A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
Q061 – Anesthetic Risk and Evaluation

Based on policies and procedures, observation, review of medical records, and staff interview, it was determined that the facility failed to ensure a physician examine 5 of 23 patients (Patient #s 8, 19, 20, 21, and 22) 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.
- Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.
- This pre-operative assessment 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.
- (c)(1) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.
- (c)(2) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.
**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.

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.(b) "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."

Q104 – Safety from Fire

- 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.
- 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.
- 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 backup emergency lighting units. Monthly tests for 30 seconds and Annual 90 minutes (1/2 hour) tests.
- In addition, based on testing and observation, one of two battery backup emergency lighting units in one of the two operating rooms did not light when tested three times.
- During the exit conference on May 15, 2015, the above findings were again acknowledged by the Administrator and Director of Nursing.
- Failing to test and document battery backup emergency lighting units could cause harm to staff and patients in time of a power failure.

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 (performed 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.
Based on review of facility documents and interviews with staff, it was determined the facility failed to maintain accurate, legible, and complete patient medical records for 12 of 22 patient charts reviewed, which has the potential risk of failing to accurately reflect the patient's current physical status and impact medical decisionmaking. (Pts # 1, 6, 11, 12, 14, 15, 16, 17, 18, 19, and 21)

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.
  2) The physician signature on the "Surgical Note" section of the "Physician Orders, Operation Record, and Surgical Safety Checklist" was dated by the RN for patients 6, 10, 14, 15, 17, 18, and 21.
  3) Medical records contained over-writes of OR time (Patients # 1 and 19), physician orders (Patient # 12), time of eyedrops administration (Patient # 12), oxygen administration vs room air (Patient # 19), OR time (Patient # 17), and vital signs (Patient # 10).
  4) Records for Patients # 1 and 21 had the procedure date whited out and new date written in. None of these medical record changes were initialed or signed.
  5) Time in the recovery room was not noted for Patient #18.
  6) Surveyors requested to review facility medical records policies related to the above-mentioned documentation issues. No policies were provided for review.

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

- Based on review of facility documents, observations on tour, and interviews with staff, it was determined that the facility failed to discard expired or unlabeled medications and supplies, which leads to a risk of infection or injury for the patient if treated with potentially contaminated or expired medications and supplies.

- 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.
  - Facility policy: "Multi-Dose Val 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, or at the recommendation of the manufacturer, or 38 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-inch eye wash, expired 2014/07; 17 tongue blades, expired 2014/11; 1 cotton-tipped applicator, expired 2014/10; 35 tongue blades, expired 2014/10, and 2 tongue blades, expired 2012/10.
  2. In the Operational Corridor Code Cart: Three (2) 21-gauge Jelco IV catheters, expired 2014/06; two (2) 22-gauge Jelco IV catheters, expired 2014/09; five (5) Smith and Nephew 7/16 inch x 1/4 inch, expired 2014/10; and one 5-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 Tubercul Purified Protein Derivative, opened and not dated with either the date of opening or the date of expiration.

Q181 – Administration of Drugs

- In the Pre-op Supply Room: One hundred (100) 2-inch by 3-inch Telfa pads, expired 2014/07; three Clear Cut slit knives, two (2) dual bevel) expired 2013/01 and one (1) 2.75 angled) expired 2014/06; and thirty-four total ACRY Sol IOL 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.
Q225 – Submission and Investigation of Grievances

- The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:
  - (1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.
  - (2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient’s representative, or the patient’s surrogate regarding treatment or care that is (or fails to be) furnished.
  - (3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient’s representative, or the patient’s surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

Q225 – Submission and Investigation of Grievances

- Based on document review and interview with staff, it was determined the facility failed to specify in its grievance process the timeframes for grievance review and the provision of a response to the complainant, which has the potential for lessened patient satisfaction and patients not being able to anticipate when they should be contacted by the facility in response to submitted complaints.
  - Review of facility policy, "Patient’s Grievance Procedure" contains: "...The center strives to provide quality care and achieve patient satisfaction. Patient grievances or complaints provide a means to measure achievement of this goal and to identify need for performance improvement...."
  - The Director of Nursing confirmed at interview 05/14/2015, that specific grievance response and resolution timelines have not been established by the facility and made available to patients.

Q233 – Privacy and Safety

- [The patient has the right to - ]
- (3) Be free from all forms of abuse or harassment
Q233 – Privacy and Safety

- Based on review of the personnel files and interview with the staff, it was determined that the facility failed to include abuse and neglect training for ASC staff, which has the potential for staff not being able to appropriately recognize and report patient abuse, with the result that patients not be appropriately responded to when experiencing or reporting potential abuse.
- Findings include:
  - Review of 9 of 9 personnel files with the Director of Nursing on 05/14/15, revealed no documentation of abuse and neglect training for staff.
  - The Director of Nursing verified on 05/14/2015, that she was unaware that the facility needed to offer abuse and neglect training to its employees during orientation and on an ongoing basis.

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.
- Based on observation, review of policies and procedures, manufacturer’s recommendations, and interviews with staff, it was determined that 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;
  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

- Findings include:
  - Tour of the facility on 04/28/15 revealed:
    - (1) A Rapicide OP/28 Solution Log sheet (High Level Disinfectant) for documentation of: solution testing date, time, temperature, and test results. It also did not contain when the solution was mixed.
    - Review of the manufacturer’s recommendations for Rapicide OP/28 High-Level Disinfectant revealed: “...Do not use Rapicide OP/28 High-Level Disinfectant beyond its stated use & reuse life (28 days)...”
    - Employee #8 confirmed in an interview on 04/28/15, that the High-Level Disinfection log did not document when the solution was mixed and when it would expire.

