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 |
|---|---|---|---|
| | 130193 | A. BUILDING: _____ B. WING _____ | 12/17/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| PLANNED PARENTHOOD OF GREATER TEXAS SURG | 7989 WEST VIRGINIA STE 102 DALLAS, TX 75237 |

| (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 |
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| T 000 | 25 TAC 135 Ambulatory Surgery Centers<br><br>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.<br>An unannounced, initial survey was conducted on site. An entrance conference was held at Planned Parenthood of Greater Texas Surgical Health Services 7989 West Virginia Drive, Suite 102 Dallas, Texas the morning of 12/16/2015 with the facility's administrative representative. It was explained to her the purpose and process of the survey. The survey was conducted under the authority of 25 TAC 135 - Ambulatory Surgical Center (ASC) Licensing Rules.<br><br>An exit conference was held the afternoon of 12/17/2105 with the administrative representatives at which time the findings of the survey were explained to them. The facility's representatives 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. This report was electronically sent to the facility. Deficiencies were cited. | T 000 | REVIEWED<br>FEB 09 2016<br>by: RJ<br><br>RECEIVED<br>FEB 01 2016<br>Zone II / Arlington | |
| T 138 | 135.5(f)(8) RIGHTS OF PATIENTS IN A LICENSED ASC | T 138 | | |

SOD - State Form

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



Kenneth S. Lambrecht 1/29/16

Texas Department of State Health Services

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| T 138 | Continued From page 1<br>(f) Information shall be available to patients and staff concerning:<br>(8) methods for expressing complaints and suggestions to the ASC<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview, the facility failed to post the Patient's Bill Rights in the main waiting room of the Ambulatory Surgery Center (ASC).<br><br>Findings Included<br>A tour of the ASC waiting area on 12/16/2015 at 10:00 AM revealed no posting of the Patient's Bill Rights in the main waiting room of the Ambulatory Surgery Center (ASC).<br><br>An interview with Personnel #7 on 12/16/2015 at 10:00 AM confirmed the above findings.<br><br>An interview with Personnel #3 on 12/17/2015 at 11:00 AM, also confirmed the above findings. | T 138 | On 12/16/15, during the DSHS survey, the ASC Manager posted the Patient's Bill Rights in the main waiting room of the Ambulatory Surgery Center (ASC). The surveyors were shown the posted Patient Rights Document in the Main Waiting Room before they left the ASC. The Patient's Bill Rights was already posted in the registration waiting room.<br>Risk and Quality Management staff (RQM) will conduct an audit twice annually to ensure compliance. | 12/16/15 |
| T 210 | 135.9(j)(4) MEDICAL RECORDS IN A LICENSED ASC<br><br>(j) The (ASC) shall include the following in patients' medical records:<br>(4) significant medical history and results of physical examination;<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview, the facility failed to include the results of a physician's physical examination in the patients' medical | T 210 | Effective 1/28/16, ASC physicians will ensure that all ASC clients, both surgical and medication abortion clients, receive a physical exam. The PPGT policy on abortion was revised on 1/29/16 to clarify that all clients receiving abortion procedures require a physical exam, including medication abortion clients.<br>RQM will complete an audit to ensure compliance Q1 2016. | 1/28/16<br><br>1/29/16 |

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| T 210 | Continued From page 2<br>records for 2 of 4 (Patient #14 and #15) patients, in that, Patient #14's and #15's medical record did not include the results of a physician's physical examination.<br><br>Findings Included<br><br>Patient #14's and #15's medical record did not include the results of a physician's physical examination.<br><br>During an interview and electronic medical record review on 12/17/2015 ending at 2:13 PM, Personnel #1 and #2 were asked for the physician's physical examination for each of the above listed patients. Personnel #1 and #2 stated, "The physical exam (section of the record) was empty," and they were unable to find evidence of a physician's physical examination for Patient #14 and #15. | T 210 | | |
| T 217 | 135.9(j)(11) MEDICAL RECORDS IN A LICENSED ASC<br><br>(j) The (ASC) shall include the following in patients' medical records:<br>(11) evidence of evaluation of the patient by a physician or advanced practice registered nurse prior to dismissal;<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview, the facility failed to include in the patient's medical record evidence of evaluation of the patient by a physician or advanced practice registered nurse prior to dismissal for 10 of 17 (Patient #1, #2, #3, #4, #5, #6, #7, #11, #12, and #13) surgical | T 217 | The medical record will clearly reflect the physicians evaluation of the client prior to discharge. The Chief Medical Officer reviewed this requirement with ASC staff on 1/23/16 and a new process was implemented on 1/23/16 to ensure compliance. On 1/29/16, the PPGT procedure for discharging a client was revised to clarify that the physician must assess the client prior to discharge. This process change was also reinforced with staff on 1/27/16 by the Director of Quality Management. RQM will audit for compliance Q1 2016. | 1/23/16<br>1/29/16<br>1/27/16 |

