Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	130019	A. BUILDING: _____ B. WING _____	11/24/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHWESTERN WOMENS SURGERY CENTER	8616 GREENVILLE AVENUE SUITE 101 DALLAS, TX 75243

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 000	25 TAC 135 Ambulatory Surgery Centers Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An unannounced, relicensure survey was conducted on site. An entrance conference was held the morning of 11/23/2015 with the facility's administrative representatives at Southwest Womans Surgical Center 8616 Greenville Avenue Dallas, Texas. It was explained to them the purpose and process of the survey. The survey was conducted under the authority of 25 TAC 135 - Ambulatory Surgical Center Licensing Rules. An exit conference was held the afternoon of 11/24/2015 with the facility's administrative representatives at which time the findings of the survey were explained to them. They were given an opportunity to provide evidence of compliance with those requirements of which non-compliance had been found. None was provided. Instructions were provided on writing plans of correction with instructions to return the plans of correction to the Arlington zone office within 10 days. Deficiencies were cited. This report was electronically sent to the facility.	T 000	RECEIVED DEC 18 2015 Zone 2 REVIEWED DEC 22 2015 by: RS	
T 121	135 4(h) ASC OPERATION (h) The governing body shall provide (in a manner consistent with state law and based on evidence of education, training, and current competence) for the initial appointment,	T 121		

SOD State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Administrator — (X6) DATE: 12-18-2015

STATE FORM 6899 SH4S11 If continuation sheet 1 of 22

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T 121	Continued From page 1 reappointment, and assignment or curtailment of privileges and practice for nonphysician health care personnel and practitioners. This Requirement is not met as evidenced by: Based on record review and interview, the Governing Board failed to ensure credentialing files were complete in 2 (#6 and #7) of 5 files reviewed. Also, the facility failed to follow their own Governing By-Laws & Medical Staff By-Laws. Findings Included A review of Physician #6's file revealed the Texas Standardized Credentialing Application on page 11 was not signed and on page 12, the signature was signed on 10/3/2012. The Texas Standardized Credentialing Application was not updated for the re-appointment to the facility for the year 2015. Also, there was no current documented evidence that the facility had checked for current or prior criminal charges. A review of the Certified Registered Nurse Anesthetist (CRNA) #7's file revealed the Texas Standardized Credentialing Application on page 11 and 12 was last signed and dated 5/14/2009. The Texas Standardized Credentialing Application was not updated for the re-appointment at the facility for the years 2011, 2013, and 2015. Also, there was no current documented evidence that the facility had checked for current or prior criminal charges. A review of the record titled, "Governing By-Laws & Medical Staff By-Laws; Article III, Medical Staff Qualifications" revealed the following	T 121	The Assistant Administrator will complete the credentialing files in question. They will also develop a new policy for the initial appointment and reappointment of physician and non physician health care personnel and practitioners. This new policy will include verification of licensure demonstrating evidence of current or prior criminal charges, as well as completion of the Texas Standardized Credentialing Application upon reappointment. The Governing By-Laws & Medical Staff By-Laws are being followed for Appointment. All credentialed files include the referenced information upon initial appointment. However, for reappointment, the Administrator and Assistant Administrator will create a new policy outlining conditions for reappointment to the medical staff. This information is currently reviewed by the Assistant Administrator during the process for reappointment to hospitals in which the physicians have admitting privileges. This information is currently shared with the governing board prior to reappointment. It will now be included in credentialing files as well.	12/18/2015

