

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 12/19/2012
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT			STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703		
(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 000	TAC 139 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An on-site unannounced survey was conducted on 12/18-19/2012 to determine the facility's compliance with the requirements of the Abortion Facility Reporting and licensing Rules. An entrance conference was conducted with the Administrator on 12/18/2012 at 12:45 PM in the Administrator's office. The purpose and process of the survey was explained and an opportunity was provided for questions and discussion. An exit conference was held in the Administrator's office on 12/19/2010 at 6:30 PM with the Administrator. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for questions and discussion.	A 000	<p style="text-align: center;">REVIEWED</p> <p style="text-align: center;">JAN 22 2013</p> <p style="text-align: center;"><i>Dr. Howells</i></p>		
A 119	[REDACTED]	A 119			

SOD - State F

LABORATORY

STATE FORM

SIGNATURE

TITLE
CORPORATE VICE PRESIDENT

(X5) DATE




01/14/13

0099

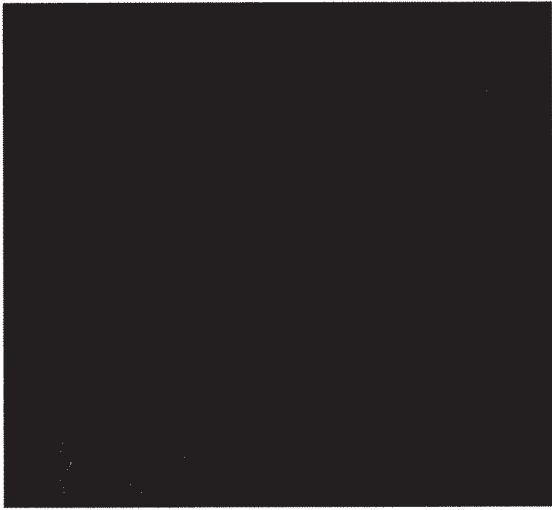
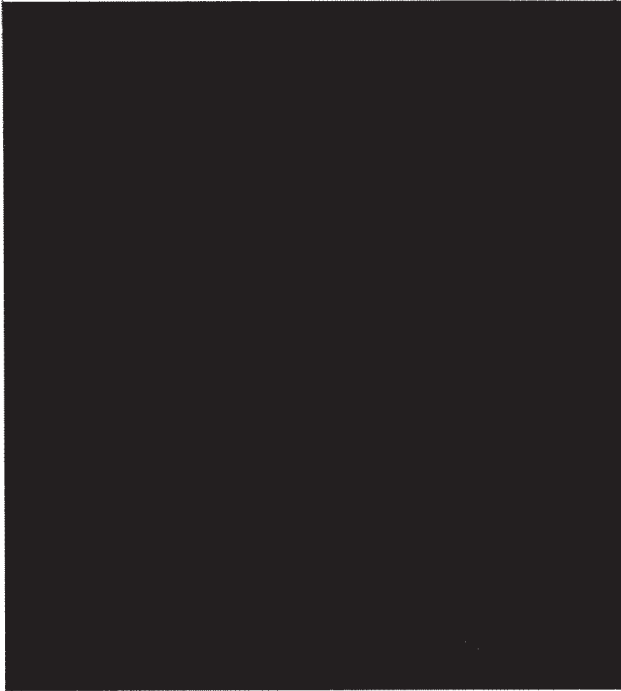

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If continuation sheet 1 of 27


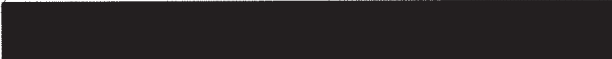


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A 119	Continued From page 1 	A 119	A119 
A 120		A 120	



Texas Department of State Health Services

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A 120	Continued From page 2 	A 120		
A 121		A 121		

