A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
The facility failed to ensure a physician examine 5 of 22 patients, immediately before surgery to assess for any changes in the patient's condition that could lend to a potential risk for the patient from use of anesthesia during the surgery.

Findings include:
- Review of facility policy entitled "ANESTHESIA EVALUATION AND ASSESSMENT" revealed: "...Patients will be seen and evaluated for their fitness for anesthesia by the anesthesiologist at least once during the pre-operative stage...the heart and lungs will be auscultated during this pre-operative assessment..."

Observation on 04/27/2015 of Patient # 8 in the pre-operative area and procedure room, revealed that the CRNA (Medical Staff # 3) did not assess the heart and lungs of the patient immediately before surgery.
Q082 – Program Data: Program Activities

• (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

• (b)(2) The ASC must use the data collected to -
  – (i) Monitor the effectiveness and safety of its services, and quality of its care.
  – (ii) Identify opportunities that could lead to improvements and changes in its patient care.

Q082 – Program Data: Program Activities

• (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

• (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

Q082 – Program Data; Program Activities

• The ASC failed to ensure the causes of adverse patient events were examined and documented and improvements were implemented in order to prevent future events.

• This affected the care of 1 of 6 patients (#16) who had cataract surgery with lens implants whose records were reviewed.

• It had the potential to affect all patients who had surgery with lens implants. The failure to examine the causes of the event and implement improvements increased the likelihood that other patients receiving lens implants could suffer an adverse event.
Q082 – Program Data: Program Activities

- Findings include:

- Patient #16 was an 81 year old male who had cataract extraction with lens implant of his right eye on 6/10/15. The medical record did not indicate any problems or complications during the procedure.

Q082 – Program Data: Program Activities

- An incident report, dated 6/11/15 at 11:50 AM, stated the surgeon called on that date and reported the incorrect lens was implanted into Patient #16’s right eye.

- The incident report stated “lens calculation 23.0 inserted was 20.0.” The report stated “immediate staff meeting held to discuss this incident, OR Procedure reviewed.”

Q104 – Safety from Fire

- 416.44(b) Hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors and the area is provided with an automatic sprinkler system. High hazard areas are provided with both fire barriers and sprinkler systems 38.3.2, 39.3.2
Q104 – Safety from Fire

- Fire drills are held at unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. 20.7.1.2, 21.7.1.2

Q104 – Safety From Fire

- Based on record review and interview it was determined that the facility failed to sound the fire alarm system during a fire drill.
- NFPA 101, Life Safety Code, 2000 edition, Chapter 21, Section 21.7.1.2 "Fire drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with the signals and emergency action required under varied conditions. When drills are conducted between 9:00 p.m. and 6:00 a.m., a coded announcement shall be permitted to be used instead of audible alarms."

Q104 – Safety from Fire

- Findings Include:
  - On April 28, 2015, the surveyor accompanied by the Administrator and Nursing Staff, reviewed the fire drill records.
  - Fire drills were held one per quarter per shift, but the fire drill held on January 8, 2015 indicated no activation of the fire alarm system. The Nursing Staff stated that the fire alarm system was not activated on every drill.
Q104 – Safety from Fire

- Failing to test and sound the fire alarm system during staff training will not familiarize the staff with conditions under an actual fire.
- The lack of training and testing of the fire alarm will potentially cause harm to patients and staff.

- Generators are inspected weekly and exercised under load for 30 minutes per month in accordance with NFPA 99, 3.4.4.1, NFPA 110, 8.4.2

- Based on record review it was determined that the facility failed to document the time it took the emergency generator to switch from normal power to emergency power and run the emergency generator for 30 minutes during the monthly tests.
- NFPA 101 Life Safety Code, 2000, Chapter 21, Section 21.2.9.2 "Where general anesthesia or life-support equipment is used, each ambulatory health care facility shall be provided with an essential electrical system in accordance with NFPA 99 Standard for Health Care Facilities."
Q104 – Safety from Fire

NFPA 99, Chapter 3, Section 3-4.1.1.8 Load Pickup. "The generator set (s) shall have sufficient capacity to pick up the load and meet the minimum frequency and voltage stability requirements of the emergency system within 10 seconds after loss on normal power."

Chapter 3, Section 3.6.4.1(b) and Section 3-4.4.1.1(b) "Generator sets shall be tested twelve (12) times a year...Generator sets serving emergency and equipment systems shall be in accordance with NFPA 110. Chapter 6 Section 6-4.1 "level 1 and Level 2 EPSSs, including all appurtenant components shall be inspected weekly and shall be exercised under load at least monthly. Section 6-4.2 "Generator sets in Level 1 and Level 2 service shall be exercised at least once monthly, for a minimum of 30 minutes."

On April 28, 2015, the Surveyor accompanied by the Administrator and Nursing Staff reviewed the emergency generator monthly load tests. The documentation indicated that none of the twelve tests had the seconds it took the emergency generator to switch from normal to emergency power. It also indicated that the emergency generator did not run for 30 minutes during the monthly test.
Q104 – Safety from Fire

- Failing to check and document the time it took the generator to switch to emergency power and allow the generator to run for the required 30 minutes could harm the patients and staff in a power outage.