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T 121	Continued From page 2 "A. Appointment. Medical Staff applicants shall be provide (sp - provided) the following information and documentation to the President, Vice President, Board and the Medical Advisory Board: a. Professional licensure and controlled substance registration, including supporting certificates; b. Professional and post-graduate education, c. A completed Texas Standardized Credentialing Application, d. If the applicant has no prior work history with the SWSC or Fairmont Center, PA, then they shall provide the names of at least two licensed professionals who have had sufficient experience in observing and working with the applicant to judge their appropriateness for a medical staff position with SWSC. The Governing Board may request a written evaluation of the applicant's professional competence, character and any other matter requested. To be provided only upon request of the Governing Board or Medical Advisory Board, e. Information regarding any pending or prior action involving denial, revocation, suspension, probation, limitation or termination of any of the following: professional licensure; controlled substances registration; membership or fellowship in any professional societies, boards, associations or organizations; appointment or other status at any hospital, clinic, HMO, PPO or other health care entity; and Medicare or Medicaid provider status; f. Information on current or prior criminal charges (other than motor vehicle citations)." An interview with Personnel #2 on 11/24/2015 at 10:00 AM confirmed the above findings.	T 121		

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T 125	Continued From page 3	T 125		
T 125	135.4(l) ASC OPERATION (l) An ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 245 and 171, Subchapters A and B (relating to Abortion and Informed Consent). This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to document a follow-up visit on a patient after receiving an abortion-inducing drug on 1 (Patient #5) of 5 charts reviewed. Findings Included A review of Patient #5's record revealed no documented follow-up visit or a reason why the follow-up visit was not conducted after receiving Misoprostol (abortion-inducing drug). An interview with Personnel #5 on 11/23/2015 at 3:45 PM confirmed the follow-up visit had been missed.	T 125	Upon review, the patient missed the follow up appointment. She was then called twice following the discovery, and it was documented that she did not have a working voicemail. The Administrator and Director of Nursing will implement a plan to retrain the nursing staff on regulations regarding provision of Medication Abortion. This will include enforcement of a policy to follow up the day of a missed appointment and again 48 hours later. Staff will document reasons for not conducting a follow up visit. A log of 2 week follow up appointments will be added to the HCG and lab monitoring logs to ensure patient follow up as well.	12/18/2015
T 153	135.6(b)(6) ADMINISTRATION OF A LICENSED ASC (b) Personnel policies shall be established and implemented to facilitate attainment of the mission, goals, and objectives of the ASC. Personnel policies shall: (6) provide adequate orientation and training to familiarize all personnel with the ASC's policies, procedures, and facilities.	T 153		

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T 153	Continued From page 4 This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to implement policies to provide adequate orientation and training for 1 of 1 sterilization personnel (Personnel #13), in that, Personnel #13's file did not evidence the required orientation and training to operate the autoclave and to sterilize instruments use for quality patient care. Findings Included Personnel #13's personnel file did not evidence the orientation and training to operate the autoclave and to sterilize instruments. During an interview on 11/24/2015 at 11:40 AM, Personnel #1 was asked if Personnel #13 had a training checklist for an Autoclave Tech to show orientation and training provided by the facility for Personnel #13 to operate the autoclave and to sterilize instruments used for quality patient care. Personnel #1 reviewed the file for Personnel #13 and stated, "No." The 08/04/2015 last reviewed, "Training Checklist" policy required, "Autoclave/Pathology Tech...Demonstrates the following (listing of all skills required)...Checked off on: Date...."	T 153	The Assistant Administrator will ensure a training checklist is placed in the file of Personnel 13. Going forward, a newer training checklist, introduced in 10/2015, will again be updated to reflect proper training and orientation of sterilization personnel.	01/04/2016
T 210	135.9(j)(4) MEDICAL RECORDS IN A LICENSED ASC (j) The (ASC) shall include the following in patients' medical records: (4) significant medical history and results of physical examination;	T 210	The Assistant Administrator will add a review of systems to evidence a physician's physical examination for patients above 15 weeks LMP. This is present in all first trimester paperwork, and will now be added for the 2nd trimester.	12/18/2015