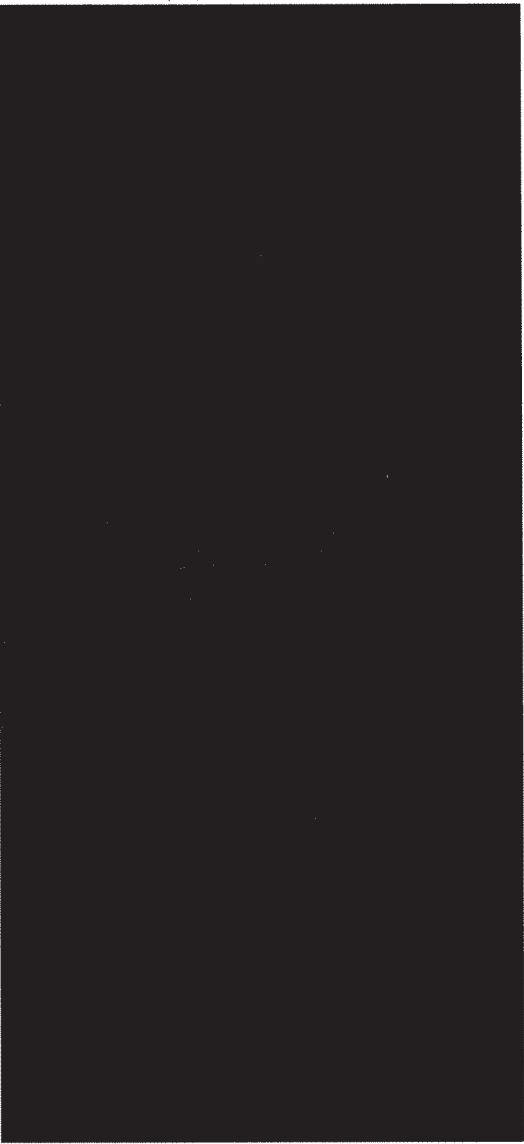
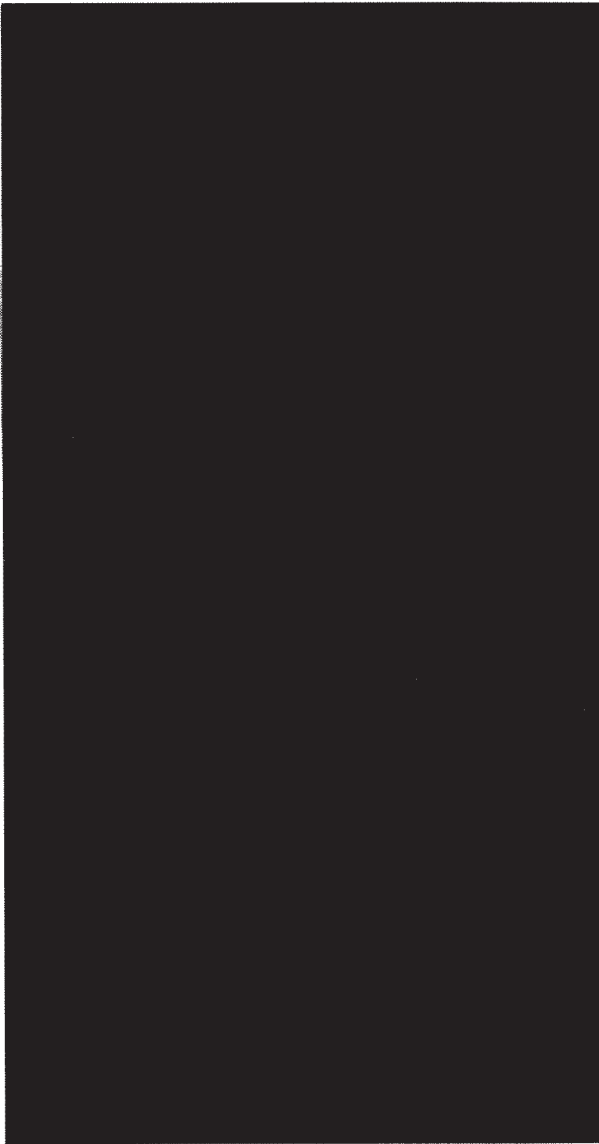
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A 121	Continued From page 3 	A 121	
A 125		A 125	