Q104 – Safety from Fire

- Emergency illumination is provided in accordance with section 7.9, 20.2.9.1, 21.2.9.1

Q104 – Safety from Fire

- Based on record review and interview with the Director of Nursing it was determined the facility failed to document the testing of two battery backup emergency lighting units in two operating rooms and maintain one of two battery back up emergency lights.
Q104 – Safety from Fire

- NFPA 101 Life Safety Code, 2000, Chapter 21, Section 21.2.9.1 "Emergency Lighting shall be provided in accordance with Section 7.9" Section 7.9.3 "A functional test shall be conducted on every required emergency lighting system at 30-day intervals for not less than 30 seconds."

- An annual test shall be conducted on every required battery-powered emergency lighting system for not less than 1 1/2 hours. Written records of visual inspections and tests shall be kept by the owner for inspection by the authority having jurisdiction...

- Findings include:
  - On May 15, 2015 the surveyor accompanied by the Director of Nursing was unable to find any written records indicating that testing was being done on the battery back up emergency lighting units Monthly tests for 30 seconds and Annually 90 minutes (1/1/2 hours) tests.
Q104 – Safety from Fire

- In addition, based on testing and observation, one of the two battery backup emergency lighting units in one of the two operating rooms did not light when tested three of three times.

Q162 – 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:

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 administration.
7. Documentation of properly executed informed patient consent.
8. Discharge diagnosis.

Q162 – Form and Content of Record

- The facility failed to maintain accurate, legible, and complete patient medical records.

- Findings include:
  - Review of medical records revealed the following:
    - 1) Anesthesia forms reviewed by surveyors for Patient #s 1, 6, 11, 12, and 21, had been pre-signed by two CRNAs (medical staff # 3 and # 4). Multiple copies of blank, pre-signed anesthesia forms were stored in the pre-op/post-op CRNA anesthesia cart. Surveyors were unable to determine by their signature which of the two CRNAs provided care to the above-mentioned patients.
Q162 – Form and Content of Record

- 2) The physician signature on the "Surgical Note" section of the "Physician Orders, Operation Record, and Surgical Safety Checklist" was dated by the RN.
- 3) Medical records contained over-writes of OR time, physician orders, time of eyedrops administration, oxygen administration vs room air, OR time, and vital signs.

- Records had the procedure date whited out and new date written in. None of these medical record changes were initialed or signed.
- Time in the recovery room was not noted.
- Surveyors requested to review facility medical records policies related to the above-mentioned documentation issues. No policies were provided for review.

Q181 – Administration of Drugs

- Drugs must be prepared and administered according to established policies and acceptable standards of practice.
Q181 – Administration of Drugs

The facility failed to discard expired or unlabeled medications and supplies, which lends to a risk of infection or injury for the patient if treated with potentially contaminated or expired medications and supplies.

Q181 – Administration of Drugs

Findings include:

• Facility policy, “Expired Drugs and Solutions,” includes: “...No expired drugs will be used in the facility. Each month a complete inventory of the pharmaceutical and solution stocks...will be performed to determine the presence of drugs and solutions expiring that month...Expired meds...are immediately removed from the facility....”

Q181 – Administration of Drugs

• Facility policy, “Multi-Dose Vial Policy and Procedure,” contains: “...Multi-dose vials will be discarded when empty, at the manufacturer's expiration date, if there is obvious or suspected contamination, at the recommendation of the manufacturer, or 28 days after opening, whichever occurs sooner....”
Q181 – Administration of Drugs

- Surveyors observed the following expired medications and supplies:
  - 1. In the Pre-op/Post-op area: one four-ounce eye wash, expired 2012/11; 17 tongue blades, expired 2013/06; 1 cotton-tipped applicator, expired 2011/08; 2 tongue blades, expired 2013/09; and 2 tongue blades, expired 2012/10.

Q181 – Administration of Drugs

- 2. In the Operative Corridor Code Cart: Three (3) 20-gauge Jelco IV catheters, expired 2014/10; two (2) 22-gauge Jelco IV catheters, expired 2014/08; five (5) Smith and Nephew IV 3000 I-hand covers 2 3/8 inch x 2 3/4 inch, expired 2014/11; and one 23-gauge Alcon infusion sleeve kit, expired 2014/10.

- 3. In the Pre-op Bay: One box Instagard PVF exam gloves, size large, expired 2014/07, and one vial of Tubersol Tuberculin Purified Protein Derivative, opened and not dated with either the date of opening or the date of expiration.

Q181 – Administration of Drugs

- 4. In the Pre-op Supply Room: One hundred (100) 2-inch by 3-inch Telfa pads, expired 2010/07; three Clear Cut slit knives, two (2.4 dual bevel) expired 2013/01 and one (2.75 angled) expired 2014/06; and thirty-four total ACRY Sol IQ Restor Multifocal Intraocular Lenses (IOL), twenty-five expired 2015/05, eight expired 2015/02, and one expired 2014/10.

