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 |
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| | 140007 | A. BUILDING: _____ B. WING _____ | 10/21/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

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| A 000 | TAC 139 Initial Comments<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 visit was made on the morning of 10/20/2015 to conduct a Re-licensure Survey to determine compliance with 25 TAC Chapter 139 State Licensing Rules for Abortion Facility.<br><br>An entrance conference was conducted with the Director of Clinic Services. The purpose of the visit and procedure for the survey was discussed.<br><br>An exit conference was conducted on 10/21/15 with the Director of Clinic Services. Deficiencies were cited. The facility's personnel was given an opportunity to provide additional information and ask questions. | A 000 | Acceptable 11/5/16 | |
| A 149 | TAC 139.44(b)(3)(A)(B)(C)(D) Orientation/Training/Demonstrated Competency<br><br>(3) the employee understands, at a minimum but not limited to, the following:<br>(A) coordination and treatment of patient care;<br>(B) sterilization and infection control policies;<br>(C) patient education/information;<br>(D) informed consent policies; | A 149 | A149<br><br>The Clinic Administrator will be responsible for ensuring all personnel working in the pathology lab has gone through the appropriate orientation process, training and demonstrate competency on decontamination and sterilization techniques. | 11/30/15 |

SOD - State Form
LABOR [redacted] ENTATIVE'S SIGNATURE TITLE (X6) DATE
Director of Clinical Svcs 11/5/16 12/08/15
STATE 6899 JME311 If continuation sheet 1 of 22

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| A 149 | Continued From page 1<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to ensure 1 (#3) of 1 was trained in the sterilization process of surgical instruments.<br><br>Observed during the tour on 10/20/2015 at 10:15 AM there were approximately 20 sterile instruments packaged in peel pouches which were being stored in a plastic container with no lid. These instruments were stored in the room where products of conception were examined and contaminated instruments were washed. The peel pouches were observed to have water stains or discoloration noted on the sterile packages. There were no chemical indicators inside the peel pouches. Also, observed the peel pouches were not sealed correctly. There is a perforated line where the pouches are to be folded. The pouches were not folded correctly which allowed outside contaminated air to enter the pouches. The peel pouches were observed to be crushed, bent, and compressed in the plastic container, which had no lid and the container was over filled with instruments. The peel packs were not labeled with the load number, date and or time. A review of the 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 in the sterilizer a load with peel pouches and 4 wrapped instrument sets on the day of tour. There was no tray in the sterilizer to separate the instruments. The instruments were lying on top of each other which allowed no room for the instruments to have air circulation for proper sterilization and drying. | A 149 | During the survey conducted on 10/21/15 the surveyor noted staff was not properly sealing the sterilization pouches, therefore according to the surveyor allowing contaminated air to get inside the pouch. There is no indication of infection control hazard to patients due to the air circulating throughout the facility, Whole Woman's Health of San Antonio has not reported an increase of infection rate.<br><br>The Director of Clinical services will facilitate an infection control training on November 30th, 2015. Staff will be required to prepare for this training by reading WWH policy for decontamination and sterilization techniques, during the training the designated trainer will show the staff the proper way to wrap, pack and sterilize instruments, by the end of the training the staff will be asked to perform each one of these steps while being evaluated by the trainer. A competency checklist will be documented and filed in the staff's personnel record.<br><br>In order to ensure compliance, the Clinic Administrator will perform randomized tracers to address staff's competency and follow through of our policies and address training needs. | |