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| T 217 | Continued From page 3<br>patients, in that, Patient #1's, #2's, #3's, #4's, #5's, #6's, #7's, #11's, #12's, and #13's medical record did not include evidence of evaluation of the patient by a physician or advanced practice registered nurse prior to dismissal.<br><br>Findings Included<br><br>Patient #1's, #2's, #3's, #4's, #5's, #6's, #7's, #11's, #12's, and #13's medical record did not include evidence of evaluation of the patient by a physician or advanced practice registered nurse prior to dismissal.<br><br>During an interview and electronic medical records review on 12/17/2105 ending at 2:13 PM, Personnel #1 and Personnel #2 was asked for the evidence of evaluation of the patient by a physician or advanced practice registered nurse prior to dismissal for each of the above listed patients. Personnel #1 stated, "The physician completes their (the patient's) procedure and does not see them in recovery unless there is a complication." Personnel #1 and Personnel #2 confirmed the above listed patients were not seen in recovery prior to going home. | T 217 | | |
| T 231 | 135.10(c) FACILITIES AND ENVIRONMENT IN A LIC ASC<br><br>(c) Facilities shall be clean and properly maintained.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to ensure a safe and sanitary environment for surgical patients. | T 231 | | |

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| T 231 | Continued From page 4<br><br>Findings Included<br><br>During an observation tour on the morning of 12/16/2015 the following unclean and unsafe environmental issues were observed:<br><br>Waiting Room:<br><br>The cabinet beneath the sink in main waiting room of the Ambulatory Surgery Center observed a large circle of a dark brown dried substance.<br><br>Pre-Op Bathroom:<br>The emergency call light in the patient pre-op bathroom was observed approximately 2 feet above the floor, rendering it out of reach and ineffective for a patient experiencing a fall on the floor to summon help in an emergency.<br><br>Also, in the pre-op patient's bathroom the surveyor observed patients' personal bags being stored on the sitting bench in the bathroom in front of the commode.<br><br>Pre-op Storage Room:<br>In the pre-op storage area patients' personnel bags being stored in a cardboard shipping box on the floor.<br><br>Post-op Bathroom:<br><br>In the patient's post-op bathroom three of the ceiling tiles had large brown water stains.<br><br>Post-op Storage Area:<br><br>Patients' snack foods were stored in cardboard shipping boxes directly on the floor and some of the food boxes were out of the cardboard box and | T 231 | The cabinet under the sink in the main waiting room was repaired on1/27/16.<br><br>On 12/21/15, a longer cord was installed for the emergency call light in the pre-op patient bathroom, ensuring a patient could reach the cord in an emergency. RQM will conduct an audit twice annually to ensure compliance.<br><br>On 12/17/15, the clinic manager relocated the personal belonging bags in the bathroom to a counter in the pre-op storage room. Additional shelves were installed in the pre op storage room on 1/27/16 to accommodate additional personal bags. On 1/27/16, the Director of Quality Management reviewed with ASC staff that personal bags must not be stored on the bathroom bench. RQM will conduct an audit twice annually to ensure compliance.<br>On 12/18/15, ASC staff unpacked the box of empty personnel bags and placed them on shelves in the main storage area. On 1/27/16, the Director of Quality Management reviewed with ASC staff the requirement to store the empty personnel bags on shelves in the main storage room. RQM will conduct an audit twice annually to ensure compliance.<br>The ceiling tiles in the post op bathroom were replaced on 1/27/16.<br>On 1/25/16, all food items were placed on shelves. On 1/27/16, the Director of Quality Management reviewed with ASC staff the requirement for food storage. RQM will conduct an audit twice annually to ensure compliance. | 1/27/16<br><br>12/21/15<br><br>12/17/15<br><br>1/27/16<br><br>1/27/16<br><br>12/18/15<br><br>1/27/16<br><br>1/27/16<br><br>1/25/15<br>1/27/16 |

