of Wexcide water and dump. Vacuum up 1 more gallon of clean water to rinse the hose and canister then dump...".</p> <p>12. At 2:15 PM on 2/2/15, interview with staff member #59, an EVS employee, indicated:</p> <ul style="list-style-type: none"> a. String head mops are utilized at the facility, and occasionally micro fiber mop heads. b. The string head mops are used for two rooms before changing out for a clean one. c. The end of day cleaning of the Wet Vac includes emptying the dirty water and wiping the machine out with a cloth which contains Wexcide cleaner. <p>13. Interview with staff member #64, the ICP, at 2:55 PM on 2/4/15, indicated:</p> <ul style="list-style-type: none"> a. EVS is not currently following ASC policies for cleaning the facility by not solely using fiber head mops, not using the fiber head mop heads as one per OR, then changing out, and improper daily cleaning of the Wet Vac. b. There is no facility/infection control policy regarding the State's reportable disease requirements. <p>14. Review of the policy "Tuberculosis</p>			

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NAME OF PROVIDER OR SUPPLIER BALL OUTPATIENT SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 2401 W UNIVERSITY AVE STE 200 OMP MUNCIE, IN 47303
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	<p>(TB) Surveillance Testing", policy number CR 2.11, with an effective date of April 2012, indicated:</p> <p>a. Under "I. Purpose", it reads: "Annual TB surveillance is required for individuals working in the Ambulatory Surgery Center (ASC) who have direct patient contact."</p> <p>b. Under "II. Scope", it reads: "This policy applies to all Ambulatory Surgery Center (ASC) staff, health care professionals and patients."</p> <p>15. Review of employee health files indicated:</p> <p>a. Staff member N1 was a CST (certified surgical tech) hired in 2009 who had no TB test done in 2014.</p> <p>b. Staff member N3 was a CST who was a new hire on 8/10/14 and lacked documentation of a two step TB test.</p> <p>c. Staff member N7 was a RN (registered nurse) hired in 2007 who had no TB test done in 2014.</p> <p>d. Staff member N9 was a LPN (licensed practical nurse) hired in 2000 who had no TB test done in 2014.</p> <p>e. Staff member N13 was a MTA (multi task assistant) hired in 2011 who had no TB test done in 2014.</p> <p>16. At 4:00 PM on 2/3/15, interview with staff member #65, the employee health nurse, and #51, the facility</p>			

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S 000 Bldg. 00	<p>administrator, indicated:</p> <ul style="list-style-type: none"> a. A TB risk assessment was agreed upon in June/July of 2014 indicating that the facility is "low risk" and that annual TB testing will not be done. b. Current policy still addresses completing annual TB testing c. The policy does not indicate that 2 step TB testing will be required at the time of hire, but that is the standard of practice at the facility. d. It was agreed that staff member N3 was not given a 2 step TB test at the time of hire, as required. <p>The visit was for a licensure survey</p> <p>Facility Number: 012159</p> <p>Survey Date: 2-2/4-15</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p>	S 000		
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S 106 Bldg. 00	<p>QA: claughlin 02/18/15</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Review the bylaws at least triennially.</p> <p>Based on document review and interview, the governing body failed to review its bylaws within the past three years.</p> <p>Findings:</p> <p>1. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide documentation indicating a recent review of the governing board bylaws by the governing body and none was provided prior to exit.</p> <p>2. The First Amended and Restated Operating Agreement (approved 10-01-09) failed to indicate a requirement for reviewing the governing board bylaws at least triennially and failed to indicate</p>	S 106	<p>Responsible: The Clinical Director is required to ensure that the governing body approves it bylaws every three years. Corrective Action: The Clinical Director will circulate a board action to re-approve the Ball Outpatient Surgery Center Operating Agreement. Continuous monitoring of document approval for the Operating Agreement and other required documents will be tracked by the Clinical Director.</p>	03/20/2015

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S 153 Bldg. 00	<p>documentation of review within the past three years.</p> <p>3. No governing board meeting documentation for 2012, 2013 and 2014 indicated that the governing board bylaws had been reviewed.</p> <p>4. During an interview on 2-04-15 at 1430 hours, clinical director A1 confirmed that no documentation indicating a review of the governing board bylaws was available.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on document review and interview, the center failed to develop and maintain documentation of orientation for personnel providing housekeeping services (EVS) in the restricted surgical environment for two contracted EVS personnel.</p>	S 153	<p>Responsible: The Clinical Director</p> <p>Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policy for Environmental Cleaning of the Surgical Suites is followed. This includes orientation and initial education, training, instruction and competency validation for the</p>	03/20/2015

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	<p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Environmental Cleaning of Surgical Suites in the Perioperative Setting (approved 4-12) indicated the following: " Personnel cleaning peri-operative areas are to receive initial education, training, instruction and competency validation for cleaning and disinfection of the peri-operative areas. " 2. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide personnel files including documentation of orientation for two contracted EVS personnel and none were provided prior to exit. 3. During an interview on 2-03-15 at 1555 hours, the offsite property manager A10 for the host hospital confirmed that no personnel files including documentation of orientation had been prepared for the contracted EVS personnel HK22 and HK23 currently providing housekeeping services in the restricted surgical areas of the surgery center. 4. During an interview on 2-04-15 at 1310 hours, the clinical nurse manager A2 confirmed that no documentation of staff orientation and training was 		<p>cleaning and disinfection of the surgery center. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. On-going compliance will be monitored via the maintenance of an up to date file for each contracted housekeeping employee. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff. Job description, competency/skills checklist, Specialized Medical Cleaning Manual, and listing of job duties are attached as Exhibit 1.</p>				

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S 156 Bldg. 00	<p>available for the EVS personnel HK22 and HK23 working at the center since 12-22-14.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on document review and interview, the center failed to establish and maintain a job description for contract personnel providing housekeeping services (EVS) in the restricted surgical environment for 2 personnel.</p> <p>Findings:</p> <p>1. During an interview on 2-02-14 at 0930 hours, the clinical director A1 was requested to provide personnel files</p>	S 156	<p>Responsible: The Clinical Director Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policy for Environmental Cleaning of the Surgical Suites is followed. This includes orientation and initial education, training, instruction and competency validation for the cleaning and disinfection of the peri-operative areas. On-going compliance with these requirements shall be monitored by the maintenance of a job description and up to date file for</p>	03/20/2015