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T 210	Continued From page 5 This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to document the results of a physical examination for 3 of 19 surgical patient's records (Patient #8, #9, and #11), in that, Surgical Patient #8's, #9's, and #11's records did not evidence a physician's physical examination. Findings Included The medical record for Surgical Patient #8, #9, and #11 did not evidence a physician's physical examination. During an interview on 11/23/2015 at 3:33 PM, Personnel #5 was asked to confirm there was no physician's physical examination documented in Patient #8's, #9's, and #11's medical record. Personnel #5 reviewed Surgical Patient #8's, #9's and #11's records and stated, "I don't see one."	T 210		
T 231	135.10(c) FACILITIES AND ENVIRONMENT IN A LIC ASC (c) Facilities shall be clean and properly maintained. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure a safe and sanitary environment for surgical patients. Also, the facility failed to monitor the temperature of the patient medication refrigerator for 18 of 21 days in the month of September, 18 of 24 days for October, and 1 of 19 days for the month of November.	T 231	The Administrator will order a new linen cart cover with splash guard to protect against high traffic and dust particles. The Director of Nursing and Nursing Coordinator will retrain nursing staff on requirements for temperature ranges and implement a policy of immediate report to supervisor of incorrect temperatures in order to be adjusted immediately.	01/07/2016

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T 231	Continued From page 6 Findings Included During an observation tour on 11/23/2015 the following unclean and unsafe environmental issues were observed: Recovery Room: During the tour on 11/23/2015 at 10:45 AM, at the entrance to the recovery room it was observed that there was no solid barrier on the bottom of the clean linen cart. This entrance area was a high traffic area. This practice had the likelihood for dust particles to contaminate the linen. During the tour it was observed that the recovery room medication refrigerator that stored patient medication was being monitored, but the temperatures were recorded below the normal range. (Normal range was 33.8 -50) A review of the record titled, "Recovery Daily Log" for the months September, October, and November 2015 revealed the following: During the month of September 2015, 18 (1, 2 , 4, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 22, 23, 24, 25, and 26) of 21 days recorded had freezing temperatures (32 degrees or below) recorded. There was no documented evidence that personnel had reported the freezing temperatures to management or a responsible administrative person. Also, there was no documentation showing the facility staff had adjusted the medication refrigerator temperature. During the month of October 2015, 18 (1, 2, 3, 5,	T 231	The soiled linen closet was full, and due to the holiday week, the linen company did not inform the Administrator of a change in pick up schedule. The linen company picks up Monday and Thursday mornings. This will be increased to Monday, Wednesday, and Friday in order to accommodate an increase in patient load in the first quarter of the year. Staff will be retrained on proper stocking and storage methods for sterile instruments to ensure packages are not ripped open when accessing them from a drawer, similar to the aforementioned incident. The 20cc syringes will be moved to a proper storage area in the cabinets of the medication alcove. The Administrator is unsure of the relevance of the container being faded or discolored as being a deficiency. Upon review, the disinfectant was tested in the presence of the surveyor and shown to be of appropriate strength. The Administrator has informed staff working in the decontamination room of the necessity of dating the open container. This policy is effective immediately. All cardboard shipping boxes and open patient supplies will be moved to proper storage levels in the storage area effective immediately. The Administrator will discuss with the nightly cleaning staff, the importance of cleaning the floor in the storage area more thoroughly. This is to be inspected every morning prior to surgery, by a member of the management team.	01/07/2016

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T 231	Continued From page 7 6, 7, 8, 14, 15, 16, 19, 20, 23, 24, 28, 29, 30, and 31) of 24 days recorded had freezing temperatures (32 or below) recorded. On October 20, 21, and 27th, 2015, there was an initial instead of a temperature recorded as required by the form. There was no documented evidence that personnel had reported the freezing temperatures to management or a responsible administrative person. Also, there was no documentation showing the facility staff had adjusted the medication refrigerator temperature. During the month of November 2015, 1 (11) of 19 days recorded had freezing temperatures (32 or below)recorded. On November 7, 2015, there was an initial instead of a temperature recorded as required by the form. There was no documented evidence that personnel had reported the freezing temperatures to management or a responsible administrative person. Also, there was no documentation showing the facility staff had adjusted the medication refrigerator temperature. This practice had the likelihood to cause patient medication to freeze. Bio-Hazard Room: During the tour on 11/23/2015 at 11:00 AM, it was observed that the bio-hazard room was full from floor to ceiling with soiled linen bags and bio-hazard boxes. There was a refrigerator in this area that stored frozen products of conception (POC), but the room was so full of soiled linen bags and bio-hazard boxes the surveyor could not get to the refrigerator to examine the contents or monitor the temperature.	T 231	The paper towels touching the holder were never used by patients and personnel. The Director of Nursing and Nursing Coordinator will ensure compliance with the storage of the oxygen tank holder.	01/07/2016