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| A 149 | Continued From page 2<br><br>A review of the autoclave load log from 9/29/2015 thru 10/19/2015 revealed no temperature, time, or pressure recorded on the log.<br><br>A review of the record titled, "Whole Women's Health Pathology Training Checklist" revealed the only record of training for Staff #3. There was no training on sterilization of sterile instruments.<br><br>Review of the policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the following:<br><br>"Maintenance of Sterility<br>Items that are packaged properly will remain sterile unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised. Commercially packaged items will be considered sterile according to the manufacturer's instructions.<br>A. All packages will be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item will be returned to the sterile area for reprocessing/sterilizing.<br>B. The indicator tape on the outside and on the inside of the pack will be checked before the instruments are used. If the indicator tape did not change the pack will be returned to the sterile area for reprocessing/sterilizing. The other packs/pouches from that load will be checked.<br>C. If instruments are ("flash") sterilized unwrapped an indicator tape or strip will be placed in the tray and presented to the providing MD along with the instrument.<br>D. Sterilized items will be handled in a manner that does not compromise the packaging of the product. | A 149 | | |

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| A 149 | Continued From page 3<br>E. Sterilized items will be transported as to maintain cleanliness and sterility and to prevent physical damage.<br>F. Sterilized items will be stored in the sterile area. This area has controlled ventilation and has restricted access.<br>G. Sterilized items will be packed in the sterilizers and positioned so the packaging is not crushed, bent, compressed, or punctured in order to ensure the packages' sterility."<br><br>An interview with Staff #3 on 10/20/2015 at approximately 3:00 PM confirmed the above findings and the policy was not being followed. Staff #3 was asked what type of training have you had on the sterilization of instruments. Staff #3 stated, "I just shadowed someone for couple of days." The interview with Staff #3 revealed the staff member was still not knowledgeable in the proper procedure of sterilizing instruments. | A 149 | | |
| A 197 | TAC 139.48(1)(A) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to provide safe and sanitary environment. | A 197 | A197<br><br>The Clinic Administrator will be responsible for ensuring the physical and environmental requirements for the facility are strictly followed. | 11/30/15 |

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| A 197 | Continued From page 4<br>During the tour of the facility on 10/21/2015 at approximately 10:00 AM the following environmental issues were observed:<br><br>The findings included:<br><br>Laboratory Area:<br><br>Patient lab supplies were being stored under the sink in the Lab room. Observed a brown substance on patients' supplies and on the floor of the sink shelf which appeared to be a leak.<br><br>Pathology Room:<br><br>Observed some type of soap being stored in the bag out of the original container on the pathology sink. There was water on the cabinet surface where instruments are placed to dry. The Administrator laid her phone down on the cabinet in the water during the tour and stated "Oh that's wet."<br>In the Pathology room beside the Biohazard container in a card board box sitting on the floor was the blue wrap for the surgical instruments.<br>In the pathology room (what the facility calls the sterile side) was another box of the blue wrap in a card board box sitting on the floor. The products of conception were being examined and contaminated instruments were being washed in this same room. The width of area discussed was approximately 3 feet that separated clean from dirty.<br>A fan was sitting on top of the surgical trays on the shelf, the under the cabinet in the Pathology room.<br><br>In the Pathology room 15 gallons of Cidex, Enzymatic solution, and bleach were being stored | A 197 | Laboratory Area: All patient supplies have been removed from the cabinet under the sink, and have been stored in a plastic container on a separate cabinet. The packaging that was stained with betadine "brown substance" has been removed from the lab and properly disposed. An infection control training outlining the proper method to store laboratory supplies was facilitated for staff on 11/11/15, and the records have been failed in the each staff's personnel record.<br><br>Recovery Room: The oxygen tank has been moved to a safer place away from risk of being knocked down by patients, visitors, or staff.<br><br>Laundry Room: The Laundry room has been re organized with the intent of maintaining a clear separation between the dirty linens, and the clean laundry. All janitorial supplies have been properly stored in a closest designated for janitorial supplies.<br><br>Physical walk through of the facility: The exam tables, and suction machines will be refurbished to address the peeling paint, and the ceiling tile with the 3 inch water mark in the lab will be replaced. | 11/11/15<br><br>11/11/15<br><br>11/12/15<br><br>11/30/15 |