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S 172 Bldg. 00	<p>including job descriptions for two contracted EVS personnel and none were provided prior to exit.</p> <p>2. The policy/procedure manual table of contents failed to indicate a job description for EVS personnel.</p> <p>3. During an interview on 2-03-15 at 1555 hours, the offsite property manager A10 confirmed that no personnel files including a center job description had been prepared for the contracted EVS personnel HK22 and HK23 currently providing housekeeping services in the restricted surgical areas of the surgery center.</p> <p>4. During an interview on 2-04-15 at 1310 hours, the clinical nurse manager A2 confirmed that the center failed to develop a job description for the EVS personnel HK22 and HK23 working at the center since 12-22-14.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p>				<p>each contracted housekeeping employee. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. Job description, competency/skills checklist, Specialized Medical Cleaning Manual, and listing of job duties are attached as Exhibit 1.</p>		

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	<p>(L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.</p> <p>Based on policy and procedure review, employee health file review, and interview, the facility failed to update their TB (tuberculosis) policy when it was determined they were a low risk facility, and failed to provide a 2 step TB test for 1 of 3 staff newly hired in 2014 (Staff member N3).</p> <p>Findings:</p> <p>1. Review of the policy "Tuberculosis (TB) Surveillance Testing", policy number CR 2.11, with an effective date of April 2012, indicated:</p> <p>a. Under "I. Purpose", it reads: "Annual TB surveillance is required for individuals working in the Ambulatory Surgery Center (ASC) who have direct patient contact."</p> <p>b. Under "II. Scope", it reads: "This policy applies to all Ambulatory Surgery Center (ASC) staff, health care professionals and patients."</p> <p>2. Review of employee health files indicated:</p>	S 172	<p>Responsible: The Clinical Director Corrective Action: Ball Outpatient Surgery Center Policy CR 2.11 will be amended to state "TB surveillance is required for initial appointments to the Medical and Allied Health Staff at the Ambulatory Surgery Center." This policy will be approved by the governing body. The Ball Outpatient Surgery Center TB Exposure Control Plan will be amended to state "New employees and new contracted healthcare workers must have a two- step test before working in the center." Continous monitoring will occur through the new hire and credentialing process. Revised policies for Tb attached as Exhibit 5.</p>	03/20/2015

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	<p>a. Staff member N1 was a CST (certified surgical tech) hired in 2009 who had no TB test done in 2014.</p> <p>b. Staff member N3 was a CST who was a new hire on 8/10/14 and lacked documentation of a two step TB test.</p> <p>c Staff member N7 was a RN (registered nurse) hired in 2007 who had no TB test done in 2014.</p> <p>d. Staff member N9 was a LPN (licensed practical nurse) hired in 2000 who had no TB test done in 2014.</p> <p>e. Staff member N13 was a MTA (multi task assistant) hired in 2011 who had no TB test done in 2014.</p> <p>3. At 4:00 PM on 2/3/15, interview with staff member #65, the employee health nurse, and #51, the facility administrator, indicated:</p> <p>a. A TB risk assessment was agreed upon in June/July of 2014 indicating that the facility is "low risk" and that annual TB testing will not be done.</p> <p>b. Current policy still addresses completing annual TB testing</p> <p>c. The policy does not indicate that 2 step TB testing will be required at the time of hire, but that is the standard of practice at the facility.</p> <p>d. It was agreed that staff member N3 was not given a 2 step TB test at the time of hire, as required.</p>			

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S 176 Bldg. 00	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on document review, observation and interview, the center failed to follow its sanitation policy/procedures and document personnel training in the principles of infection control safety practices and effective housekeeping procedures in the restricted surgical environment for two contracted environmental services (EVS) personnel.</p> <p>Findings:</p> <p>1. The policy/procedure Environmental Cleaning of Surgical Suites in the Perioperative Setting (approved 4-12) indicated the following: "Personnel cleaning peri-operative areas are to receive initial education, training, instruction and competency validation for cleaning and disinfection of the</p>	S 176	<p>Responsible: The Clinical Director Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policy for Environmental Cleaning of the Surgical Suites is followed. This includes orientation and initial education, training, instruction and competency validation for the cleaning and disinfection of the surgery center. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. On-going compliance will be monitored via the maintenance of an up to date file for each contracted housekeeping employee. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff. Job description, competency/skills checklist, Specialized Medical</p>	03/20/2015

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S 226 Bldg. 00	<p>peri-operative areas."</p> <p>2. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide personnel files including documentation of training and competency for two contracted EVS personnel and none were provided prior to exit.</p> <p>3. During an interview on 2-03-15 at 1555 hours, the offsite property manager A10 for the host hospital confirmed that no personnel files including documentation of training and competency had been prepared for the contracted EVS personnel HK22 and HK23 currently providing housekeeping services in the restricted surgical areas of the surgery center.</p> <p>4. During an interview on 2-04-15 at 1310 hours, the clinical nurse manager A2 confirmed that no documentation of staff training and competency validation was available for the EVS personnel HK22 and HK23 working at the center since 12-22-14.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p>		Cleaning Manual, and listing of job duties are attached as Exhibit 1.		

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	<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 and interview, the center failed to maintain its list of all contracted services, including the scope and nature of services provided, for 12 services.</p> <p>Findings:</p> <p>1. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide a list of all contracted services including the provider name and scope of services provided and none was provided prior to exit.</p> <p>2. Quality Assessment and Improvement (QA) reports for the 3rd and 4th Quarter of 2014 failed to indicate a business name or alternative identifier associated with the current service provider for the following: biohazardous waste disposal CS1, biomedical engineering CS2, electrocardiogram service CS3, housekeeping service CS3, laboratory / pathology CS4, laundry service CS5, medical record consultant CS6 and CS7, pest control service CS8, pharmacy consultant CS9, radiation exposure</p>	S 226	<p>Responsible: The clinical director is responsible to evaluate and review all contracted services provided at the Ball Outpatient Surgery Center(BOSC). The results are to be provided to the BOSC quality/operations committee and board of managers. Corrective Action: The clinical director will ensure that all contracted services are evaluated and reviewed. A report detailing the monitoring and results will be provided to the BOSC Quality/Operations committee and Board of Managers. The monitoring will go into affect immediately. On-going compliance will be monitored via review of the minutes from the Quality/Operations team meetings and Board of Managers. BOSC Contracted Services Monitoring Tool attached as Exhibit 2 (red font shows services scored as "not monitored" being monitored on a regular basis; blue font shows services added for regular monitoring in the future).</p>	03/20/2015	