Texas Department of State Health Services

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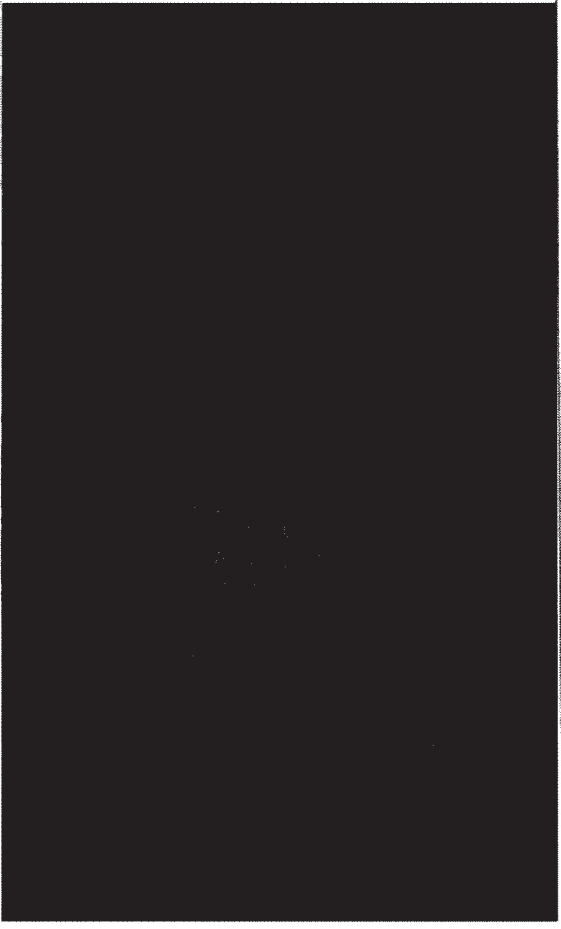

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A 126 A 126	Continued From page 5 	A 126 A 126	


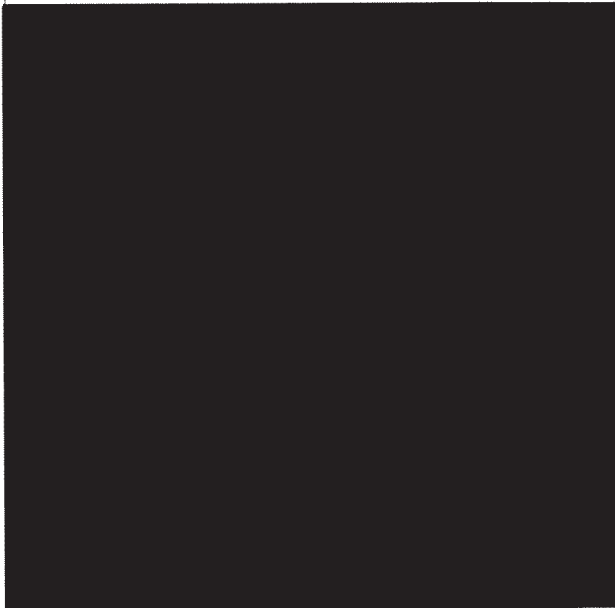
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A 126	Continued From page 6 	A 126		

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A 126	Continued From page 7 	A 126		
A 230		A 230		

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A 230	Continued From page 8 	A 230	
A 247	139.44(c) Orientation, Training, Competency (c) The facility shall ensure that staff responsible for sterilization of critical surgical instruments are trained by the facility to meet the requirements of §139.49(d) of this title (relating to Infection Control Standards) and demonstrate competency in performing the sterilization procedures at the facility.	A 247	

Texas Department of State Health Services

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A 247	Continued From page 9 This Requirement is not met as evidenced by: Based on demonstration and interview the facility failed to ensure the staff was trained in sterilization process of surgical instruments. Review of the policy titled "Whole Womans Health Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed "sterilized items will not be moved onto a non-sterile surface until dry inside and out." "Maintenance of Sterility 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. 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. 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. 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. D. Sterilized items will be handled in a manner that does not compromise the packaging of the product. E. Sterilized items will be transported as to maintain cleanliness and sterility and to prevent physical damage.	A 247	A 247 The Administrator will be responsible for ensuring the proper Orientation, Training, and Competency of all staff responsible for sterilization of critical surgical instruments. Training will be facilitated by the Director of Medical Services on Infection Control in order to address the following items: 1) Decontamination, Sterilization, and Storage of Sterile Supplies. 2) Autoclave Manufacturer's Instructions. 3) Proper handling of Instruments (clean vs. sterile) 4) Medication Therapy Practices. 5) Competency Evaluation. In order to ensure compliance, the Director of Medical Services will conduct random/unannounced inspections to address overall compliance. The first unannounced QA visit will happen within 60 days of this report.	04-15-13