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| A 197 | Continued From page 5<br>directly on the floor.<br><br>Patient Storage Closet:<br><br>In the patient care closet, where patient supplies are stored it was observed there were sanitary pads on the floor. Dust particles were on the floor next to the sanitary pads along with a biohazard sharps container and card board boxes. The patient supplies were open on the shelves, and it was observed that there were card board shipping boxes on the shelves beside the open patient supplies. Also, there were card board shipping boxes stored on top of the open patient supplies. Card board boxes can harbor parasites, insects, and microorganisms.<br>"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." (AAM1 ST46-Section 5.2 Receiving items).<br><br>Recovery Room:<br><br>During the tour of the recovery room on 10/20/2015 at 3:00 PM observed 2 card board shipping boxes on the floor of the recovery room. The boxes were full of patients' supplies (blue pads). The lid was open to the boxes making it available for contaminants to enter the boxes.<br><br>There was an oxygen tank sitting on the floor in the recovery area with a holder. The oxygen tank was beside the water fountain, which made it accessible to be knocked over by staff, patients, and family members.<br><br>An interview with Staff #1 on 10/20/2015 at 3:00 PM confirmed the above findings. | A 197 | In order to monitor compliance with the physical an environmental requirements for the facility, the Administrator will perform a walk-through of the physical plant on a weekly basis to ensure all supplies are properly stored, ad equipment and instruments are in optimum condition. | |

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| A 197 | Continued From page 6<br><br>Laundry Room:<br><br>During a tour of the facility on 10/20/15 and 10/21/15 of the survey card board shipping boxes were stored in front of the (2) soiled linen hampers on the floor in the laundry area. There were 4 boxes which contained paper towels and bathroom tissue stacked in front of the soiled linen hamper, and the washer and dryer. In this same area across from the soiled linen cart (approximately 3 feet) was an open wire rack where patient gowns, physicians ' scrubs, and patient blankets were being stored. There were no barriers on the bottom shelf and no cover over the shelving. On the shelf with the clothing items was an autoclave. Above the patient gowns, physicians' scrubs, and patient blankets were package of paper towel rolls. There was clothing articles piled on top of the dryer along with boxes of fabric softener. Beside the dryer was another soiled linen hamper that had a shipping box on top of the linen hamper. Observed that all 3 linen hampers had soiled linen in them. The linen hampers were all labeled with biohazard label. This laundry area stayed cluttered with shipping boxes and observed that none of the staff members had ever moved or cleaned the area during the 2 day survey.<br>An interview with Staff #1 on 10/21/2015 at approximately 12:00 PM confirmed the above findings. Staff #1 stated, "The boxes are here because we just got supplies."<br>Observed no change in the laundry area during the survey dates of 10/20-21/2015.<br><br>Tour of the facility on 10/20/15, the following observations were made:<br>-Through out the facility, base boards were lifting | A 197 | | |

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| A 197 | Continued From page 7<br>at some of the seams and "yellowing dirt" was observed along the base of the baseboards.<br>- In the recovery room, the exam table had rust around each drawer and around the drawer handles.<br><br>- In the procedure room- Amelia:<br>the drawers of the exam table had rust and peeling paint.<br><br>-In the procedure room -Georgia:<br>The emesis basins, used for patients, were stored under the sink.<br>The suction machine, the bumper around the machine had fallen off the machine and was covered in dust.<br>In the Lab room:<br>A ceiling tile had water damage.<br>-The crash cart in the hallway of the facility was covered in dust.<br>Interview on 10/20/15 with the staff S#1, confirmed the above findings. | A 197 | | |
| A 213 | TAC 139.49(b)(1)(A)(I)(ii) Infection Control Standards<br><br>(A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph.<br>(i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments.<br>(ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and apply them to all patients receiving care in facilities, | A 213 | A213<br><br>The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.<br><br>Whole Woman's Health of San Antonio has developed a performance record for the usage of Manual Vacuum Aspirator (MVA) in order to track the usage and performance of the MVA's in rotation. (See log attached) | 11/30/15 |