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S 230 Bldg. 00	<p>monitoring CS10, steam sterilizing provider CS11, and single-use medical device reprocessor CS12. The quarterly reports failed to indicate that the following services were being evaluated and reviewed: the electrocardiogram provider CS3, a medical record consultant CS7, a pest control provider CS8, a steam sterilizing provider CS11 and the single-use medical device reprocessor CS12.</p> <p>3. On 2-02-15 at 1635 hours, the clinical director A1 confirmed that the QA reports of contracted services failed to indicate a business name or alternative identifier associated with the majority of current service providers described above and confirmed that the reports failed to indicate the electrocardiogram provider CS3, the MR consultant CS7, the pest control provider CS8, the steam sterilizing provider CS11 and the single-use medical device reprocessor CS12.</p> <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</p>			

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	<p>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. Based upon document review and interview, the governing board failed to ensure a periodic review of the center was performed by a minimum of 3 physicians having no financial interest in the center.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws and Rules and Regulations (approved 1-13) indicated the following: "The duties of the Medical Advisory Board shall be: ...to establish a Utilization Review (UR) Committee ...the utilization review committee shall consist of at least three physicians, none of whom have a financial interest in the center ...the utilization review committee shall meet as often as is reasonably necessary, but not less than quarterly."</p> <p>2. UR documentation dated 10-09-14, 7-10-14, 4-10-14, 1-09-14 and 10-13-13 indicated that two physicians (MD20 and MD21) were conducting the periodic UR committee review of medical records.</p>	S 230	<p>Responsible: Clinical Director and Medical Director Corrective Action: As specified in the Medical Staff Bylaws the Ball Outpatient Surgery Center Utilization Review Committee will consist of a minimum of 3 physicians having no financial interest in the center. A new member will assigned to the committee to meet requirements before the next UR committee meeting. Ongoing compliance will be monitored by the Clinical Director and Medical Director and reflected in the committee minutes.</p>	03/24/2015

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S 310 Bldg. 00	<p>3. During an interview on 2-04-15 at 1500 hours, the clinical director A1 confirmed that the UR committee documentation indicated activity by only two physicians with no financial interest in the center.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor. Based on document review and interview, the center failed to ensure that all services were evaluated through its quality assessment and improvement (QA) program for 5 of 12 (CS3, CS7, CD8, CS11 and CS12) contracted services.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Improvement Plan (approved 8-11) failed to indicate a requirement for documenting and reporting the ongoing</p>			S 310	<p>Responsible: The clinical director is responsible to evaluate and review all contracted services provided at the Ball Outpatient Surgery Center(BOSC). The results are to be provided to the BOSC quality/operations committee and board of managers. Corrective Action: The clinical director will ensure that all contracted services are evaluated and reviewed. A report detailing the monitoring and results will be provided to the BOSC Quality/Operations committee and Board of Managers. The monitoring will go into affect</p>		03/20/2015

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S 328 Bldg. 00	<p>evaluation of all contracted services.</p> <p>2. Quality Assessment and Improvement (QA) reports for the 3rd and 4th Quarter of 2014 failed to indicate that the following services were currently being evaluated and reviewed: the electrocardiogram provider CS3, a medical record consultant CS7, a steam sterilizing provider CS11 or the single-use medical device reprocessor CS12.</p> <p>3. On 2-02-15 at 1635 hours, the clinical director A1 confirmed that the QA reports of contracted services failed to indicate that the hospital electrocardiogram provider CS3, MR consultant CS7, pest control provider CS8, hospital central sterilizing service CS11 or the single-use medical device reprocessor CS12 were being evaluated and reviewed.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(b)</p> <p>(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:</p>		<p>immediately. On-going compliance will be monitored via review of the minutes from the Quality/Operations team meetings and Board of Managers. BOSCC Contracted Services Monitoring Tool attached as Exhibit 2 (red font shows services scored as "not monitored" being monitored on a regular basis; blue font shows services added for regular monitoring in the future).</p>		

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	<p>(1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.</p> <p>Based on document review and interview, the center failed to document an action in response to opportunity for improvements through the Quality Assurance (QA) program.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Management / Improvement Program (approved 4-12) indicated the following: " ...the committee also reviews the results of numerous ongoing programs for monitoring various aspects of the operation that may impact on the quality of care including, but not limited to ...medical record review reports ... "</p> <p>2. The medical record consultant reports dated 12-11-14, 9-16-14, 6-09-14, 3-24-14 and 12-18-13 indicated several ongoing documentation concerns related to verbal orders for medications, history and physical exams, operative notes and final progress notes.</p> <p>3. The 2014 QA committee minutes dated 1-8-15, 10-09-14, 7-10-14 and 4-10-14 lacked documentation indicating the concerns identified by the medical</p>	S 328	<p>Responsible: Clinical Director Corrective Action: Concerns identified by the Ball Outpatient Surgery Center contracted medical record consultant and presented to the quality committee will be identified in the quality committee minutes along with an action plan for the center to improve on those deficiencies. On-going compliance will be monitored by the clinical director to ensure action is taken as a result of the reports provided by the Medical Record Consultant.</p>	03/20/2015

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S 404 Bldg. 00	<p>record consultant were presented and discussed and the minutes lacked documentation of a committee action or finding in response to the ongoing medical record documentation concerns.</p> <p>4. During an interview on 2-04-15 at 1515 hours, the clinical director A1 confirmed that no 2014 QA committee documentation indicated a response to the concerns reported by the medical record consultant.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(b)</p> <p>(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p> <p>Based on policy and procedure review, other document review, observation, and interview, the infection control committee failed to ensure an effective infection control program in relation to: physician response to the monthly request of patient post op infections; follow up to employee verbal self reporting history of Varicella; the hole observed in the wall</p>	S 404	<p>Responsible: Clinical Director, Infection Control Committee, Medical Staff, Board of Managers Corrective Action: To improve on the efficiency of the Ball Outpatient Surgery Center Infection Control Program the following actions will be taken.1.) The Ball Outpatient Surgery Center will make multiple attempts to follow-up with</p>	03/20/2015