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T 231	Continued From page 8 On the second day of survey (11/24/2015) at 10:00 AM, the bio-hazard room was full of soiled linen bags (approximately 25) on the floor and stacked to the ceiling, the soiled linen cart was full. Again, the surveyor could not get to the refrigerator to examine the contents or monitor the temperature. Also, observed were soiled linen bags on the floor of the recovery patient bay area. The biohazard closet was too full to hold any more soiled linen bags. Operating Room: (Supply Drawer) The drawer that held sterile instruments was so full that when the drawer was opened the top instrument package (vaginal speculum) was observed to have a hole in the sterile package. Medication Alcove: Observed under the hand washing sink was a plastic container full of 20 cc syringes along with cleaning products. During the tour of the medication alcove, when the surveyor was washing her hands and had reached for the paper towels, it was observed that below the paper towel dispenser was a plastic basket with patient syringes. The water was dripping onto the syringes. This was shown to Personnel #2 and she acknowledged that water was dripping from washed hands onto the patient syringes. Decontamination Room:	T 231		

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T 231	Continued From page 9 Observed a gallon of Ortho-Phthalaldehyde opened and not dated to when the container was opened. Also, observed the container of cold disinfectant was faded and discolored. The cover was off the plastic container that was storing the Ortho-Phthalaldehyde solution. A review of the facility policy titled, "Guidance for Employees Using Ortho-Phthalaldehyde" revealed the following: "The container used to soak the equipment in Ortho-phthalaldehyde (Cidex® OPA) must be covered at all times except when the employee is manipulating the equipment or working with the solution (testing, neutralizing or disposing of the Ortho-phthalaldehyde)" Per the Ortho-Phthalaldehyde guidelines: "Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container can be used for up to 75 days (providing the 75 days does not extend past the expiration date listed on the container) until used." Storage Area: It was observed that cardboard shipping boxes were being stored with open patient supplies on the shelves in the storage area. Also, on the shelves were open critical patient supplies that were stored on the shelves near the floor where dust particles could contaminate the supplies. Observed the floor of the storage area was covered in trash, dust and dirt particles. The cart that was storing the clean linen was covered in	T 231		

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T 231	Continued From page 10 dust and dirt particles. An oxygen tank holder was lying across some oxygen tanks and the dirty wheel of the holder was lying against the open paper towels that were used by patients and personnel. The nationally accepted standards set forth by the Association for the Advancement of Medical Instrumentation state, "External shipping containers have been exposed to unknown and potentially high microbial contamination. Also, shipping cartons, especially those made of corrugated material, serve as generators of and reservoirs for dust." (AAMI 5T46-Section 5.2 Receiving Items). An interview with Personnel #2 on 11/23/2015 at approximately 10:30 AM confirmed the findings from above.	T 231		
T 258	135.11(b)(11)(A-G) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (11) A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, shall be assured through the provision of adequate space, equipment, and personnel. (A) Provisions shall be made for the isolation or immediate transfer of patients with communicable diseases. (B) All persons entering operating rooms shall be properly attired. (C) Acceptable aseptic techniques shall be used by all persons in the surgical area.	T 258	The Administrator will enforce a policy requiring disposable head covers to be worn on the surgical floor, which will be provided by the surgery center for the staff.	01/04/2016