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A 247	<p>Continued From page 10</p> <p>F. Sterilized items will be stored in the sterile area. This area has controlled ventilation and has restricted access.</p> <p>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."</p> <p>Observed during the tour on 12/18/2012 staff #7 had removed peel pouches from the steam sterilizer. The peel pouches were wet and moisture had collected inside the peel pouches. On touring the sterilization area and procedure rooms where sterile instruments were stored, found approximately twenty (20) peel pouches with water stain or discoloration noted on the sterile packages. 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 the sterilizer was loaded with 7 peel pouches and large speculum (instrument) on the day of tour. It was observed when the pouches were removed from the small sterilizer, the pouches were stacked on top of each other and the pouches were coming out of the sterilizer wet.</p> <p>Review of the autoclave load log for the last 6 months (6/5/2012 -12/18/2012) revealed 92 loads had been ran with multiple Tri Packs (instruments placed in a peel pouch) and single item instruments also placed in a peel pouch in one load. Documentation showed staff #2, #4, #6, and #7 had run loads in the small autoclave.</p> <p>A record review of an in-service titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" held for the staff on 2/9/2012 was presented by the Administrator. Observation, record review of autoclave load</p>	A 247		

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A 247	Continued From page 11 logs, and interview with staff members revealed the staff was still not knowledgeable in the proper procedure of sterilizing instruments and the facility had an infection control issues. An interview with the Administrator on 12/18/2012 at 4:30 PM confirmed there were multiple peel pouches with water stains found in the procedures rooms and sterilization area. Staff # 4, #6, #7, and including her did not have the training or knowledge to recognize the moisture in the peel pouches was an infection control issue. Also the in-service held back in February by the Administrator was not sufficient to educate the facility staff members on recognizing infection control issues.	A 247	
A 261	139.46(3)(B) Staffing Requirements (3) Direct patient care staff. (B) Nursing staff. The nursing staff shall include a registered nurse(s) or a licensed vocational nurse(s). This Requirement is not met as evidenced by: Based on record review and interview the facility failed to staff the clinic with a licensed vocational nurse (LVN) that meets the experience requirements according to the facility job description for a licensed vocational nurse (LVN). A review of the record titled "Job Description Licensed Vocational Nurse/Licensed Practical Nurse revealed, "Experienced required: One to two years of previous experience as an LVN. Previous experience in a clinical setting is preferred."	A 261	A261 The Clinic Administrator will be responsible for ensuring compliance with the Department's requirements for nursing staff. Whole Woman's Health has updated the Licensed Vocational Nurse Job Description to reflect the following criteria: Previous experience in a clinical setting preferred. To ensure compliance with the staffing needs required by the Departments as well as Whole Woman's Health policies and descriptions, the Human Resources Department will conduct a preliminary screening of applicants to filter those that meet the criteria.

01-31-13

Texas Department of State Health Services

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A 261	Continued From page 12 A review of staffing records and personnel records revealed the licensed vocational nurse in the facility did not meet the experience requirements according of the facility job description of having one to two years experience as a licensed vocational nurse. In the personnel record documentation showed staff # 9 obtained LVN license on 2/21/2012 and was hired 5/30/2012 which is only 4 months after license was obtained. An interview with staff #1 (Administrator) on 12/19/2012 at 3:30 PM, confirmed the full time licensed vocational nurse obtained licensed 2/21/2012 and was hired 5/30/2012. The Administrator confirmed the full time licensed vocational nurse did meet the experience requirements of the facility's job description.	A 261	
A 317	139.49(d)(4)(A) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (4) Items to be disinfected and sterilized. (A) Critical items. (i) Critical items include all surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body and shall be sterilized in accordance with this subsection. (ii) All items that come in contact with the sterile field during the operative procedure shall be sterile. This Requirement is not met as evidenced by: Based on observation and interview the facility failed to maintain the sterility of the surgical	A 317	A317 The Clinic Administrator will be responsible for ensuring Infection Control Standards are followed. Training will be facilitated by the Director of Medical Services on Infection Control in order to address the following items: 1) Decontamination, Sterilization, and Storage of Sterile Supplies. 2) Autoclave Manufacturer's Instructions. 3) Proper handling of Instruments (clean vs. sterile) 4) Medication Therapy Practices. 5) Competency Evaluation. In order to ensure compliance, the Administrator will inspect the integrity of surgical packs (CSR wrapped and sterilized) the night before surgical session for a period of 6 months, at this time an evaluation form will be completed for the staff responsible for sterilization, and successful compliance will conclude. Random spot checks will continue to take place from this point forward.