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	<p>outside operating room #5; and dusty blanket warmers in the restricted hallway outside operating room suites.</p> <p>Findings:</p> <p>1. Review of the "Infection Prevention and Control Program", chapter 7 - Infection Prevention & Control", "policy number" IPC 7.02, with an effective date of April 2013, indicated:</p> <p>a. On page 4, in section "4) Reporting and Surveillance", it reads: "A. The Infection Control Practitioner (ICP) will monitor and track infections...i. Physician Communication - The ICP or contracted designee will provide patient lists to each physician working in the ASC (ambulatory surgery center) monthly. The responsible physician is expected to confirm the details of any reported infection to the ICP...".</p> <p>2. Review of the ASC "...4th Quarter 2013 News Letter", sent from the physician board chair to all physicians, indicated:</p> <p>a. At the bottom of page one, the last paragraph reads: "Of interest, we are now sending E-mails to each surgeon for post-operative infection surveillance. Due to changes in hospital epidemiology staff, they are no longer able to include our outpatient cases with review of our inpatient cases. Please respond in a</p>		<p>physicians who fail to respond to requests of possible infections for their surgery patients. The medical director will follow-up with physicians who do not respond to requests for gaining information regarding possible post op infections of surgery patients.2.) Ball Outpatient Surgery Center employees are leased from IU Health Ball Memorial Hospital. IU Health Ball Memorial Hospital currently has a plan in place to address changes in CDC requirements in regards to Varicella. The plan initially called for employees to be drawn over three years. 2015 is the final year of that plan and all employees leased to the Ball Outpatient Surgery Center will be completed by June 30, 2015.3.) It is the expectation of the Ball Outpatient Surgery Center that the physical plant be properly maintained. Repairs to the facility are performed at BOSC's request by the building landlord IU Health Ball Memorial Hospital. A work order was entered for the referenced wall penetration and successfully completed by 03/03/2015.4.) Cleanliness is a key component of the Ball Outpatient Surgery Center Infection control plan. Accumulation of dust on the blanket warmers will be addressed by adding a date to the Cleaning/Expiration Log. Staff are reminded to monitor the dust level in their assigned areas</p>				

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	<p>timely as fashion as possible to these E-mails!!!".</p> <p>3. Review of the physician response lists (for reporting patient infections from the list sent by the ASC department secretary on behalf of the ICP) indicated:</p> <ul style="list-style-type: none"> a. 18 of 38 physicians failed to respond to the request for July and August 2014. b. 15 of 35 surgeons failed to respond to the request, with a total of 455 surgery patients, in September and October 2014. (The July/August list did not include surgery totals/physician as the September/October list did.) c. 9 physicians failed to respond to both the July/August request and the September/October request. <p>4. At 2:50 PM and 3:05 PM on 2/4/15, interview with staff member #63, the ASC department secretary, indicated:</p> <ul style="list-style-type: none"> a. There is no follow up when physicians fail to respond to requests of possible infections for their surgery patients. b. The report, listing physicians who failed to respond to the request of possible patient infections post surgery, is provided to the infection control committee, but there is no follow up to encourage physicians to report. <p>5. At 2:55 PM on 2/4/15, interview with</p>		and adjust cleaning schedules as needed. Ongoing compliance will be monitored during the facility walkthroughs performed by the EOC committee.	

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	<p>staff member #64, the ICP, indicated:</p> <p>a. There is no encouragement by the medical director, or board, in gaining information regarding possible post op infections of surgery patients.</p> <p>b. The ICP "mostly relies on the 30 day admits" to the local hospital, but may be missing patients who are given antibiotics for post op infections at follow up post op visits, and don't require a hospital admission.</p> <p>6. Review of the contracted/partial owner hospital policy "Immunizations", policy number "File No: EHS-7-P, with a revision date of 6/4/12, indicated:</p> <p>a. On page 3, it reads: "VARICELLA: All health care personnel should have documentation of two varicella (chickenpox) vaccines or a titer that shows immunity. Any health care personnel that is not immune and does not have a medical contraindication should receive the two doses 4 weeks apart. EHS (employee health services) can administer the vaccines...EHS is drawing blood on current employees to check for varicella immunity. This is a three year plan to get everyone completed..."</p> <p>7. Review of employee health files indicated:</p> <p>a. 1 of two MHTs (multi task</p>			

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	<p>technicians) had a self reported history of having had varicella as a child.</p> <p>b. 1 of 4 CSTs (certified surgical techs) had a self reported history of having had varicella as a child.</p> <p>8. Review the list of ASC staff indicating those who have unknown immunity to varicella, based on self reported history of disease at the time of hire, indicated that 29 of 59 employees are of unknown communicable disease status.</p> <p>9. At 3:40 PM on 2/3/15 and 9:00 AM on 2/4/15, interview with staff member #65, the employee health nurse (at the hospital), indicated:</p> <p>a. Per the hospital policy, employees with only verbal confirmation of varicella or non-immune status are required to wear a mask when caring for a patient in precautions for Varicella, or if exposed to varicella, they are to have a titer drawn.</p> <p>b. The current IC plan is ineffective as those who are non-immune, or of unknown immune status, may be exposed in the community, and not just when caring for a patient with varicella, which would be a rare occurrence in the ASC. And, the non-immune staff member could be incubating for 14 to 21 days and infecting other staff, patients, and/or their family members.</p>			

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	<p>c. The three year plan to draw titers is in effect at the hospital. The ASC will be the last to have titers drawn after all hospital employees have been drawn.</p> <p>10. While on tour of the surgery center, in the company of staff member #50, the clinical nurse manager, at 2:50 PM on 2/2/15, it was observed that:</p> <p>a. A hole was noted in the hallway wall, just above the handrail, across from OR (operating room) #5.</p> <p>b. The hole was noted to be at least 3 inches long, 2 inches wide and 2 1/2 to 3 inches deep to the insulation.</p> <p>c. A work order, sent to the hospital, was dated 1/20/15 and taped to the handrail to alert staff that a request for repair had been made.</p> <p>11. Review of the 3rd and 4th quarter Quality review of Contracted Services for 2014, it was indicated that the hospital's maintenance department is "to respond to facility maintenance issues within 24 hours - Goal 100%, and emergency maintenance issues within 30 minutes...". This was listed as a "constant effort" in the 4th quarter evaluation.</p> <p>12. At 3:00 PM on 2/2/15, interview with staff member #51, the facility administrator, indicated:</p> <p>a. No response was received from the</p>			

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	<p>plant operations staff at the host hospital/partial owner of the ASC, to report that they had received the work order.</p> <p>b. There has been no communication, regarding the work order, with the ASC.</p> <p>c. The contracted hospital maintenance department is not meeting goals for response time to requests for repairs.</p> <p>13. At 3:01 PM on 2/2/15, staff member #51 e-mailed plant operations (staff member #60) to ask what the progress was on "fixing this hole in the drywall". (e-mail provided) The responding e-mail was at 5:05 PM on 2/2/15 and stated "I will check with my team. Do you know when the original request was submitted?".</p> <p>14. At 12:55 PM on 2/3/15, interview with staff member #60, the director of plant operations at the hospital, indicated:</p> <p>a. He had received an e-mail from staff member #51 on 2/2/15 notifying their department regarding the hole and asking what the status of progress in fixing it was, as surveyors were interested in knowing the status of repair.</p> <p>b. This staff member had "just begun to address the issue this AM" and that their staff "prioritizes work orders", but that this staff member, nor their supervisor, had ever seen this work order.</p>			