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T 258	Continued From page 11 (D) Only authorized persons shall be allowed in the surgical area. (E) Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile. (F) Environmental controls shall be implemented to assure a safe and sanitary environment. (G) Operating rooms shall be appropriately cleaned before each operation. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the following was observed: A. The facility's surgical personnel failed to wear the proper operating room attire. Surgical personnel were observed on 11/23/2015 not wearing any type of head covers as they entered and exited the surgical area. Also, the facility failed to ensure that their own policy regarding proper attire was followed by surgical personnel. Findings Included During a tour of the operating room and procedure rooms on 11/23/2015 at approximately 10:30 AM, surgical personnel were observed not wearing any type of head covers as they entered and exited the surgical area. A review of the undated, facility policy titled, "Surgical Attire" revealed the following: "PURPOSE: To promote high-level cleanliness and hygiene within the surgical	T 258		

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T 258	Continued From page 12 environment and provide a barrier to contamination between patient and personnel POLICY: All persons entering the Operating Room shall be attired according to the guidelines established for the surgery center and in accordance with OSHA regulations. GUIDELINES: 1. All persons within the semi-restricted and restricted areas of the surgical suite are required to wear proper surgical attire In the operating room surgical attire shall include scrub clothes or protective coveralls, bouffant cap, shoe covers, masks, and protective eye wear (as indicated below). 2. Freshly laundered surgical scrubs will be provided by the center for all persons. Scrub clothes should be changed whenever they become visibly soiled. 3. Surgical attire minimizes bacterial shedding and may consist of a one-piece coverall or surgical scrubs Loose fitting tops should be tucked into trousers. 4. Shoe covers are to be worn when gross contamination can be reasonably anticipated and should be changed when they become torn, wet or soiled. Shoe covers are removed before leaving the OR suite. 6. All possible head and facial hair, including sideburns and necklines, are to be covered. Hair covers are to be removed before leaving the surgery center." As per the AORN (Association of PeriOperative	T 258		

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T 258	Continued From page 13 Registered Nurses) guidelines titled, "Recommended practices for surgical attire" revealed the following· "Clean surgical attrite, including shoes, head covering, masks, jackets, and identification badges should be worn in the semi restricted and restricted areas of the surgical or invasive procedure settings " An interview with Personnel #5 on 11/23/2015 at 11 00 AM confirmed the above findings that head coverings were not being worn and the facility policy was not followed for surgical attire B. The facility failed to monitor and record the temperature and humidity where sterile instruments were stored and in the surgical rooms where care was provided for surgical patients. This had the likelihood to cause a fire hazard and microbial growth in areas where sterile supplies were stored or procedures were performed Findings Included: During the tour on 11/23/2015 at 11 00 AM, there were no temperature and humidity logs to monitor the storage areas where sterile instruments were being stored. The Administrator of the facility was able to show the surveyor a computer system that does show the humidity readings in operating room #1, but the other 2 procedure rooms and the sterilization room where sterile instruments were stored did not have humidity readings. A review of the AORN (Association of periOperative Registered Nurses) "Perioperative Standards and Recommended Practices",	T 258	The Administrator will work with HVAC vendor to update monitors and control of the humidity in all areas where sterile instruments are stored. This will go into a daily log to be recorded by the sterilization personnel in accordance with AORN Perioperative Standards and Recommended Practices.	01/11/2016

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T 258	Continued From page 14 Recommended Practices for a Safe Environment of Care revealed the following "Temperature should be maintained between 68 degrees F to 73 degrees F (20 degrees to 23 C) within the operating room suite and general work areas in sterile processing. Relative humidity should be maintained between 30% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas and should be maintained below 70% in sterile storage areas. Low humidity increases the risk of electro static charges, which pose a fire hazard in an oxygen-enriched environment or when flammable agents are in use and increases the potential for dust. High humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed. Humidity should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system. Temperature should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system." An interview with Personnel #1 on 11/24/2015 at 10:00 AM confirmed the above findings C. The facility failed to maintain the sterility of the surgical instruments. On 11/23/2015 instruments were observed not placed in the sterilizer per	T 258		