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| A 213 | Continued From page 8<br>regardless of their diagnosis or presumed infection status.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to maintain performance records for the usage of the Manual Vacuum Aspiration (handheld syringe used for manual evacuation for an abortion). Also, the facility failed to follow their own policy processing the Ipas MVA Plus.<br><br>A review of records revealed no documentation that the facility was keeping records of how many times the MVA had been used.<br><br>A review of the manufactures' guideline on the Ipas MVA revealed the following:<br>"Providers can choose the disinfectant/sterilization method that best results 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."<br>During a tour of the facility on 10/20/2015 at 10:50 AM observed multiple MVA's on the counter at the nursing station in an open container with no lid. Also, observed a MVA lying on the second shelf of a rolling cart. The MVA was lying on an open surface with no cover over the MVA. The cart was used to carry supplies in and out of the procedure room.<br>A review of the facility policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the | A 213 | The medical director will conduct an inspection of all MVA's in rotation to assess their current condition and need for replacement. This audit will be documented and kept in the performance record binder. All MVA's devises will be stored in a closed plastic container before use.<br><br>A staff training will be provided by the Director of Clinical Services to ensure the staff understand the process to decontaminate and sterilize these devises, as well as the steps to inspect them before use and document the number of times it is used.<br><br>In order to ensure compliance with this requirement, the Clinic Administrator will conduct a monthly audit of the performance record log as well as the condition of the MVA's. | |

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| A 213 | Continued From page 9<br>following:<br><br>"Cleaning and Processing the Ipas MVA Plus:<br><br>*Clean it by washing all surfaces thoroughly in warm water and detergent. Detergent is preferable to soap, which can leave a residue. As an alternative, an enzymatic cleaner, a solution specifically designed to clean blood and tissue from surgical instruments, can be used.<br><br>*For a high-level disinfectant soak, place all the parts in the soak for the amount of time directed on the bottle. Ipas recommends Cidex or Cidex OPA, or Sporox II, however, Cidex OPA is the Facility's approved disinfectant soak. Ipas MVAs must soak in Cidex OPA for at least 12 minutes.<br><br>*The Ipas MVA Plus can be used between 25 and 50 times when following the Ipas processing instructions. The Ipas MVA should always be inspected before next use, and should be discarded at any signs of damage or is not functioning properly.<br><br>*Aspirators need to be stored in dry, covered containers or packages to protect them from dust and other contaminants."<br><br>An Interview with Staff #1 on 10/21/2015 at 10:30 AM confirmed the facility was not keeping a record of how many times the MVA had been used. | A 213 | | |
| | | | A242 | |
| A 242 | TAC 139.49(d)(5)(D)(i)(ii) Infection Control Standards<br><br>D) Packaging.<br>(i) All wrapped articles to be sterilized shall be | A 242 | The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the sterilization procedure is strictly monitored. | 10/22/15<br>11/30/15 |

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| A 242 | Continued From page 10<br>packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds. (ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.<br><br>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to document on the instrument packages the following: the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used.<br><br>Observed during the tour of the sterilization room on 10/20/2015 at approximately 10:14 AM the peel pouches in the plastic container and the peel pouches that were being removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used. The wrapped instruments that were removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used.<br><br>An interview with the Staff #3 on 10/20/2015 at 11:00 AM confirmed the above findings. | A 242 | All instruments have been re sterilized and the date, time, load # and autoclave ID has been documented on each pouch and pack.<br><br>The Director of Clinical services will facilitate an infection control training on November 30th, 2015 staff will be required to prepare for this training by reading WWH policy for decontamination and Sterilization techniques. During the training, the designated trainer will show the staff the proper way to wrap, pack, and label instruments to be sterilized. By the end of the training the staff will be asked to perform each one of these steps while evaluated by the trainer. A competency checklist will be documented and filed in the staff's personnel record.<br><br>In order to ensure compliance, the Clinic Administrator will perform randomized tracer to address staff's competency and follow through of our policies and address training needs. | 11/30/15 |
| A 245 | TAC 139.49(d)(5)(F)(iii)(iv)(v) Infection Control Standards | A 245 | | 11/30/15 |