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A 317	Continued From page 13 instruments before coming into contact with the sterile field. During the tour of the facility on 12/18/2012 with staff #2 observed in the sterilization area and procedure rooms approximately twenty (20) peel pouches with water stain or discoloration noted on the sterile packages. These pouches were available for patient care use. Six surgical procedures had been performed that day. An interview with the Administrator on 12/18/2012 at 4:30 PM confirmed there were multiple peel pouches with water stains available for patient care use.	A 317		
A 320	139.49(d)(5)(A) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures. (A) Equipment. A licensed abortion facility shall provide sterilization equipment adequate to meet the requirements of this paragraph for sterilization of critical items. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of critical items.	A 320	A320 The Administrator will be responsible for ensuring follow through of Infection Control Standards 139.49 (d)(5)(A) 03-04-13 Corrective Action and Monitoring plan See A317, A126.	

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A 320	Continued From page 14 This Requirement is not met as evidenced by: Based on observation and interview the facility staff members (#2, #4, #6, and #7) failed to perform the correct procedure for the sterilization of the surgical instruments. Review of the policy titled "Whole Womans Health Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed "sterilized items will not be moved onto a non-sterile surface until dry inside and out." "Maintenance of Sterility 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. 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. 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. 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. D. Sterilized items will be handled in a manner that does not compromise the packaging of the product. E. Sterilized items will be transported as to maintain cleanliness and sterility and to prevent physical damage.	A 320		

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A 320	Continued From page 15 F. Sterilized items will be stored in the sterile area. This area has controlled ventilation and has restricted access. 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." Observed during the tour on 12/18/2012 staff #7 had removed peel pouches from the steam sterilizer. The peel pouches were wet and moisture had collected inside the peel pouches. On touring the sterilization area and procedure rooms where sterile instruments were stored, found approximately twenty (20) peel pouches with water stain or discoloration noted on the sterile packages. 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 the sterilizer was loaded with 7 peel pouches and large speculum (instrument) on the day of tour. It was observed when the pouches were removed from the small sterilizer, the pouches were stacked on top of each other and the pouches were coming out of the sterilizer wet. Interview with the Sterilizer Representative on 12/19/2012 at 10:00 AM at the facility revealed the sterilizer had a gasket leak and the door on the autoclave was not opening properly. Questioned when the safety checks were completed why were these problems not identified? He stated "that during the safety check only electrical safety is checked and not the functional checks of the equipment. The functional check is more expensive and the facilities do not want to pay for the functional check." The representative ran multiple loads that day to try and get the pouches to come out dry.	A 320		

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703		
(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 320	Continued From page 16 To receive a dry load only 2 pouches could be ran in a load. The representative also informed surveyor that the facility did have the appropriate trays in the sterilizer to sterilize the instruments correctly. Review of the autoclave load log for the last 6 months (6/5/2012 -12/18/2012) revealed 92 loads had been ran with multiple Tri Packs (instruments placed in a peel pouch) and single item instruments also placed in a peel pouch all in the same load. It was documented on the autoclave log that staff members #2, #4, #6, and #7 had ran loads in the small autoclave. An interview with the Administrator on 12/18/2012 at 4:30 PM confirmed there were multiple peel pouches with water stains and staff # 4, #6, #7, and including herself did not have the training or knowledge to recognize the moisture in the peel pouches was an infection control issue.	A 320		
A 328	139.49(d)(5)(D)(ii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (D) Packaging. (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. This Requirement is not met as evidenced by: Based on observation, record review, and interview the facility failed to document the date and time of sterilized, sterilizing load number, and autoclave.	A 328	A328 The Administrator will be responsible for ensuring proper follow through of Infection Control protocols, including accurate labeling of autoclaved instruments. Staff training will be facilitated to address the sterilization protocol, and proper labeling to include: 1) Date and time 2) Load # 3) Autoclave 4) Type of pack (1st tri pack, Lam pack, D&E, etc...) 5) Staff Initials In order to ensure compliance, the Administrator will inspect the proper sterilization record on the surgical packs the night before session for a period of 6 months, at this time an evaluation form will be completed for the staff responsible for sterilization, and successful compliance will conclude. Random spot checks will continue to take place from this point forward.	03-04-13