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| T 231 | Continued From page 5<br>sitting directly on the floor.<br><br>Post-op Area:<br><br>There was no gauge on the oxygen tank, but was available for patient usage in an emergency situation.<br><br>The vital sign machine was available for patient use, but the preventive maintenance sticker for electrical safety check indicated last checked 9/2014 due date of 9/2015.<br><br>Main Storage Area:<br><br>The cabinet covering where sterile instruments were wrapped was peeling and cracking. Also, underneath the cabinet, empty cardboard shipping boxes were being stored on the floor in the same area where the sterile instruments were wrapped. This had the likelihood to contaminate supplies which could cause an infection due to the condition of the cabinet and cardboard shipping boxes being stored on the floor.<br><br>It was observed that cardboard shipping boxes were being stored with open patient supplies on the shelves in the storage area. There were cardboard shipping boxes stored on the top shelf over the open sterile supplies. Also, open sterile patients' supplies were stored on the shelves near the floor where dust particles could contaminate the supplies.<br><br>Nine cardboard shipping boxes filled with the patients' personal bags were stored on the floor in the area where sterile open patient supplies were | T 231 | On 12/18/15, the gauge was installed on the oxygen tank. On 1/27/16, the Dir. Of Quality Management reviewed with ASC staff that equipment must be fully assembled and 'ready to use'. RQM will conduct an audit twice annually to ensure all tanks have gauges. The vital sign machine was removed from patient use on 12/16/15 & marked "do not use". On 1/27/16, the Dir. of Quality Management reviewed with staff that all medical equipment in any patient area must have a preventative maintenance sticker. Items that have not been inspected must be clearly marked "Do Not Use", until maintenance is performed. RQM will conduct an audit twice annually. The cabinets covering sterile instruments are scheduled to be replaced on 2/1/16. The ASC Manager ensured that all empty boxes in the ASC were removed on 12/16/15, including the boxes stored on the floor, the boxes stored with open patient supplies, boxes on the shelf above sterile supplies, & the 9 boxes on the floor filled with bags. On 1/27/16, procedures were updated to include that PPGT staff must empty shipping containers upon receipt and the Dir. of Quality Management reviewed this requirement with ASC staff on 1/27/16. RQM will conduct an audit twice annually to ensure compliance. On 12.16.15, the ASC Manager relocated the open sterile patient supplies from the shelves to cabinets located in the storage room. On 1/27/16, the Dir. of Quality Management reviewed storage requirements for sterile supplies with ASC staff. RQM will conduct an audit twice annually to ensure compliance. | 12/18/15<br><br>12/16/15<br><br>1/27/16<br><br>2/1/16<br><br>12/16/15<br><br>1/27/16<br><br>1/27/16<br><br>12/16/15<br><br>1/27/16 |

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| T 231 | Continued From page 6<br>stored.<br><br>There were 2 suction machines with no preventive maintenance safety check stickers. Personnel #7 was asked do you use these machines. Personnel #7 stated, "No these are just extras." The machines were not labeled "Do not use" and were available for patient's use.<br><br>Cardboard shipping boxes filled with biohazard sharps containers were stored on the floor in the area where sterile open patient supplies were stored.<br><br>There were numerous patient supplies being stored on the floor in the storage area.<br><br>Trash and dust particles were observed on the floor of the storage area where the open sterile supplies were stored.<br><br>The nationally accepted standards set forth by the Association for the Advancement of Medical Instrumentation (AAMI) 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).<br><br>Janitorial Closet:<br><br>A mop bucket with dirty brown water was observed. Personnel #7 was asked who cleans the operating rooms and was this the mop bucket they use. Personnel #7 stated, "No we use a different mopping system, the contract housekeeping crew uses this bucket I think, but let me check and make sure." | T 231 | On 12/16/15, a "do not use' sticker was placed on the suction machines by the manager who removed them from patient use. On 1/27/16, the Director of Quality Management reviewed with staff the policy that all medical equipment must have a preventative maintenance sticker. If maintenance has not been done, the equipment must be marked "Do Not Use" until maintenance has been performed. RQM will conduct an audit twice annually to ensure compliance.<br>On 12/16/15, the ASC manager emptied the box of sharps containers. On 1/27/16, procedures were updated to include that PPGT staff must remove supplies from shipping containers upon receipt and the Dir of Quality Management reviewed this requirement with ASC staff on 1/27/16.The sharps containers are now stored on a shelf. RQM will conduct an audit twice annually to ensure proper storage.<br>On 12/17/15, the ASC Manager unpacked all patient supplies on the floor in the storage area & placed them in the designated location. On 1/27/16, the Dir. of Quality Management reviewed storage requirements for sterile supplies with ASC staff. RQM will conduct an audit twice annually to ensure compliance. The Dir. of Quality Management reviewed with ASC staff the need to ensure that the ASC is free from trash and dust particles at all times. RQM will conduct an audit twice annually to ensure compliance.<br>Shelves were installed in the janitorial closet on 12/22/15. On 1/25/16, management informed the janitorial staff to consistently move shelving & clean under them on a routine basis & to empty mop buckets every night after cleaning. | 12/16/15<br>1/27/16<br><br>12/16/15<br>1/27/16<br><br>1/27/16<br><br>12/17/15<br>1/27/16<br><br>12/22/15<br>1/25/16 |