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| | 140007 | A. BUILDING: _____ B. WING _____ | 10/21/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

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| A 245 | Continued From page 11<br>(F) Biological indicators.<br>(iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.<br>(iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.<br>(v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to maintain a log for biological indicators (BI) that included time, load identification, and contents of the load. Also, the facility failed to follow their own policy.<br><br>Findings include:<br><br>Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave.<br><br>An interview with Staff #3 on 10/20/2015 at 10:15 AM stated she was a medical assistant and the person responsible for the autoclave. Staff #3 stated, "I run a biological indicator (BI) test with the 1st load every day that the autoclave is ran."<br><br>A review of the record titled, "Biological Indicator Log " on 10/20/2015 at 11:00 AM revealed the following: the time the biological was placed in the autoclave was left blank and the time the | A 245 | A245<br><br>The Clinic Administrator will be responsible for ensuring all infection control standards are met by ensuring the Biological Indicator (BI) log is completed and accurate.<br><br>All BI test performed after the survey conducted on 10/21/15 have been accurately documented on the BI log to include time and load ID, contents, and the 24 hr reading with the time it was run.<br><br>The Director of Clinical Services will facilitate a training for all staff working in the pathology lab on how to run biological indicators (BI) and how to properly document the test and results of the spore test. The Director of Clinical Services will observe each staff run the BI test and document it on the log.<br><br>The Clinic Administrator will monitor compliance with this standards by conducting an audit of the sterilization and BI logs on a monthly basis to ensure adequate competency, and address training needs. | 11/30/15<br><br>10/21/15 |

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| A 245 | Continued From page 12<br>biological was read 24 hours later was left blank. Also, the load identification and contents of the load was not documented on the biological log.<br><br>A review of the log for the date 9/30/2015 revealed the control biological was left blank.<br><br>A review of facility policy titled, "Procedure for Pathology" revealed the following:<br><br>"Biological Indicators<br>The efficacy of the sterilizing process will be monitored with reliable biological indicators. (i.e. Bacillus stearothermophilus) appropriate for the type of sterilizer used.<br>A. These indicators will be included in one run each day of use per sterilizer.<br>B. A log will be maintained with the load identification, biological indicator results, and identification of the contents of the load.<br>C. If a test is positive, the sterilizer will immediately be taken out of service and will not be put back into service until it has been serviced and successfully tested.<br>D. All available items will be recalled and reprocessed if a sterilizer malfunction is found."<br>An interview on with Staff #3 on 10/20/2015 at 10:15 AM revealed the biological log was not completed and facility policy had not been followed. | A 245 | | |
| A 247 | TAC 139.49(d)(5)(H)(i)(ii)(iii) Infection Control Standards<br><br>(H) Maintenance of sterility.<br>(i) Items that are properly packaged and sterilized shall remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of | A 247 | A 247<br><br>The Clinic Administrator will be responsible for ensuring all Infection Control Standards are accurately followed by ensuring medication therapy protocol is followed. | 11/30/15 |

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| A 247 | Continued From page 13<br>being compromised.<br>(ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations.<br>(iii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to discard medication not administered in a timely manner.<br>During a tour of the facility with the Administrator on 10/21/2015 at 9:46 AM observed a syringe on the second shelf of a rolling cart in the Pathology room. There were no staff members in the room. The Administrator was asked what is that syringe for and why was the syringe left unattended. The Administrator stated, "It was for today's procedure," Surveyor showed the syringe to the Administrator and the syringe was labeled "Lidocaine 10/20/2015." The syringe had been left from the the previous day procedures.<br>An interview with the Administrator on 10/21/2015 at 9:46 AM confirmed the above findings. | A 247 | The unused lidocaine syringe found on the rolling cart in the pathology room from the previous surgery day was immediately disposed of.<br><br>The Clinical coordinator performed a thorough check of all procedure rooms, pathology lab and nurse's station to ensure there are no unused medications. An in service will be facilitated to all surgical staff in order to ensure their understanding on the proper way to prepare medications for each day of services, and how to dispose of all unused medications at the end of session.<br><br>The Clinical Coordinator will be responsible for ensuring this practice is strictly followed, by conducting an end of day walk through and check of each procedure room, pathology lab, and nurses station. Findings will be immediately communicated to the Clinic Administrator. | |
| A 249 | TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards<br><br>J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.<br>(i) Sterilized items shall be transported so as to | A 249 | A249<br><br>The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed. | 11/30/15<br>12/9/15 |