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 328	Continued From page 17 Observed on tour of the sterilization room on 12/18/2012 at approximately 4:00 PM the peel pouches in the sterilization room that were being removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and autoclave. An interview with the Administrator on 12/18/2012 at 5:00 PM confirmed there was missing documentation on the items coming from the autoclave load.	A 328	
A 339	139.49(d)(5)(H)(ii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (H) Maintenance of sterility. (ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer ' s recommendations. This Requirement is not met as evidenced by: Based on record review, observation, and interview, the facility failed to assure expired medications were removed from patient care areas. The facility also failed to require necessary documentation of the date multidose vials were opened and accessed. This lack of date makes it impossible to determine if the medication is beyond the safe use date as defined by the United States Pharmacopeia The US Pharmacopeia (USP 2008), General Chapter 797, Pharmaceutical Compounding/ Sterile Preparations, requires multidose vials to	A 339	A339 The Administrator will be responsible for ensuring the Medication Therapy Protocol is being followed. Training will be conducted by the Director of Medical Services on Medication Therapy Practices, as well as evaluate the competency of the staff working with medications. 03-04-13 In order to monitor the compliance with this requirement the Director of Medical Services will conduct an internal inspection, and evaluation of the clinics Infection Control and Patient Care within 60 days of this report.

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 339	Continued From page 18 be discarded 28 days after initial stopper penetration unless the manufacturer specifies otherwise. The vial should be labeled to reflect the penetration date or the beyond-use date. -United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations. Second Edition, June 1, 2008. Observed on tour of the facility on 12/18/2012 in the laboratory area where the medication refrigerator is kept 2 bottles of Depo-Provera. The first bottle of Depo-Provera was opened with the date of 11/1/2012. Second bottle had no label of when the vial was opened. An interview with the Administrator on 12/18/2012 at 5:30 PM confirmed the multidose vials of Depo-Provera had one expired and the other bottle not labeled with a date of when the vial was opened.	A 339		
A 340	139.49(d)(5)(H)(iii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (H) Maintenance of sterility. (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. This Requirement is not met as evidenced by: Based on observation and interview the facility failed to maintain the sterility of the surgical instruments. Observed during the tour on 12/18/2012 staff #7	A 340	A 340 The Administrator will be responsible for insuring compliance with Infection Control Standards 139.49 (d)(5)(H)(iii) Corrective Action, See A317, and A326.	03-04-13