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	<p>c. Since the hole is in the restricted corridor outside OR #5, it presents an infection control issue as it cannot be cleaned/disinfected appropriately.</p> <p>15. Review of the policy and procedure "Blanket and Fluid Warmers", policy number PSF 10.19, with an approval and effective date of April 2013, indicated:</p> <p>a. On page 2 under "VI. Procedures A. Warming Cabinets Used for Blankets Only...2. Cleaning: to reduce the spread of infectious agents, the interior of the warmer will be wiped down by staff members monthly and when visibly soiled...C. Warming Cabinets Used for Blankets and Fluids Simultaneously...2. Cleaning: to reduce the spread of infectious agents, the interior of the Warmer will be wiped down by staff members monthly and when visibly soiled...".</p> <p>16. At 2:30 PM on 2/2/15, while on tour of the restricted area back hallway outside the OR suites, it was observed that two blanket warmers had an accumulation of dust present between the bottom shelf (plenum) and base of the interior of the blanket warmers.</p> <p>17. Review of the January 2015 "Monthly Cleaning/Expiration Date Log", indicated the Blanket warmer was</p>			

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S 640 Bldg. 00	<p>cleaned (and fluid dates checked) during that month by nursing staff. (No specific date of cleaning was noted, just nursing initials for the person who cleaned the warmers.)</p> <p>18. Interview with the clinical nurse manager, staff member #50, at 2:30 PM on 2/2/15, indicated:</p> <p>a. It is thought that perhaps the nursing staff was only wiping down the walls of the warmers and forgetting to clean the bottom shelf.</p> <p>b. If monthly cleaning of the warmers is not sufficient to reduce the dust build up, a bimonthly cleaning may need to take place.</p> <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete. Based on policy and procedure review, medical record review, and interview, the facility failed to ensure that medical records were legible and complete for 9 of 28 records reviewed (Pts. #1, #2, #5, #7, #8, #9, #10, #11, and #25).</p>	S 640	<p>Responsible: The Clinical Director is responsible to ensure that Ball Outpatient Surgery Center's Content of the Medical Record policy is followed. Corrective Action: Ball Outpatient Surgery Center Policy CLR 6.00 Content of the Medical Record requires that each</p>	03/20/2015	

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	<p>Findings:</p> <p>1. Review of the policy "Content of Medical Records", policy number CLR 6.00, with an effective date of July 2012, indicated:</p> <p>a. On page 3, in item C., it reads: "The following apply to all entries in the Medical Record: 1. All entries must be legible and complete,...".</p> <p>b. On page 7, in item 7. d., it reads: "A post-operative progress note must be present in the medical record immediately after surgery to provide pertinent information until the complete operative report is available...".</p> <p>2. Review of the policy "File No: NSP-152-P, with a revision date of 6/6/13 and titled "Indiana University Health Medical Staff", indicated: "I. GENERAL DOCUMENTATION STANDARDS A. The following practice standards define the MINIMUM expectations for documentation...C. All medical record entries whether electronic or on paper must be legible, complete, dated, timed and signed with name and credentials...".</p> <p>3. Review of medical records indicated:</p> <p>a. Pt. #1 had:</p> <p>A. No documentation as to whether or not the patient had an advanced directive on the "Pre-op Phone Call Record",</p>		<p>medical record be complete and legible. CLR 6.00 also requires: 1. the presence of a post-operative progress note be present in the medical record until the complete report is available. 2. All medical record entries whether electronic or paper be dated, timed and signed. 3. Documentation of an advanced directive. The Ball Outpatient Surgery Center shall ensure that medical records are complete and accurate. This will be accomplished by: 1. assigning staff daily to review the days medical records, 2. performing internal medical record audits at periodic intervals and 3. employing the services of a contracted medical record consultant to perform medical record audits which will be shared with Ball Outpatient Surgery Center Employees and with the medical staff.</p>				

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	<p>document number 11978.</p> <p>A. No brief operative note in either the paper chart, or the EMR (electronic medical record).</p> <p>B. No date and time of authentication of orders (document #10437).</p> <p>C. Illegible orders written on the order document form #10437.</p> <p>D. Illegible notation by the surgeon on the History and Physical.</p> <p>b. Pt. #2 had:</p> <p>A. No physician authentication, date, and time on the pre op orders on document #10447.</p> <p>B. No date and time with authentication of orders on the form #11895.</p> <p>C. Illegible notations by the surgeon on the document "Consent to Surgery/Procedure".</p> <p>c. Pt. #5 had the area crossed out where staff was to document whether or not the patient had an advanced directive on the "Pre-op Phone Call Record" form. (The information was also absent in the EMR in the "Pre-procedure checklist" section.)</p> <p>d. Pt. #7 lacked documentation on the "Pre-op Phone Call Record" as to whether or not the patient had an advanced directive.</p>			

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	<p>e. Pt. #8 lacked a date and time with the physician authentication of orders on the form #10414.</p> <p>f. Pt. #9 lacked a date and time with the physician authentication of orders on the form #11975, for the dosing of Acetaminophen.</p> <p>g. Pt. #10 lacked a date and time with the physician authentication of orders on the forms #10419 (2 forms), 10447, and 10437.</p> <p>h. Pt. #11 lacked a date and time with the physician authentication of orders on the forms #10419 and 11895.</p> <p>i. Pt. #25 lacked documentation on the form "Patient Transfer Note" as to the patient's "Condition on transfer".</p> <p>4. At 10:00 AM on 2/4/15, interview with staff member #55, a registered nurse and clinical informatics coordinator, indicated:</p> <p>a. Review of the paper charts and EMRs, for the patients listed in 3. above, indicated lack of documentation and illegibility was acknowledged.</p> <p>5. At 1:40 PM on 2/4/15, interview with staff member #50, the clinical nurse manager, indicated:</p>			

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S 664 Bldg. 00	<p>a. A re-review of paper charts and EMRs for the patients listed in 3. above indicated lack of documentation and illegibility was acknowledged.</p> <p>b. The policy listed in 2. above is a requirement for all physicians in an agreement with the local hospital, who also is a co-owner of the surgery center.</p> <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(f)(9)</p> <p>All patient records must document and contain, at a minimum, the following:</p> <p>(9) A written or dictated report describing techniques, findings, and tissue removed or altered.</p> <p>Based on policy and procedure review, medical record review, and interview, the facility failed to ensure that operative notes were written, per specified time frames, for 1 of 2 patients (pt. #1) for surgeon #61, and 1 of 1 patient (pt. #10) for surgeon #62.</p>	S 664	<p>Responsible: The Clinical Director is responsible to ensure that Ball Outpatient Surgery Center's Content of the Medical Record policy is followed. Corrective Action: Ball Outpatient Surgery Center Policy CLR 6.00 Content of the Medical Record requires that each</p>	03/20/2015