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| A 249 | Continued From page 14<br>maintain cleanliness and sterility and to prevent physical damage.<br>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.<br>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.<br>(iv) Storage of supplies shall be in areas that are designated for storage.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.<br><br>FINDINGS:<br><br>During a tour of the facility on 10/20/2015, multiple peel pouches were stored in a plastic container in the pathology room. Also, the peel pouches were found in a blue tote bag on a rolling cart that was used for storage of the sterile instruments.<br><br>Approximately 20 peel packs were crushed and compressed in the plastic container which had no lid and was stored in the pathology room, where products of conception were examined and contaminated instruments were washed. The facility had no area designated for storage of sterile peel pouches.<br><br>An interview with Staff #3 on 10/20/2015 at approximately 11:00 AM confirmed the above findings. | A 249 | The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, have reorganized the area and identified storage space outside of the pathology and sterilization room. They have designated storage space on the surgical hall closet in order to adequately stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.<br><br>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.<br><br>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings. | |

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| A 255 | Continued From page 15 | A 255 | | |
| A 255 | TAC 139.49(d)(5)(K)(i)(ii)(iii) Infection Control Standards<br><br>(K) Disinfection.<br>(i) The manufacturer's written instructions for the use of disinfectants shall be followed.<br>(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.<br>(iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas.<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to follow the manufacturer's written instructions for the use of cold disinfectant (Cidex) utilized on surgical instruments. Also, the facility failed to provide a disinfectant log for the Cidex being utilized in the facility for the disinfection of surgical instruments.<br><br>Findings:<br><br>During the tour of the Pathology room on 10/21/21 at 9:47 AM revealed a large clear plastic container labeled Cidex. The container was covered, but there was no label to indicate when the Cidex was mixed. Also, under the sink in the pathology room was a gallon of open Cidex with no label as to when the container was open. There was a glass suction jar ¾ full with a green liquid substance and written on the side of the glass jar was Cidex. There was no label or date as to when the liquid substance was mixed.<br><br>During the tour of the Pathology room (where cold disinfectant was located) on 10/20/2015 at | A 255 | A255<br><br>The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the proper labeling and documenting of decontaminating solutions.<br><br>Whole Woman's Health of San Antonio uses the Metrex disinfection log which contains all the information required by the manufacturer's instructions. (See Attached)<br><br>This log tracks the date solution prep, expiration and staff preparing solution, this log is kept on a binder labeled Cidex OPA Plus log, and a memorandum directing staff to document on the solution's original container the date it was opened, and when it expires according to the manufacturer's instructions will be included in this binder as well as circulated during the infection control training scheduled for 11/30/15 | 11/30/15 |