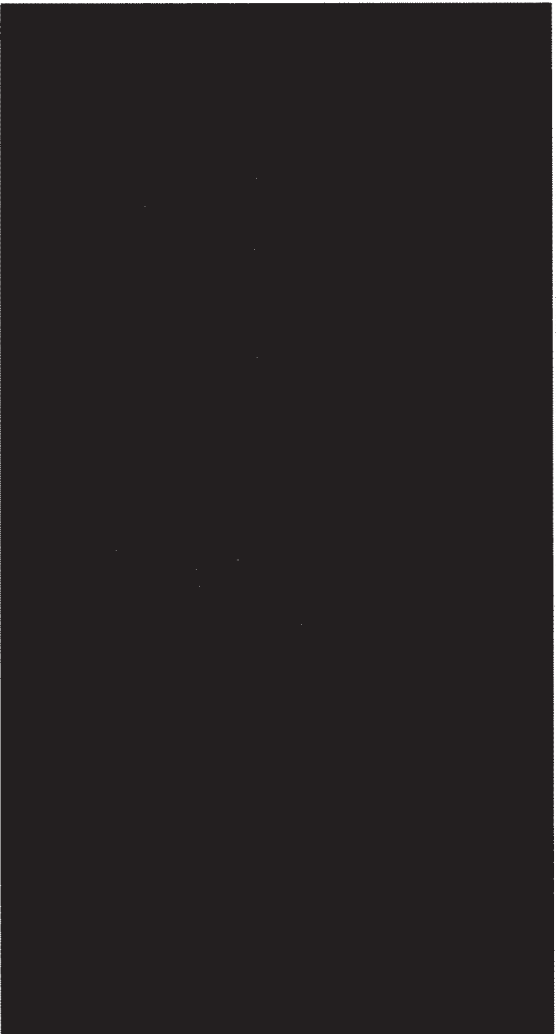


Texas Department of State Health Services



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A 340	Continued From page 19 was removing peel pouches from the steam sterilizer. The peel pouches were wet and moisture had collected inside the peel pouches. On touring the sterilization area and procedure rooms where sterile instruments were stored, found approximately twenty (20) peel pouches with water stain or discoloration noted on the sterile packages. 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 the sterilizer was loaded with 7 peel pouches and large speculum (instrument) on the day of tour. It was observed when the pouches were removed from the small sterilizer, the pouches were stacked on top of each other and pouches were coming out of the sterilizer wet. Interview with staff #7 12/18/2012, questioned do you know wet packages and moisture in the peel pouches is an infection control issues? Staff #7 stated "no." An interview with the Administrator on 12/18/2012 at 4:30 PM confirmed there were multiple peel pouches with water stains and staff #7, did not have the training or knowledge to recognize the moisture in the peel pouches was a infection control issue.	A 340		
A 351	139.49(d)(5)(L)(ii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (L) Performance records. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall	A 351		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 351	Continued From page 20 be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) identification of operator(s); (VI) results of biological tests and dates performed; and; (VII) time-temperature recording charts from each sterilizer(if not provided on sterilizer recording charts). This Requirement is not met as evidenced by: Based on observation, record review, and interview the facility failed to document the date and time of sterilizer load, sterilizing load number, or the type of sterilizer on 40 of 112 loads. Review of the autoclave load log for the last 6 months (6/5/2012 -12/18/2012) revealed 40 of 112 loads had missing documentation (date and time of sterilizer load, sterilizing load number, or the type of sterilizer). 6/8/12---no documented time on load #1, 6/8/12---no documented autoclave name or number on load #2 6/9/12---no documented autoclave number on load #1 6/12/12---no documented time on load #1 6/13/12---no documented time on load #1 6/21/12---no documented time on load #2 6/23/12---no documented time on load #1 6/25/12---no documented time on load #1 7/2/12---no documented time on load #1 7/5/12---no documented time on load #3	A 351	A351 The Clinic Administrator will be responsible for ensuring all sterilization practices are compliant with Infection Control Standards. Training will be facilitated by the Director of Medical Services in order to address the proper documentation of sterilization practices on the Autoclave log. Note: Whole Woman's Health did not report an increase of patient infection complications during the time period noted on this deficiency report (06-05-12 to 12-18-12). In order to monitor compliance with Infection Control Standards the Administrator will conduct an audit of the Autoclave Log every day after sterilization is complete for a period of 6 months. At this time an evaluation form will be completed for the staff responsible for sterilization, and successful compliance will conclude.	03-04-13

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 351	Continued From page 21 7/10/12---no documented time on load #1 7/11/12---no documented time on load #1 7/11/12---no documented time on load #2, load number documented was in correct. 7/12/12---no documented time on load #1 7/13/12---no documented time on load #2, no contents documented of what was in the load 7/14/12---no documented time on load #1 7/16/12---no documented time on load #1 7/17/12---no documented time on load #1 7/18/12---no documented time on load #1 7/28/12---no documented time on load #1 8/1/12---no documented time on load #1 8/7/12---no documented time on load #1 8/9/12---no documented time on load #1 8/15/12---no documented time on load #1 8/21/12---no documented time on load #1 8/25/12---no documented time on load #1 9/7/12---no documented time on load #1 9/20/12---no documented time on load #1 9/24/12---no documented time on load #1 10/2/12---documented in the wrong area on the load form 10/3/12---no documented autoclave number on load #1 10/10/12---no documented time on load #1 10/13/12---no documented date on load #1 10/29/12---no documented time on load #1 Between 10/31/12 and 11/10/12 no documented dates of loads ran and only found one load in a weeks time , but no documented date. 11/27/12---no documented time on load #1 12/8/12---no documented time on load #1 12/8/12---no documented autoclave name or number on load #2 12/12/12---no documented time on load #1 12/18/12---no documented time on load #1 An interview with the Administrator on 12/18/2012 at 5:30 PM confirmed there was missing documentation on the autoclave load log.	A 351		

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A 422		A 422	A422 
A 423		A 423	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 423	Continued From page 23 	A 423		
A 444	139.56(a) Emergency Services (a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility have admitting privileges or have a working arrangement with a physician(s) who has admitting privileges at a local hospital in order to ensure the necessary back up for medical complications.	A 444		