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	<p>Findings:</p> <p>1. Review of the policy "Completion of Medical Records", policy number MS 2.03, with an amended date of July 2013, indicated:</p> <p>a. On page 2, under section "IV. Policy Statements", it reads: "...C. Operative reports shall be dictated within 48 hours following surgery. A post-operative progress note must be present in the medical record immediately after surgery to provide pertinent information until the complete operative report is available...".</p> <p>2. Review of the policy "Content of Medical Records", policy number CLR 6.00, with an effective date of July 2012, indicated:</p> <p>a. On page 7., in section "7. Operative/Procedure Reports", it reads: "a. Operative reports must be written or dictated immediately following any surgical or invasive procedure that is performed under general anesthesia...d. A post-operative progress note must be present in the medical record immediately after surgery to provide pertinent information until the complete operative report is available...".</p> <p>3. Review of medical records indicated:</p> <p>a. Pt. #1 had a urology procedure performed under general anesthesia, on</p>		<p>medical record be complete and legible. CLR 6.00 also requires: 1. the presence of a post-operative progress note be present in the medical record until the complete report is available. 2. All medical record entries whether electronic or paper be dated, timed and signed. 3. Documentation of an advanced directive. The Ball Outpatient Surgery Center shall ensure that medical records are complete and accurate. This will be accomplished by: 1. assigning staff daily to review the days medical records, 2. performing internal medical record audits at periodic intervals and 3. employing the services of a contracted medical record consultant to perform audits which will be shared with Ball Outpatient Surgery Center Employees and with the medical staff. Continuous monitoring of the content and legibility of the Ball Outpatient Surgery Center will occur through the above referenced audits.</p>	

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S 672 Bldg. 00	<p>11/11/14 by surgeon #60, had the post operative brief note documented, and had a dictated operative report dated 11/14/14.</p> <p>b. Pt. #10 had a urology procedure performed under general anesthesia, on 11/7/14 by surgeon #61, had the post operative brief note documented, and had a dictated operative report dated 11/12/14.</p> <p>4. At 1:45 PM on 2/4/15, interview with staff member #51, the facility administrator, indicated:</p> <p>a. Operative reports are to be dictated immediately after a surgery and not 3 days or 5 days after the procedure, as was done by surgeons #60 and #61 for patients #1 and #10.</p> <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, medical record review, and interview, the facility failed to ensure that transfer</p>	S 672	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that transfer forms are completed for</p>	03/20/2015

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	<p>forms were completed for 5 of 9 patients (Pts. #1, #2, #3, #13, and #20).</p> <p>Findings:</p> <p>1. Review of the facility policy "Transfer of a Patient", policy number DT 10.00, with an approval and effective date of April 2012, indicated:</p> <p>a. In section "IV. Procedures", it reads: "...B. Complete the transfer paperwork/forms...1. The physician will need to complete the "Request to Transfer" form for all patient transfers..."</p> <p>2. Review of patient records indicated:</p> <p>a. Pt. #1 was transferred from the ASC (ambulatory surgery center) on 11/11/14 and lacked the transfer form required per facility policy.</p> <p>b. Pt. #2 was transferred from the ASC on 9/30/14 and lacked the transfer form required per facility policy.</p> <p>c. Pt. #3 was transferred from the ASC on 9/11/14 and lacked the transfer form required per facility policy.</p> <p>d. Pt. #13 was transferred to another facility on 2/2/15 and lacked the transfer form required per facility policy.</p> <p>e. Pt. #20 was transferred to another facility on 12/18/14 and lacked the transfer form required per facility policy.</p> <p>3. At 9:15 AM on 2/4/15, review of on line medical records with staff members</p>		<p>all transfers as specified in Ball Outpatient Surgery Center policy Transfer of a Patient DT 10.00. The policy will be amended to state that "A transfer form is required for all patient's discharged to another facility require the completion of a transfer form. Patients discharged to home do not require completion of a transfer form." This policy requirement will be communicated to all staff and monitored via medical record reviews to ensure 100% compliance. Revised Transfer Policy attached as exhibit 4.</p>	

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	<p>#55 and #56, RN (registered nurse) informatics coordinators, indicated:</p> <p>a. Transfer forms could not be found for patients #3, #13, and #20. (Patient charts #1, and #2 were paper documents printed out by the medical records staff for review.)</p> <p>4. At 1:40 PM on 2/4/15, interview with staff member #50, the clinical nurse manager, indicated:</p> <p>a. After further review of the on line medical record for patients #1 and #2, no transfer form could be found for the patients, as required to be completed by nursing staff at the time of transfer.</p> <p>b. Pt. #13 was sent to the ED (emergency department) at the time of admission, so it was thought that a transfer form was not indicated. (The pre op nurse had documented the patient's arrival to the ASC.)</p> <p>5. At 9:35 AM on 2/4/15, interview with PACU (post anesthesia care unit) nurse #54, indicated:</p> <p>a. Some of the patients who were transferred had their surgery canceled due to complications noted in the pre op area.</p> <p>b. It was thought that if a case was canceled, and the surgery did not take place, a transfer form was not needed.</p>			

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S 704 Bldg. 00	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(1)</p> <p>The medical staff shall do the following:</p> <p>(1) Conduct outcome-oriented performance evaluations of its member at least biennially.</p> <p>Based on document review and interview, the governing body failed to assure that medical staff reappointment included a review of the candidate's surgical case history in accordance with its medical staff bylaws for 10 of 10 (MD02, MD11, MD12, MD13, MD14, MD15, MD16, MD17, MD18 and MD19) medical staff credential files reviewed.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 1-13) indicated the following: "No physician may become or remain a member of the active staff with clinical privileges unless his or her activity in the center is sufficient to allow the center to monitor and evaluate the physician's professional performance, judgment and clinical skills..." The bylaws failed to establish a specific assessment process including the criteria and frequency for</p>			S 704	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that ongoing professional peer evaluation is included in the credentialing process for reappointments. Documentation of that evaluation will be maintained for each member of the medical staff. To monitor on-going compliance the attached peer evaluation worksheet will be included in the reappointment process and maintained in each member's file. Professional peer evaluation worksheet attached as Exhibit 3.</p>		03/20/2015