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| T 231 | Continued From page 7<br><br>In the janitorial closet the surveyor observed no shelving and cleaning supplies and trash bags were being stored directly on the floor. Also, two drinking cups were sitting on the floor. The cleaning supplies were next to the bucket of dirty brown water.<br><br>Laundry Room:<br><br>The surveyor observed 2 bags of clean linen being stored directly on the floor of the laundry room. The facility had a contract linen service, but the surveyor observed patients' laundry in the washer and dryer. Also, Personnel #7 reached into the washer and picked up the dirty linen without personnel protective equipment (PPE).<br><br>A review of the facility's policy titled, "Laundry Policy and procedure" revealed the following:<br><br>"PURPOSE:<br>A. Implement control measures used to minimize the risk of an exposure to blood or other potentially infectious materials through the handling of contaminated laundry<br>B. Provide clients with safe and clean laundry to reduce the incidence of health-care associated infections.<br>II. ON-SITE PROCEDURE<br>A. PPGT (sic) (Planned Parenthood Greater Texas) family planning health centers will use only disposable items that do not require laundering.<br>B. PPGT (sic) Ambulatory Surgical Centers (ASC) will comply with the following procedure.<br>1. Storing Soiled Laundry<br>Soiled laundry should be placed in clearly identified containers or baskets. Soiled and clean laundry processes must be separated and arranged to provide a one-way traffic pattern from | T 231 | On 12/22/15, shelving was added to the janitorial closet for the storage of supplies. On 1/25/16, PPGT management informed the janitorial staff that they are required to empty mop buckets every night after cleaning and the floors in the janitorial closet must remain clean and free of clutter. RQM will conduct an audit twice annually to ensure compliance.<br><br>Effective 1/28/16, cabinets are utilized for the storage of linen. On 1/27/16, the Director of Quality Management reviewed with staff the requirements for laundry storage. RQM will conduct an audit twice annually to ensure compliance.<br><br>On 1/27/16,the Director of Quality Management reviewed with the ASC clinic staff the PPGT procedure for sorting soiled laundry, emphasizing that gloves and gowns must be worn while sorting soiled laundry. RQM will conduct an audit twice annually to ensure compliance | 12/22/15<br><br>1/25/16<br><br>1/28/16<br>1/27/16<br><br>1/27/16 |

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| T 231 | Continued From page 8<br>soiled to clean areas.<br>2. Sorting Soiled Laundry<br>Employees must:<br>a. Wear appropriate personal protective equipment (PPE) while sorting soiled laundry.<br>b. Handle soiled laundry as little as possible with minimal agitation.<br>c. Do not sort or rinse laundry at the location where it was used.<br>d. Place wet laundry in leak-proof labeled containers at the location where it was used.<br>e. Whenever laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, place and transport the laundry in bags or containers which prevent soak-through and/or leakage of fluids to the exterior<br>f. Place and transport visibly contaminated laundry in bags or containers labeled with the biohazard symbol or placed in red bags."<br><br>Bio-Hazard Waste Room:<br><br>The biohazard waste storage room had an unsealed cement floor. There were extra patient call light cords and a wall clock observed being stored on the floor in the biohazard room. This had the likelihood for blood to leak from the biohazard bags to the unsealed cement floor making it difficult to clean and an infectious risk to personnel entering the room.<br><br>The above findings were confirmed in an interview with Personnel #7 the morning of 12/16/2015 during the tour of the facility. | T 231 | On 12/22/15, the floor in the biohazard storage room was sealed in order to minimize the risk of infection.<br><br>The extra call light cords and clock were removed from the biohazard storage by the ASC Manager on 12/21/15. RQM will conduct an audit twice annually to ensure equipment is not stored on the floor in the biohazard room. | 12/22/15<br><br>12/21/15 |
| T 232 | 135.10(d) FACILITIES AND ENVIRONMENT IN A LIC ASC | T 232 | | |