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T 258	Continued From page 15 manufacture guidelines and were wet when removed from the sterilizer. Peel packages were being cut and taped for longer instruments. Also, the facility failed to ensure that their policy was followed. There were 145 autoclave loads ran between 11/2/2015 and 11/23/2015 in the facility. Findings Included: During the tour of the sterilization room on 11/23/2015 at 10:45 AM, Personnel #13 was observed removing peel pouches from the Pelton steam sterilizer. The peel pouches were wet and moisture had collected inside the peel pouches. A review of the steam sterilizer operation guide recommends no more than 1.8 lbs. if using the appropriate tray and pouches may not be stacked. It was observed when the pouches were removed from the small sterilizer that, the pouches were stacked on top of each other and pouches were coming out of the sterilizer wet. Also, observed that peel packages were cut and taped together to make a longer peel package. Cutting and taping changes the integrity of the original peel package. A shelf full of instruments and unwrapped, uncovered MVA's were observed. Personnel #13 was asked what are those instruments on that shelf used for. Personnel #13 stated, "Those are decommissioned instruments." The shelf was not labeled to alert other personnel that work in the facility to not use these instruments for patient care. In interview with Personnel #13 on 11/23/2015 at 11:00 AM, Personnel #13 was asked if they were aware that wet packages and moisture in the peel pouches was an infection control issue. Personnel #13 stated "No."	T 258	The Administrator will retrain sterilization personnel on appropriate sterilization techniques. Larger autoclaves will be ordered to accommodate the number of instruments being used and to ensure allotted time for dry cycle. Appropriate sized peel packages will be ordered for the different instruments used within the facility. The sterilization room will be relabeled and reorganized to ensure compliance and understanding of sterilization personnel. New logs will be created to reflect requirements within policies and procedures.	01/07/2016

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T 258	Continued From page 16 A review of the record titled, "Autoclave Log" dated from 11/2/2015 thru 11/23/2015 revealed the following: A review of the autoclave log revealed no documentation of temperature reached, pressure reached, length of time sterilized, and load contents. A review of the undated, facility's policy titled, "Sterilization of Supplies" revealed the following: Guidelines: All items will have decontamination processing per guidelines prior to sterile processing. 1. Steam Sterilization of Packaged Items Using the Sterilizer a. Instrument sets will be sterilized in perforated trays or containers specially designed for that purpose. b. All instruments will be held open and unlocked. Items with removable parts are disassembled. c. Small items may be placed in peel packs in the pan. d. An internal chemical indicator will be placed in each pack to be sterilized. e. Each item will be labeled with content, date of processing and the load number. f. Items will be sterilized at the appropriate temperature, pressure and length of time depending on the contents of the load and sterilizer used. A daily record of each load contents, temperature reached, pressure reached, length of time sterilized and results of biological indicator will be kept by the autoclave technician."	T 258		

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T 258	Continued From page 17 An interview with Personnel #13 on 11/23/2015 at 11:30 AM confirmed the peel pouches were wet and personnel did not have the training or knowledge to recognize that moisture in the peel pouches was an infection control issue. There were 145 autoclave loads ran between 11/2/2015 and 11/23/2015 in the facility.	T 258		
T 259	135.11(b)(12)(A-D) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (12) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be developed, implemented and enforced. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing, and sterilization of critical items (reusable items), as well as for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment. (A) Policies and procedures shall be developed following standards, guidelines, and recommendations issued by the Association of periOperative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC) and, if applicable, the Society of Gastroenterology Nurses and Associates (SGNA). Standards, guidelines, and recommendations of these organizations are available for review at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas. Copies may also be obtained directly from each organization, as follows: AORN, 2170 South Parker Road, Suite 300, Denver Colorado, 80231, (800) 755-2676; APIC, 1275 K Street, Northwest, Suite 1000, Washington, District of	T 259	The administrator will review and develop a new policy for maintaining performance records for the usage of the MVA. This will include labeling the instruments and documenting their usage in daily logs.	01/07/2016