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| A 255 | Continued From page 16<br>10:45, Staff #3 was asked where the cold disinfectant log was. Staff #3 stated, "I don't have a disinfectant log." During a tour of the Pathology room on 10/21/2015 at 9:50 AM, a disinfectant log was observed, but the log was blank.<br><br>A review of the log titled, "Solution Testing log Sheet for: Metricide OPA" revealed the date solution was opened was 10/9/2015 and the expiration date was 12/23/2015. The OPA-Cidex is only stable for 14 days from day the solution is mixed. This log location/department was written as Path room/Sonography. Staff #3 was asked on 10/20/2015 at 10:45 AM what was the green substance in the glass jar under the sink in the Pathology room. Staff #3 stated, "I don't know that belongs to the sonographer."<br><br>A review of the manufactures' guideline revealed the following:<br>"CIDEX OPA Solution may be reused for up to a Maximum of 14 days provided the required conditions of ortho-phthalaldehyde concentration and temperature exist based upon monitoring described in the Direction for use. Do not rely solely on day in use. Concentration of this product during its reuse life must be verified by the CIDEX OPA Solution Test Strips prior to each use to determine that the concentration of orto-phthalaldehyde if above the MEC of 3%. The Product must be discarded after 14 days.<br>Use CIDEX OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb ortho-phthalaldehyde from the air."<br>A review of the manufactures' guideline on the | A 255 | The Cidex solution currently in use by the pathology staff has been placed in a container with a tight lit. The Cidex used to disinfect the ultrasound transducer will be placed in a glass jar labeled with date the solution was prepared and the expiration date.<br><br>In order to ensure compliance with this requirement the Administrator will conduct a monthly audit of the Cidex log and a walk through of the pathology room to ensure this solution is properly stored and labeled. | |

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| A 255 | Continued From page 17<br>OPA gallon container revealed the following: "Usage: NO ACTIVATION IS REQUIRED. Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used.<br><br>Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC (Minimum Effective Concentration). "<br><br>An interview with the Staff #1 on 10/21/2015 at 11:00 AM confirmed the above findings. | A 255 | | |
| A 257 | TAC 139.49(d)(5)(L)(ii)(I - V) Infection Control Standards<br><br>(L) Performance records.<br>(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:<br>(I) the sterilizer identification;<br>(II) sterilization date and time;<br>(III) load number;<br>(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);<br>(V) identification of operator(s); | A 257 | A257<br><br>The clinic administrator will be responsible for ensuring all infection control standards are strictly followed by ensuring the Autoclave Load Log is completed and adequately tracks the performance of the autoclave. | 11/30/15 |

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| A 257 | Continued From page 18<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure.<br><br>Findings include:<br><br>Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave.<br><br>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclave.<br><br>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the load identification, date, time, duration and temperature of exposure phase during the operational phase of the autoclave.<br><br>A continued interview with Staff #3 confirmed these were all the autoclave records available. | A 257 | Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments.<br><br>A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave foe each load.<br><br>In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation and training needs. | |
| A 258 | TAC 139.49(d)(5)(L)((ii)(VI)(VII) Infection Control Standards<br><br>(L) Performance records.<br>(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall | A 258 | | 11/30/15 |

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| A 258 | Continued From page 19<br>be maintained either manually or machine generated and shall include:<br>(VI) results of biological tests and dates performed; and<br>(VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts).<br><br>This Requirement is not met as evidenced by:<br>Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure.<br><br>Findings include:<br><br>Observation on 10/20/2015 at 10:15 AM revealed a designated " Pathology" room with one (1) Pelton Delta Q autoclave.<br><br>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.<br><br>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave.<br><br>An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave. | A 258 | A 258<br><br>The Clinic Administrator will be responsible for ensuring all infection control standards are strictly followed. Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments.<br><br>A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave foe each load.<br><br>In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation. | 11/30/15 |

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| A 259 | Continued From page 20 | A 259 | | |
| A 259 | TAC 139.49(d)(5)(M) Infection Control Standards<br><br>(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review to the facility within two hours of request by the department.<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview, the facility failed to maintain preventive maintenance records for the autoclave.<br><br>Findings include:<br><br>Observation on 10/20/2015 at 10:15 AM revealed a designated " Pathology" room with one (1) Pelton Delta Q autoclave.<br><br>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.<br><br>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave. | A 259 | | 11/30/15 |

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 |
|---|---|---|---|
| | 140007 | A. BUILDING: _____ B. WING _____ | 10/21/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

| (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 |
|---|---|---|---|---|
| A 259 | Continued From page 21<br>An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave. | A 259 | | |