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| T 232 | Continued From page 9<br>(d) An emergency call system shall be provided and readily accessible to staff and patients in all areas of the facility.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to ensure a safe and functional environment as the emergency call light in the pre-op bathroom was not accessible to a patient that might experience a fall.<br><br>Findings included:<br><br>During a tour of the facility the morning of 12/16/2015, the emergency call light in the patient's pre-op bathroom was observed approximately 2 feet above the floor, rendering it out of reach for a patient that might experience a fall on the floor to summon help in an emergency.<br><br>The above findings were confirmed in an interview with Personnel #7 on the morning of 12/16/2015, during the tour of the facility. | T 232 | On 12/21/15, a longer cord was installed on the emergency call light in the pre-op bathroom. | 12/21/15 |
| T 233 | 135.10(e) FACILITIES AND ENVIRONMENT IN A LIC ASC<br><br>(e) All equipment, including emergency equipment, shall be properly maintained and periodically tested.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to ensure that the oxygen equipment was ready for patient use in an emergency situation. | T 233 | | |

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| T 233 | Continued From page 10<br>Findings Included<br><br>During a tour of the facility on 12/16/2015 at approximately 11:00 AM the surveyor observed an oxygen tank available for use in the post-op area. If an emergency had occurred with a patient in post-op, there was no regulator gauge on the oxygen tank to be able to turn the oxygen on. This was the only oxygen tank in the post-op area.<br><br>An interview with Personnel #7 12/16/2015 at approximately 11:00 AM confirmed the above findings. | T 233 | On 12/18/15, the gauge was installed on the oxygen tank for patient usage in an emergency situation. On 1/27/16, the Director of Quality Management reviewed with ASC staff that Equipment for use in Emergency situations must be fully assembled, maintained per protocol and be stored 'ready for use'. RQM will conduct an audit twice annually to ensure all tanks have gauges. | 12/18/15<br><br>1/27/16 |
| T 258 | 135.11(b)(11)(A-G) ANESTHESIA & SURGICAL SVCS IN A LIC ASC<br><br>(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.<br>(A) Provisions shall be made for the isolation or immediate transfer of patients with communicable diseases.<br>(B) All persons entering operating rooms shall be properly attired.<br>(C) Acceptable aseptic techniques shall be used by all persons in the surgical area.<br>(D) Only authorized persons shall be allowed in the surgical area.<br>(E) Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile.<br>(F) Environmental controls shall be implemented to assure a safe and sanitary environment.<br>(G) Operating rooms shall be appropriately cleaned before each operation. | T 258 | | |

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| T 258 | Continued From page 11<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview,<br><br>A. The facility's personnel failed to wear the proper operating room attire and follow the facility's policy on Surgical Attire.<br><br>B. The facility failed to monitor the temperature and humidity where sterile instruments were stored. This had the likelihood to cause a fire hazard and microbial growth in areas where sterile supplies were stored.<br><br>C. The facility's personnel failed to maintain the sterility of the surgical instruments. There were 20 peel pack packages observed in the sterile instrument storage area that were not sealed correctly. This had the likelihood to cause contamination and microbial growth in the sterile instrument packages.<br><br>D. The facility failed to know the Hepatitis B status of 2 (#6 and #8) of 4 personnel working in the Ambulatory Surgery Center. This had the likelihood to place personnel and patients at a risk to be exposed to the Hepatitis B virus.<br><br>Findings Included:<br><br>A. During a tour of the operating room and procedure rooms on 12/17/2015 at approximately 12:30 PM, the surveyor observed the personnel not wearing any type of head covers as they | T 258 | On 1/27/16, the Director of Quality Management reviewed with ASC staff proper OR attire, including head covers. RQM will conduct an audit twice annually to ensure compliance.<br><br>Effective 1/2/2016, staff are logging the temperature and humidity where sterile items are stored. On 1/27/16, The Director of Quality Management reiterated this documentation requirement with ASC staff. RQM will conduct an audit Q1 2016 to ensure compliance.<br>On 12/16/15, all instruments in peel packs were re sterilized. On 1/27/16, the Director of Quality Management reviewed with ASC staff proper sealing of peel packs. RQM will conduct an audit twice annually to ensure compliance.<br><br>On 1/27/16, HepB titers were drawn on the ASC staff that required a titer to supplement their previously documented vaccination record. | 1/27/16<br><br>1/2/16<br>1/27/16<br><br>12/16/15<br>1/27/16<br><br>1/27/16 |