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T 259	Continued From page 18 Columbia, 20005-4006, (202)789-1890; CDC, 1600 Clifton Road, Atlanta, Georgia, 30333, (800) 311-3435; SGNA, 401 North Michigan Avenue, Chicago, Illinois, 60611-4267, (312) 321-5165. (B) Policies and procedures shall also address proper use of external chemical indicators and biological indicators. (C) Performance records for all sterilizers shall be maintained for a period of six months. (D) Preventive maintenance of all sterilizers shall be completed according to manufacturer's recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least one year and shall be available for review to the facility within two hours of request by the department. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the usage of the Manual Vacuum Aspiration (MVA, handheld syringe used for manual evacuation for an abortion). Findings Included A review of records revealed no documentation that the facility was keeping records of how many times the MVA had been used. A review of the manufacturer's guideline on the Ipas MVA revealed the following: "Providers can choose the disinfectant/sterilization method that best results	T 259		

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T 259	Continued From page 19 their practice. As a guideline, the Ipas MVA Plus can be used between 25-50 times when following the Ipas processing instructions provided in its package insert. Whichever method of disinfection/ sterilization is chosen, the Ipas MVA needs to be inspected before next use. If the Ipas MVA plus shows signs of damage or is not functioning properly, it should be discarded." During a tour of the facility on 11/23/2015 at 10:50 AM multiple MVA's were observed on the counter in the sterilization room. Personnel #13 was asked how does the facility keep up with the number of the MVA had been used. Personnel #13 stated, "If the physician tells me, its not working properly." An interview with Personnel #13 on 11/23/2015 at 10:50 AM confirmed the facility was not keeping a record of how many times the MVA had been used.	T 259		
T 261	135.11(b)(14) ANESTHESIA & SURGICAL SVCS IN A LIC ASC (14) Periodic calibration and/or preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to have a safety check conducted on the new suction machine that was being used in operating room #1 prior to patient use.	T 261	The Administrator and Assistant Administrator will implement a policy to ensure that all new equipment is inspected and approved by vendor prior to patient use.	12/18/2015

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T 261	Continued From page 20 Findings Included During a tour of operating room #1 on 11/23/2015 at 10:45 AM no safety inspection label was observed on the suction equipment. An interview with Personnel #2 on 11/23/2015 at 11:00 AM stated, "The suction machine is new and we need to get it checked." Personnel #2 confirmed the suction machine had not had an electrical safety check and had been used on patients. This facility performs approximately 50 cases a day between 3 operating/procedure rooms.	T 261		
T 395	135.43(a) HANDLING AND STORAGE OF GASES, ANESTHETICS, A Handling and Storage of Gases, Anesthetics, and Flammable Liquids. (a) An ambulatory surgical center (ASC) shall comply with the requirements of this section for handling and storage of gases, anesthetics, and flammable liquids. The ASC premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the facility. This Requirement is not met as evidenced by: Based on observation and interview, the Ambulatory Surgical Center (ASC) failed to ensure 2 of 2 oxygen tanks were in holders in the surgical area. Findings Included During a tour of operating and procedure rooms on 11/23/2015 at 10:45 AM, one oxygen tank was	T 395	The Director of Nursing and Nursing coordinator will review requirements of storage of gases, and ensure compliance with the oxygen of storage tanks within the facility.	01/04/2015

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T 395	Continued From page 21 observed in the operating room #1 standing upright not stored in a holder. Also, there was a oxygen tank in the storage area not stored in a holder. The unsecured oxygen tanks had the likelihood of being knocked over which is a safety hazard for patients and personnel. An interview with the Personnel #2 on 11/23/2015 at 11:00 AM confirmed the oxygen tanks were not stored properly in a holder.	T 395		