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	<p>conducting the periodic evaluation of each medical staff applicant or candidate for reappointment.</p> <p>2. On 2-02-15 at 0930 hours, the clinical director A1 was requested to provide evidence of ongoing professional peer evaluation (OPPE) with the credential files for MD02, MD11, MD12, MD13, MD14, MD15, MD16, MD17, MD18 and MD19 and no OPPE documentation was provided prior to exit.</p> <p>3. During an interview on 2-04-15 at 0900 hours, the governing board president MD01 confirmed that the medical staff bylaws lacked an assessment process with specified intervals for evaluating each medical provider including the scope and frequency of procedures, the appropriateness of a diagnosis related to a standard of care, and a clinical performance evaluation based in part on the outcome of the surgical intervention.</p> <p>4. During an interview on 2-03-15 at 1605 hours, the governing board president MD01 confirmed that the center lacks documentation of a physician performance review (OPPE) component for each credential file reviewed.</p>			

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S 756 Bldg. 00	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(J)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(J) A requirement that each physician's services, , dentist's services, and podiatrist's services are to be reviewed and analyzed at specified intervals at regular meetings, including, but not limited to, the following:</p> <p>(i) Appropriateness of diagnoses and treatments rendered related to a standard of care and anticipated or expected results. (ii) Performance evaluation based on clinical performance indicated in part by the results or outcome of surgical intervention. (iii) Scope and frequency of procedures.</p> <p>Based on document review and interview, the governing body failed to assure that the medical staff bylaws included a provision for the periodic review of each medical staff provider's surgical case history .</p>	S 756	Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that ongoing professional peer evaluation is included in the credentialing process for reappointments. Documentation of that evaluation will be	03/20/2015

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S 010 Bldg. 00	<p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 1-13) indicated the following: "No physician may become or remain a member of the active staff with clinical privileges unless his or her activity in the center is sufficient to allow the center to monitor and evaluate the physician's professional performance, judgment and clinical skills ..." The bylaws failed to establish a specific assessment process including the criteria and frequency for conducting the periodic evaluation of each medical staff applicant or candidate for reappointment.</p> <p>2. During an interview on 2-04-15 at 0900 hours, the governing board president MD01 confirmed that the medical staff bylaws lacked an assessment process with specified intervals for evaluating each medical provider including the scope and frequency of procedures, the appropriateness of a diagnosis related to a standard of care, and a clinical performance evaluation based in part on the outcome of the surgical intervention.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p>		maintained for each member of the medical staff. To monitor on-going compliance the attached peer evaluation worksheet will be included in the reappointment process and maintained in each member's file. Professional peer evaluation worksheet attached as Exhibit 3.				

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	<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 interview, the facility failed to ensure the implementation of its policy related to multi dose vials in one anesthesia cart observed.</p> <p>Findings:</p> <p>1. Review of the policy "Medication Use Policy, policy number PMM 11.07, with an effective date of July 2012, indicated:</p> <p>a. On page 4 under "Administration", in section D., it reads: "...When utilizing multi-dose vials, the vial with the unused portion must be dated to indicate expiration within 28 days."</p> <p>2. While on tour of operating room #1 at 2:05 PM on 2/2/15, in the company of staff member #50, the clinical nurse manager, it was observed in the anesthesia cart that one multi dose vial of Zofran 40 mg/20 ml and one multi dose vial of Neostigmine 10 mg/ml were opened, but not dated with a 28 day</p>	S 010	<p>Responsible: Clinical Director & Medical Director</p> <p>Corrective Action: Ball Outpatient Surgery Center policy PM 11.07 requires that when using multi-dose vials, the vial with the unused portion must be dated to indicate expiration within 28 days. The clinical director and medical director will send notice to all staff and physicians of this requirement. On-going compliance will be monitored by routine monitoring of the clinical areas.</p>	03/20/2015

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NAME OF PROVIDER OR SUPPLIER BALL OUTPATIENT SURGERY CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 2401 W UNIVERSITY AVE STE 200 OMP MUNCIE, IN 47303			
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S 154 Bldg. 00	<p>expiration date.</p> <p>3. Interview with two of the RNs (registered nurses) cleaning the surgery suite at 2:10 PM on 2/2/15 indicated they check the anesthesia care each day and throw away the multi dose vials that anesthesiologists fail to date when opened with the 28 day expiration date.</p> <p>4. At 2:10 PM on 2/2/15, interview with staff member #50 indicated that the destruction of opened multi dose vials, due the the lack of dating by anesthesia, is wasteful to the surgery center.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(C)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(C) Operational and maintenance control records must be established and analyzed at least triennially.</p>						

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	<p>These records must be readily available on the premises. Based on document review and interview, the center failed to ensure that its operating rooms (OR) were maintained in accordance with national standards and that operational control records for OR ventilation were available if requested.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The American Institute of Architects (2001 edition) Guidelines for Design and Construction of Hospital and Health Care Facilities indicated the following: "Part 9.5L [Outpatient Surgery Centers] ... mechanical heating, ventilation, and air conditioning shall be as described for similar areas in Section 9.31 and Table 7.2 Table 7.2: Operating Room (OR) minimum total air exchanges per hour : 15." 2. The policy/procedure Environmental Controls in the Ambulatory Surgery Center (approved 4-12) indicated the following: "The ASC will maintain a minimum of 15 ACH (air changes per hour) in the operating room, of which a minimum of 3 ACH should be fresh air ... maintenance of the environmental systems in the ASC will be coordinated with facilities management." 3.. During an interview on 2-02-15 at 1200 hours, the director of facilities A8 	S 154	<p>Responsible: The Clinical Director Corrective Action: The Clinical Director shall ensure that facility standards are met and maintained at the Ball Outpatient Surgery Center. The Ball Outpatient Surgery Center contracts for facility support. The contracted service provider is required to maintain the physical plant to current standards. This includes maintenance of the minimum required air exchanges per hour and annual testing. This information shall be maintained by the clinical director and continuously monitored.</p>	03/24/2015

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S 174 Bldg. 00	<p>was requested to provide documentation indicating the OR air exchanges per hour for the 5 operating rooms at the center and none was provided prior to exit.</p> <p>4. During an interview on 2-03-15 at 1510 hours, the facilities manager A9 confirmed that no documentation of OR air exchange measurements was available.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(5)(A)</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>(5) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:</p> <p>(A) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:</p> <p>(i) Asepsis. (ii) Cross-contamination prevention. (iii) Safe practice.</p>			