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| T 258 | Continued From page 12<br>entered and exited the surgical area.<br><br>A review of the facility policy titled, "Standard Precaution and PPE" revealed the following:<br><br>"F. Head covers/shoe covers<br>Surgical caps/hoods and/or shoe covers/boots are used in any instances where "gross Contamination' is anticipated. If worn, they must be charged when visibly soiled, wet, or worn and always be removed prior to leaving the surgical or procedural area."<br><br>As per the AORN (Association of Perioperative Registered Nurses) guidelines titled, "Recommended practices for surgical attire" revealed the following:<br><br>"Clean surgical attire, 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."<br><br>An interview with Personnel #7 on 12/17/2015 at 12:30 PM confirmed the above findings that head coverings were not being worn and the facility policy was not followed for surgical attire.<br><br>B. During the tour on 12/16/2015 at 12:16 PM, there were no temperature and humidity logs to monitor the storage areas where sterile instruments were being stored. Also, the facility had no temperature and humidity gauges to monitor the storage area where sterile instruments were stored.<br>A review of the AORN (Association of Perioperative Registered Nurses) "Perioperative Standards and Recommended Practices"; Recommended Practices for a Safe Environment | T 258 | Effective 1/2/2016, staff are logging the temperature and humidity where sterile items are stored. On 1/27/16, The Director of Quality Management reiterated this documentation requirement with ASC staff. RQM will conduct an audit Q1 2016 to ensure compliance. | 1/2/16<br><br>1/27/16 |

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| T 258 | Continued From page 13<br>of Care revealed the following:<br>"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.<br>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.<br><br>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.<br><br>Humidity should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system.<br><br>Temperature should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system."<br><br>An interview with Personnel #8 on 12/16/2015 at 12:16 PM confirmed the above findings.<br><br>C. During the tour on 12/16/2015 with Personnel #8, the surveyor observed peel packages were that were not sealed correctly. The peel packages had a perforated line where the package was to be folded, but the packages were not folded on | T 258 | On 1/27/16, the Director of Quality Management retrained ASC staff on the proper sealing of peel packs, proper labelling requirements and the need for a chemical indicator with each peel pack. RQM will conduct an audit twice annually to ensure compliance. | 1/27/16 |

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| T 258 | Continued From page 14<br>the perforated line which had caused the packages not to be sealed and allowing for contamination. Some of the packages were not labeled with a date or the load number and the chemical indicator was missing.<br><br>An interview with Personnel #8 on 12/16/2015 at 12:30 PM confirmed the peel pouches were not sealed and labeled correctly. Personnel #8 stated, "The girls assisting me did not have the knowledge to recognize that the peel pouches were not sealed or labeled correctly and that they would need further training."<br><br>D. A review of #6's personnel file revealed no documentation of the Hepatitis B status.<br>A review of #8's personnel file revealed no documentation of the Hepatitis B status.<br>A review of the standard of care guidelines for "OSHA (Occupational Safety & Health Administration); Occupational Exposure to Blood borne Pathogens" revealed the following:<br><br>"Persons at substantial risk of HBV who are demonstrated or judged likely to be susceptible should be vaccinated. They include the following:<br>1. Persons with occupational risk. HBV is a major infectious occupational hazard for health care and public safety workers. The risk of acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and per mucosal exposure to blood or blood products. Any health-care or public-safety worker may be at risk for HBV exposure depending on the tasks that he or she performs. If those tasks involve contact with blood or blood-contaminated body fluids, such workers should be vaccinated. Vaccination should be considered for other workers depending on the nature of the task. Risks among health-care professionals vary | T 258 | On 1/27/16, HepB titers were drawn on the ASC staff that required a titer to supplement their previously documented vaccination record. | 1/27/16 |