Q241 – Sanitary Environment

- (2) A biological testing log that did not have the results of the biological testing for all of the sterilizer loads run from 04/20/15 through 04/27/15.
  - Review of the biological indicator log revealed no documentation of results for 6 loads run from 04/20/15 through 04/27/15.
  - Review of the policy entitled “BIOLOGICAL TESTING” revealed: “...biological spore tests of all sterilization equipment will be conducted every day prior to routine sterilization schedule and on each load of implantables (or according to the manufacturer’s recommendation) to ensure proper sterilization control...”
  - Employee #8 confirmed in an interview on 04/28/15, that there was no documentation of the biological indicator results on the above mentioned dates.

Q241 – Sanitary Environment

- (3) The surveyor observed Patient #3’s procedure in Operating Room #. 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 #3.
  - 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 5:10 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.

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

(6) 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 1/2 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.

The Director of Nursing confirmed the breaks in the flooring integrity during an interview 04/27/2015.
Q241 – Sanitary Environment

Based on observation, review of policies, procedures, manufacturer’s recommendations, and interview with staff, it was determined that the administrator failed to require staff to protect the health and safety of patients and staff, as evidenced by staff not following the biological indicators and high level disinfectant/test strips directions for use (DFU), which has the potential for inaccurate test results.

Q241 – Sanitary Environment

Finding include:

Tour of the facility on 03/12/15, revealed a 3M Attest biological incubator with 3M Attest biological indicator test vials. There were 3 biological indicators laying beside the incubator. The surveyor asked the Surgical Technician/Employee #6 why the indicators were laying on the counter? She stated that since it was Thursday, the only day the surgical center was open that she would run the 3 biological indicators taken from the first load of each of the 3 autoclaves and not place them in the incubator until Monday 03/16/15. Surveyor asked if the facility did high level disinfection for any of it’s instruments? Employee # 6 showed the surveyor a covered metal tray filled with Metricide dated 01/23/15. The high level disinfectant test strip bottle had 25 of 60 strips remaining in the bottle. The bottle did not have a lid on it and there was no open date on the “open date line”.

Review of the manufacturer’s recommendations for Metricide revealed: “...Precautions...the users MUST adhere to the Directions for Use, because any modifications will affect the safety and effectiveness of the germicide...solutions may be used up to 28 days...”

Q241 – Sanitary Environment

Based on observation, review of policies and procedures, manufacturer’s recommendations, and interviews with staff, it was determined that the administrator failed to ensure that staff adhere to professionally acceptable standards of practice and reduce the potential for inadequate cleaning and disinfection and increased risk of infection, as evidenced by:

1. Two (2) of two pink patient recliners with tears in their upholstered surfaces;
2. Five (5) patient stretcher/surgical beds containing large amounts of tape residue on the lateral sides of the headrests;
3. Staff not consistently performing hand hygiene;
4. Expired biologicals and inconsistent use of cataract tray sterilization cycles;
Findings include:

1. During the tour 05/27/15, surveyors observed two upholstered chairs in the PACU open area near the nurses station. One chair contained a crescent tear approximately 1/2 inch in length and an approximately 1/4 inch long nick in the left armrest fabric. The second chair contained breaks in the left armrest fabric measuring approximately 1/8 inch in length, 1/4 inch in length, and 1/4 by 2/3 inches. The chair stuffing was exposed within the latter break in the armrest surface. The right armrest of the same chair contained an L-shaped tear approximately 1/2 by 1/3 inch in length.

The PCT (#5) confirmed 05/27/15, the breaks in the chairs’ upholstered surfaces frequently touched by patients.

2. Observation on 05/27/15 revealed tape adhesive residue on both sides of the headrests of stretcher beds #s 2, 3, 5, 10, and 13. The PCT (#6) confirmed the presence of the tape residue 05/27/15 at 14:10 p.m., and further stated that tape is frequently used by physicians to secure patients’ heads for surgical procedures.

3. Observation on 05/27/15 revealed Employee #8, preparing to start an IV on Patient #3 in the pre-operative area. Employee #8 prepared the supplies needed for the procedure. She located the site she wanted to use and donned gloves without sanitizing her hands. She was unable to access the vein, removed the catheter, discarded it, and ungloved and discarded the gloves. She then located another site to insert the peripheral catheter, touched her face, then picked up a new pair of gloves and donned them without sanitizing her hands.

4. 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 facility attached a "BIBRA SANIT" autoclave. The facility also had a "RENAISSANCE" autoclave. The facility uses the "AMSCO-STERILIZATION CONTAINER SYSTEM" for the cataract trays. The surveyor asked Employee #3 to show the preset cycles used to sterilize the cataract trays. The preset cycles are as follows:

- Cycle: Prevac 6
  - Temperature: 275.0°F
  - Exposure time: 4 minutes
  - Dry time: 20 minutes

- Cycle: Prevac 7
  - Temperature: 275.0°F
  - Exposure time: 4 minutes
  - Dry time: 5 minutes

The facility was not following the manufacturer's recommendation for the instruments run on the Prevac 7 cycle, which were the same instruments run at night on the recommended cycle. She also confirmed that the facility policy did not follow the manufacturer's recommendations.
Q244 – Infection Control

• 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.

Q244 – Infection Control

• Based on document review and interview with staff, it was determined 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 of 11 of 11 ASC medical staff files revealed no documentation of infection control training.

• The Director of Nursing / Infection Program Coordinator (#7) 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.

Questions?

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