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 _____ | 08/29/2013 |

| 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 |
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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 entrance conference was conducted with the clinic Director of Operations of Whole Woman's Health of San Antonio. The purpose of the unannounced onsite survey (Initial licensure) and survey process were explained. An opportunity was provided for questions and discussion.<br><br>An Initial licensure survey was conducted per 25 TAC 139.31 to determine the abortion facility's compliance with the requirements at 25 TAC 139 (abortion facility licensing rules) using the applicable survey report form.<br><br>An exit conference was conducted with the Administrator of the abortion facility. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for questions and discussion.<br><br>No evidence of compliance was provided where noncompliance was identified. | A 000 | | |
| A 124 | [redacted] | A 124 | | |

SOD - State Form

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



§245.023

Texas Department of State Health Services

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| A 124 | Continued From page 1 [redacted] | A 124 | | |



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| A 321 | Continued From page 2 | A 321 | | |
| A 321 | 139.49(d)(5)(B) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<br>(B) Environmental requirements. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the written policies and procedures for their use shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment<br><br>This Requirement is not met as evidenced by:<br>1. Based on observations, review of staff training records, and staff interviews Whole Woman's Health of San Antonio failed to implement and enforce acceptable environmental controls in cleaning and preparing instruments for sterilization.<br>The findings included:<br>a. During an inspection of the sterile processing area with the clinic administrator at 11:45 a.m. on 8/28/13 staff member # 4 demonstrated the process for receiving, decontaminating, and processing surgical instruments. The demonstration revealed several functions performed in the small room were not distinctly separated and prevented the sequence of moving items from soiled to clean without cross contamination.<br>b. A review of staff files conducted on 8/29/13 revealed no evidence of staff training for environmental requirements.<br>c. Interviews with the administrator and the director of operations following their own review | A 321 | | |

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| A 321 | Continued From page 3<br>of the findings revealed they could not provide evidence of compliance with the requirement. | A 321 | | |
| A 333 | 139.49(d)(5)(F)(iii) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<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><br>This Requirement is not met as evidenced by:<br>1. Based on reviews of the autoclave and biological indicator logs, policy and procedures, and staff interviews Whole Woman ' s Health failed to follow the manufacturer ' s instructions for recording the results of the biological spore tests.<br>The findings included:<br>a. Reviews of the autoclave and biological indicator logs with the clinic administrator and director of operations conducted on 8/29/13 revealed staff members sporadically used biological indicators in the first load of the day and failed to record 24 hour and 48 hour test results as positive or negative as required.<br>b. A review of the policy and procedure " Protocol for Recording the Autoclave Sterilization Results in Load Logs " did not include instructions to document the results as positive or negative according to manufacturer ' s instructions.<br>c. Interviews with the clinic administrator and director of operations revealed they could not | A 333 | | |

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| A 333 | Continued From page 4<br>provide evidence of compliance with the requirements. | A 333 | | |
| A 335 | 139.49(d)(5)(F)(v) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<br>(F) Biological indicators.<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>1. Based on inspection of sterile packs, reviews of the autoclave and biological indicator logs, policy and procedures, and staff interviews Whole Woman ' s Health failed to identify and record items in a manner to be recalled following a sterilizer malfunction.<br>The findings included:<br>a. An inspection of sterile packs and autoclave logs conducted on 8/29/13 with the clinic administrator and staff member #4 revealed instrument packs or single items that had been already used could not be identified for recall.<br>b. After a review of the policy " Protocol for Recording the Autoclave Sterilization Results in Load Logs " and an interview with the director of operations following her review of the findings she could not provide evidence of compliance with the requirement. | A 335 | | |

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| A 347 | Continued From page 5 | A 347 | | |
| A 347 | 139.49(d)(5)(K)(i) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<br>(K) Disinfection.<br>(i) The manufacturer ' s written instructions for the use of disinfectants shall be followed.<br><br>This Requirement is not met as evidenced by:<br>1. Based on an inspection of disinfectants used in the facility and staff interviews Whole Woman ' s Health failed to follow manufacturer ' s instructions for the effective use of disinfectants to decontaminate or reduce the bio-burden in cleaning instruments prior to sterilization.<br>The findings included:<br>a .An Inspection of cidex in use in the sterile processing area at 12:00 p.m. with the clinical administrator on 8/29/13 staff member # 4 explained the facility ' s use of cidex for disinfecting instruments not suitable for steam sterilization. According to her - the solution was good for 28 days and she was responsible for checking the strength prior to each use. Upon testing the strength of the cidex the test strip revealed it failed and was ineffective for use.<br>b. An interview with the clinic administrator revealed the use of cidex was not being tracked with infection control or quality assurance activities. | A 347 | | |