- The DON also confirmed the expirations 04/27/2015, and further stated that the IOLs were awaiting return to the manufacturer, but that they had not been segregated from other supplies or labeled as such.
Q233 – Privacy and Safety

- [The patient has the right to - ]
- (3) Be free from all forms of abuse or harassment

Q241 – Sanitary Environment

- The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

Q241 – Sanitary Environment

- The administrator failed to ensure staff adhere to professionally acceptable standards of practice and reduce the potential for inadequate disinfection and increased risk of infection, as evidenced by:
  - 1. Staff not following directions for use (DFU) for the sterilization of surgical instruments;
  - 2. Biological indicators not being read or results documented;
Q241 – Sanitary Environment

- 3. Single-use items being reused;
- 4. Staff not disinfecting stethoscope between patients;
- 5. Multiple areas of tape fragments and residue on the patient carts and IV poles; and CRNA taking tape from the side of the bed during IV insertion procedure and
- 6. Non-intact flooring within the Operative Suite.

Q241 – Sanitary Environment

- (3) The surveyor observed Patient # 8's procedure in Operating Room #1. The patient was administered oxygen via mask during the procedure.
- Once the procedure was completed, the staff removed the patient's mask and left the oxygen extension tubing connected to the wall unit.
- Surveyor observed the room being cleaned/disinfected for the next case. Patient # 22 was brought into the room and his oxygen mask and tubing was connected to the same extension tubing used by Patient # 8.

Q241 – Sanitary Environment

- Surveyors also observed that staff in the Pre-Operative area were re-using tourniquets during the placement of intravenous lines.
- Employee # 2 confirmed in an interview on 04/28/15, that the oxygen extension tubing packaging states "single use" and that the staff had not been changing the extension tubing between surgical procedures.
- The Director of Nursing (#1) confirmed 4/28/15 at 1520 hours, that facility tourniquets are labeled as single-use only, and should not be re-used even if disinfected between patients.
Q241 – Sanitary Environment

• (4) Medical staff # 3 picked up a stethoscope from the top of the anesthesia cart. The stethoscope had a white cloth-like material underneath it.

• She listened to Patient # 3 heart and lungs, then placed the stethoscope back on top of the anesthesia cart on the white cloth-like material. She did not disinfect the stethoscope before or after use.

The Director of Nursing relayed to the surveyors on 04/28/15, that she spoke with Medical Staff # 3 about disinfecting the stethoscope between patients.

• Medical Staff # 3 relayed that she places the stethoscope on top of the sani-wipe. She does not change the sani-wipe between patients, nor does she wipe down the stethoscope with the sani-wipe.

Q241 – Sanitary Environment

• (5) Surveyors observed that the IV poles attached to the patient beds contained multiple surgical tape fragments and sticky areas of tape residue.

• Tape residue was also evident on the silver metal strips behind the armrests along the left edge of each bed. Also observed CRNA (Medical Staff # 3) pulling a piece of surgical tape from the side of the bed and placing directly over the IV insertion site.
Q241 – Sanitary Environment

- The Director of Nursing confirmed on 04/28/15, the areas of tape and tape residue on the patient beds.

- The DON also confirmed that in an interview with the CRNA, that the CRNA does place the tape on the side of the bed and then over the insertion site.

- She relayed that she makes the piece long enough so that the middle of the tape goes over the insertion site.

Q241 – Sanitary Environment

- Surveyors observed that the flooring seam in the doorway area leading into the Pre-op/PACU was cracked for a length of approximately 36 inches and the floor puffed up and open to the air for approximately 5-6 inches on both sides of the seam.

- Surveyors also observed during the facility tour that the flooring in the Operative Corridor was cracked along the three seamed areas immediately outside the Operating room. The center area of the Operating room also contains multiple nicks and small tears up to 1/2 inch in length. These breaks in the integrity of the flooring render it unable to be adequately cleaned and disinfected.

Q241 – Sanitary Environment

- Review of policy entitled: "HAND HYGIENE POLICY AND PROCEDURE" revealed: "...effective hand hygiene reduces the incidence of healthcare-associated infections...handwashing may also be used for routinely decontaminating hands in the following clinical situations: before having direct contact with patients...before inserting...peripheral vascular catheters, or other invasive devices..."

- Employee # 8 confirmed on 05/27/15, that she did not sanitized her hands before donning her gloves twice while starting the IV on Patient # 3.
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.

The facility failed to provide routine infection control training to members of the ASC (Ambulatory Surgical Center) medical staff.

Findings include:

- The policy entitled: "INFECTION PREVENTION AND CONTROL PROGRAM" contains: "Scope of the Infection Prevention Program...Major Activities...Surveillance...Outbreak Investigation...Policy and Procedure Review and Revision...Staff Education...Quality Assurance...Consultation...". The document contained no mention of infection control education for medical providers.

Review all ASC medical staff files revealed no documentation of infection control training.

The Director of Nursing / Infection Program Coordinator confirmed at interview 05/28/2015 at 10:15 a.m., that the ASC's medical staff members do not currently receive infection control training upon granting of privileges, with some refresher training thereafter.