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	<p>Based on policy and procedure review, document review, observation and interview, the facility failed to ensure that environmental services staff provided cleanliness to guard against the transmission of disease in four areas toured and in interview with the contracted environmental services staff.</p> <p>Findings:</p> <p>1. Review of the policy "Bloodborne Pathogens Exposure Control Plan", policy number IPC 7.10, with an effective date of July 2012, indicated:</p> <p>a. On page 8, in section "11. Housekeeping", it reads: "a. All work areas shall be maintained in a clean and sanitary condition...d. Follow manufacturer recommendations for environmental surface and equipment disinfection..."</p> <p>2. Review of the policy "Environmental Cleaning of Surgical Suites in Perioperative Settings", policy number IPC 7.18, with an effective date of July 2012, indicated:</p> <p>a. Under "I. Purpose", it reads: "To establish and reestablish safe, clean environment after each surgical and invasive procedure and to provide guidance for the environmental cleaning and disinfection in the peri-operative setting. Application of these practices</p>	S 174	<p>Responsible: The Clinical Director Corrective Action: The clinical director shall ensure that the Ball Outpatient Surgery Center Policies for Environmental Cleaning are followed. This includes orientation and initial education, training, instruction and competency validation for the cleaning and disinfection of the peri-operative areas. On-going compliance with these requirements shall be monitored via the maintenance of an up to date file for each contracted housekeeping employee. This file will include documentation of the required orientation, training and policy review. Orientation includes approved equipment, solutions and appropriate procedures. The clinical director will ensure that annual file reviews are performed for all existing contracted housekeeping staff to ensure compliance. New staff will be properly oriented before providing service to the Ball Outpatient Surgery Center. Job description, competency/skills checklist, Specialized Medical Cleaning Manual, and listing of job duties are attached as Exhibit 1.</p>	03/20/2015			

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	<p>should result in a clean environment for patients and minimize the exposure risk of health care personnel and patients to potentially infectious microorganisms."</p> <p>3. At 1:55 PM on 2/2/15, it was observed in the women's locker room that an accumulation of dust was present on the top of women's lockers.</p> <p>4. At 2:40 PM on 2/2/15, while on tour of the surgery center in the company of staff member #50, the clinical nurse manager, it was observed in the decontamination room that an accumulation of dust was on the ceiling air vent and a ceiling mounted speaker.</p> <p>5. Interview with staff member #50, the clinical nurse manager, at 2:40 PM on 2/2/15, indicated acknowledgement that there was:</p> <ul style="list-style-type: none"> a. Dust on the tops of the women's lockers. b. A large accumulation of dust on the air vent and speaker in the ceiling of the decontamination room indicating these were not cleaned as expected by environmental cleaning staff. <p>6. At 2:45 PM on 2/2/15, while on tour of the surgery center in the company of staff member #50, the clinical nurse manager, it was observed that the "Laser</p>			

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	<p>Sonics #7113" machine and the "Breast Analyzer" machine had accumulations of dust on the side edges and lower edges of the machines.</p> <p>7. Interview with staff member #50, the clinical nurse manager, on 2/2/15 at 2:45 PM, indicated agreement that the two machines (listed in 6. above) were not cleaned/disinfected appropriately, to reduce the possible transmission of disease, or that may cause infection.</p> <p>8. At 2:10 PM on 2/3/15, while observing a patient in pre op, it was observed that the tops of the suction canisters in pre op bays #2, #3, and #4 had dust on the tops of the canisters.</p> <p>9. At 3:30 PM on 2/3/15, while observing a patient in the PACU (post anesthesia care unit), it was observed that the top of the code cart was dusty and with debris, especially behind the defibrillator.</p> <p>10. Review of the EVS (environmental services) housekeeping processes binder, from the housekeeping closet in the surgery suite area of the ASC, indicated: a. On the page "Cleaning Methods for Sterile Areas", it reads: "...Micro fiber flat mops and cleaning cloths are used for cleaning all surfaces..One mop head and</p>			

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	<p>three (3) cleaning cloths are used for each operating room...".</p> <p>b. On the page titled; "Operating Room-Equipment, Tools, Products, and Supplies", it reads: "Supplies Micro fiber cloths Tools Micro fiber flat mop head...".</p> <p>c. On the page titled: "Sterile Hallways", it reads: "Procedures: 1. Using a micro fiber flat mop, wipe down all walls and ceiling surfaces...".</p> <p>11. Review of the policy "Environmental Cleaning of Surgical Suites in Perioperative Settings", policy number IPC 7.18, with an effective date of July 2012, indicated:</p> <p>a. On page 4, under "AFTERCARE", it reads: "...Wet Vac Care Titan Wet Vac: This Wet Vac can only hold 8 gallons...At the end of the day after all rooms have been terminally cleaned, the (Titan) Wet Vac will need to be decontaminated. Follow these steps: Vacuum up 1 gallon of clean water to rinse debris from the hose, then vacuum up a gallon of Wexcide water and dump. Vacuum up 1 more gallon of clean water to rinse the hose and canister then dump...".</p> <p>12. At 2:15 PM on 2/2/15, interview with staff member #59, an EVS employee, indicated:</p>			

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S 180 Bldg. 00	<p>a. String head mops are utilized at the facility, and occasionally micro fiber mop heads.</p> <p>b. The string head mops are used for two rooms before changing out for a clean one.</p> <p>c. The end of day cleaning of the Wet Vac includes emptying the dirty water and wiping the machine out with a cloth which contains Wexcide cleaner.</p> <p>13. Interview with staff member #64, the ICP, at 2:55 PM on 2/4/15, indicated:</p> <p>a. EVS is not currently following ASC policies for cleaning the facility by not solely using fiber head mops, not using the fiber head mop heads as one per OR, then changing out, and improper daily cleaning of the Wet Vac.</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 failed to ensure the</p>	S 180	Responsible: Clinical Director Corrective Action: The	03/20/2015

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	<p>safety management committee meetings included representatives from administration and patient care services.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Management of the Environment of Care (approved 4-12) failed to indicate a requirement for an administrative representative to attend and participate with the review of safety functions by the committee. 2. Safety Committee/Environment of Care (EOC) meeting minutes dated 12-10-14, 8-28-14, 6-19-14, 5-22-14, and 2-19-14 failed to indicate that an administrative representative had attended the EOC meetings. 3. During an interview on 2-03-15 at 1040 hours, the safety officer A4 confirmed that an administrative representative did not attend the EOC meetings in 2014. 		<p>clinical director will ensure that a member of Admistration is present during Safety/Security/Environment of Care Meetings. The Clinical Director will continously monitor compliance by reviewing the meeting minutes to ensure participation.</p>	