Texas Department of State Health Services

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A 444	Continued From page 24 This Requirement is not met as evidenced by: Based on observation, record review, and interview the facility failed to follow their own Emergency Medical Protocol for a patient transfer to the hospital. A review of the record titled "Emergency Medical Protocol" revealed "Only a physician licensed in the State of Texas can diagnose, treat, and release a patient from care in this office. If the physician feels that the patient 's care can be managed within the resources of Whole Woman ' s Health, appropriate medical care will be given according to acceptable medical standards. If the physician determines that a patient ' s medical emergency cannot be managed within the resources of this office, the patient will be transported by the physician or via ambulance to an appropriate hospital." An interview with the facility physician on 12/19/2012 at 10:00 AM revealed a patient had increase bleeding problem after the abortion procedure had been completed. The patient was transferred by private car to the local hospital. A review of the record titled "Complication Log " for the past year of 2012, revealed no documentation of a patient having a bleeding complication after an abortion procedure. An interview within the Administrator on 12/19/2012 at 10:30 AM confirmed the patient was transferred to the local hospital for a bleeding complication. Also confirmed by the Administrator the complication log does not contain any information about this occurrence or that the facility documented that the bleeding complication occurred.	A 444	A444 Whole Woman's Health of Beaumont is compliant with the Department's requirements for Emergency Services 139.56(a) Whole Woman's Health has and follows a written Medical Emergency Protocol, and the physician has admitting privileges at a local hospital. Whole Woman's Health of Beaumont Medical Emergency Protocol states: "Only a physician licensed in the state of Texas can diagnose, treat, and release a patient from care in this office. (Staff #1 is a Texas Licensed physician that diagnosed, treated, and released the patient from our facility) If the physician feels that the patient's care can be managed within the resources of Whole Woman's Health, appropriate Medical care will be given according to acceptable medical standards. (The physician treated the patient's post op bleeding onsite, with surgical intervention and medication therapy according to the standard of care.) If the physician determines that a patient's medical emergency cannot be managed within the resources of this office, the patient will be transported by the physician, or via ambulance to an appropriate hospital. (The physician's judgment was that the patient was stable, ambulatory, non emergent, and did not required transfer. The physician referred the patient to meet him at the hospital for observation only.)"	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/19/2012
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A 455	<p>139.57(c)(1)(B) Discharge and Follow-up</p> <p>(c) The facility shall develop and implement written policies and procedures for: (1) examination or referral of all patients who report complications, as identified in the list required by subsection (a)(1) of this section, to the facility after an abortion procedure. The written policy and procedure shall require: (B) documentation of the facility's action following a patient's reporting of post-abortion complications to be placed in the patient's record; and</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview the facility failed to document a post-abortion complication.</p> <p>An interview with the facility physician on 12/19/2012 at 10:00 AM revealed a patient had increase bleeding problem after the abortion procedure had been completed. The patient was transferred by private car to the local hospital.</p> <p>A review of the record titled "Complication Log " for the past year of 2012, revealed no documentation of a patient having a bleeding complication after an abortion procedure.</p> <p>Surveyor asked for occurrence reports for the facility and the Administrator reported that the facility had not had any occurrences.</p> <p>An interview within the Administrator on 12/19/2012 at 10:30 AM confirmed the patient was transferred to the local hospital for a bleeding complication. Also confirmed by the Administrator the complication log does not contain any information about this occurrence or that the</p>	A 455	<p>A455</p> <p>The Administrator will be responsible for ensuring discharge and follow up protocols are strictly followed.</p> <p>Whole Woman's Health of Beaumont will create a protocol for Physician identification of perioperative complications as well as postoperative complications.</p> <p>The Director of Medical Services will facilitate training for the staff on the above mentioned definitions of complication.</p> <p>The physician will identify the complications, and the staff will track them, by utilizing the Complication log established in the facility.</p> <p>The Administrator will trend the findings for the Medical Director to review and assess the need for case review or performance improvement.</p> <p>The Director of Medical Service, as well as the Medical Director will monitor the Complications log on a quarterly basis during Quality Assurance analysis.</p>	03-04-13

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A 455	Continued From page 26 facility documented that the bleeding complication occurred.	A 455		