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| T 258 | Continued From page 15<br>during the training and working career of each individual but are often highest during the professional training period. For this reason, when possible, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions before workers have their first contact with blood."<br>An interview with Personnel #4 on 12/17/2015 at 9:00 AM confirmed the facility did not know the Hepatitis B status of two of the personnel working at the Ambulatory Surgery Center | T 258 | | |
| T 261 | 135.11(b)(14) ANESTHESIA & SURGICAL SVCS IN A LIC ASC<br><br>(14) Periodic calibration and/or preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to maintain preventative maintenance records for two suction machines and one automatic vital sign machine that were available for patient use in the surgical area.<br><br>During a tour of the surgical area on 12/16/2015 at 10:00 AM, the surveyor observed two suction machines and one vital sign machine that had expired preventative maintenance stickers. The equipment inspection sticker showed a expiration date of 09/2015.<br><br>An interview with Personnel #7 on 12/16/2015 at 11:00 AM confirmed the above findings. This | T 261 | On 12/16/15, a "do not use' sticker was placed on the suction machines. On 1/27/16, the Director of Quality Management reviewed with ASC staff the policy that staff must ensure that all medical equipment in the ASC has a documented preventative maintenance sticker. These items without a sticker must be clearly marked "Do Not Use", until maintenance has been performed and documented.<br>RQM will conduct an audit twice annually to preventative maintenance is documented for all equipment in use. | 12/16/15<br><br>1/27/16 |

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| T 261 | Continued From page 16<br>facility performs approximately 150 cases a month.<br>. | T 261 | | |
| T 267 | 135.12(a) PHARMACEUTICAL SERVICES IN A LIC ASC<br><br>Pharmaceutical Services.<br>(a) The ambulatory surgical center (ASC) shall provide drugs and biologicals in a safe and effective manner in accordance with professional practices and shall be in compliance with all state and federal laws and regulations. The ASC shall be licensed as required by the Texas State Board of Pharmacy and comply with 22 Texas Administrative Code, §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center).<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to store medication in a safe and secure area in the facility's pharmacy.<br><br>During a tour of the surgical area the morning of 12/16/2015, the surveyor observed 2 cases of Lidocaine 1% in an unlocked storage area of the surgical center.<br><br>The above findings were confirmed in an interview with Personnel #7 the morning of 12/16/2015 during the tour of the facility. | T 267 | On 1/25/16, the ASC charge nurse relocated Lidocaine 1% to a locked drawer. RQM will conduct an audit twice annually to ensure that all medications are secure in the ASC. | 1/26/15 |
| T 335 | 135.25(b) COMPLAINTS<br><br>(b) All licensed ambulatory surgical centers are | T 335 | | |

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| T 335 | Continued From page 17<br>required to provide the patient and his/her guardian at time of admission a written statement identifying the department as the responsible agency for ambulatory surgical centers complaint investigations. The statement shall inform persons to direct complaint to the Department of State Health Services, Manager, Health Facility Compliance Group, Post Office Box 149347, Austin, Texas 78714-9347, (888) 973-0022. This information shall also be prominently and conspicuously posted for display in an area of the facility that is readily available to patients, families and visitors. Complaints may be registered with the department by phone or in writing. A complainant may provide his/her name, address, and phone number to the department. Anonymous complaints may be registered. All complaints are confidential.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the ambulatory surgery center (ASC) failed to prominently and conspicuously display a written statement identifying the Department of State Health Services as the responsible agency for patient, families, and visitors to file a complaint against the facility.<br><br>Findings Included<br><br>A tour of the ASC waiting area on 12/16/2015 at 10:00 AM revealed no posting/statement informing patient, families, and visitors on how to file a direct complaint to the Texas Department of State Health Services against the facility.<br><br>An interview with Personnel #7 on 12/16/2015 at 10:00 AM confirmed the above findings. | T 335 | On 12/16/15, the ASC manager posted in the ASC waiting room the required statement informing the patient, families, and visitors on how to file a direct complaint to the Texas Department of State Health Services against the facility. The surveyors were shown the posting in the Main Waiting Room before they left the ASC. RQM will conduct an audit twice annually to ensure compliance. | 12/16/15 |

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| T 335 | Continued From page 18<br><br>An interview with Personnel #3 on 12/17/2015 at 10:00 AM, also confirmed the above findings. | T 335 | | |