Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B. WING 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER AAR 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (XS) COMPLETE (X4) (D (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 000 TAC 139 Initial Comments A 000 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 REVIEWED space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. JAN 2 2 2013 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 119 A 115 SOO - State F CORDULATE VICE PRESIDENT SIGNATURE LABORATORY STATE FORM

Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL PROVIDER'S PLAN OF CORRECTION (XS) COMPLETE DATE PREFIX TAG (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) A 119 Continued From page 1 A 119 A119 A 120 A 120 SOD - Slate Form STATE FORM 83V411 If continuation sheet 2 of 27

Texas Department of State Health Services (X3) DATE SURVEY COMPLETED STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B. WING ___ 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 (X5) COMPLETE DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION 10 (X4) ID (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) PREFIX PREFIX TAG TAG DEFICIENCY) A 120 Continued From page 2 A 120 A120 A 121 A 121 SOD - State Form STATE FORM 6689 If continuation sheet, 3 of 27 83V411

Texas Department of State Health Services (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION COMPLETED ANO PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING 8. WING ___ 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 (X5) COMPLETE PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PREFIX ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) A 121 A 121 Continued From page 3 A 121 A 125 A 125 SOD - State Form 6194 If continuation sheet, 4 of 27 STATE FORM 83V411

If continuation sheet 5 of 27

Texas Department of State Health Services (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WING __ 12/19/2012 008137 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCEO TO THE APPROPRIATE TAG DEFICIENCY) A 125 A 125 Continued From page 4 A 125 SOD - State Form

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B. WNG_ 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 (XS) COMPLETE DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX TAG TAG DEFICIENCY) A 126 Continued From page 5 A 126 A 126 A 126

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STATEMENT OF DEFICIENCIES (X3) DATE SURVEY COMPLETED (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B. WNG _ 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (X5) COMPLETE DATE (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) A 126 | Continued From page 6 A 126 SCD - State Form

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WING __ 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) A 126 Continued From page 7 A 126 A 230 A 230 SOD - State Form STATE FORM If continuation sheet 8 of 27

Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED DENTIFICATION NUMBER. A. BUILDING B. WNG __ 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) IO 103 (X5) COMPLETE DATE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) A 230 Continued From page 8 A 230 A 247 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.

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A RUUDING B. WING 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID OX 53 (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLETE PREFIX PREFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) A 247 Continued From page 9 A 247 This Requirement is not met as evidenced by: Based on demonstration and interview the facility failed to ensure the staff was trained in A 247 sterilization process of surgical instruments. The Administrator will be responsible for Review of the policy titled "Whole Womans ensuring the proper Orientation, Training, Health Decontamination, Disinfection, and Competency of all staff responsible for Sterilization, and Storage of Sterile Supplies" sterilization of critical surgical instruments. revealed "sterilized items will not be moved onto 04-15-13 a non-sterile surface until dry inside and out." Training will be facilitated by the Director of "Maintenance of Sterility Medical Services on Infection Control in Items that are packaged properly will remain order to address the following items: Decontamination, Sterilization, and sterile unless the package becomes wet or torn. has a broken seal, is damaged in some way, or is Storage of Sterile Supplies. Autoclave Manufacturer's suspected of being compromised. Commercially Instructions. packaged items will be considered sterile Proper handling of Instruments according to the manufacturer's instructions. (clean vs. sterile) A. All packages will be inspected before use. If a Medication Therapy Practices. package is torn, wet, discolored, has a broken 5) Competency Evaluation. seal, or is damaged, the item will be returned to the sterile area for In order to ensure compliance, the Director reprocessing/sterilizing. of Medical Services will conduct B. The indicator tape on the outside and on the random/unannounced inspections to inside of the pack will be checked address overall compliance. The first unannounced QA visit will happen within 60 before the instruments are used. If the indicator tape did not change the pack will be returned to days of this report. 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

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prevent physical damage

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FORM APPROVED Texas Department of State Health Services (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CUA (X2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A BUILDING 8 WING 12/19/2012 008137 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 PROVIDER'S PLAN OF CORRECTION (X4) IO SUMMARY STATEMENT OF DEFICIENCIES (X.5) (EACH CORRECTIVE ACTION SHOULD BE COMPLETE FACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX DATE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY A 247 A 247 Continued From page 10 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. 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. A record review of an in-service titled "Decontamination, Disinfection, Sterilization, and

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Storage of Sterile Supplies" held for the staff on 2/9/2012 was presented by the Administrator. Observation, record review of autoclave load

Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CUIA (X3) DATE SURVEY OX20 MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES (X4) IO PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLETE TAG REGULATORY OR LSC IDENTIFYING INFORMATION CROSS-REFERENCED TO THE APPROPRIATE TAG DATE **DEFICIENCY**) A 247 Continued From page 11 A 247 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 261 139.46(3)(B) Staffing Requirements A 261 (3) Direct patient care staff. A261 (8) Nursing staff. The nursing staff shall include a registered nurse(s) or a licensed vocational The Clinic Administrator will be responsible nurse(s). for ensuring compliance with the Department's requirements for nursing staff. Whole Woman's Health has updated the Licensed Vocational Nurse Job Description This Requirement is not met as evidenced by: to reflect the following criteria: Previous Based on record review and interview the facility experience in a clinical setting preferred. 01-31-13 failed to staff the clinic with a licensed vocational To ensure compliance with the staffing needs nurse (LVN) that meets the experience required by the Departments as well as requirements according to the facility job Whole Woman's Heath policies and description for a licensed vocational nurse (LVN). descriptions, the Human Resources Department will conduct a preliminary A review of the record titled "Job Description screening of applicants to filter those that Licensed Vocational Nurse/Licensed Practical meet the criteria. Nurse revealed, "Experienced required: One to two years of previous experience as an LVN. Previous experience in a clinical setting is

preferred."

Texas Department of State Health Services (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING 8. WING 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD SE PREFIX PREFIX REGULATORY OR LISC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY A 261 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. A317 licensed vocational nurse obtained licensed 2/21/2012 and was hired 5/30/2012. The The Clinic Administrator will be responsible for ensuring Infection Control Standards are Administrator confirmed the full time licensed followed. vocational nurse did meet the experience requirements of the facility's job description. Training will be facilitated by the Director of Medical Services on Infection Control in A 317 A 317 139.49(d)(4)(A) Infection Control Standards order to address the following items: 1) Decontamination, Sterilization, and (d) Policies and procedures for decontamination, Storage of Sterile Supplies. disinfection, sterilization, and storage of sterile Autoclave Manufacturer's supplies. (4) Items to be disinfected and Instructions. Proper handling of Instruments sterilized. (clean vs. sterile) (A) Critical items. Medication Therapy Practices. (i) Critical items include all surgical instruments 5) Competency Evaluation. and objects thatare introduced directly into the bloodstream or into other normally sterile areas of In order to ensure compliance, the 03-04-13 the body and shall be sterilized in accordance Administrator will inspect the integrity of with this subsection surgical packs (CSR wrapped and sterilized) (ii) All items that come in contact with the sterile the night before surgical session for a period field during the operative procedure shall be 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 This Requirement is not met as evidenced by: to take place from this point forward.

Based on observation and interview the facility failed to maintain the sterility of the surgical

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION (DENTIFICATION NUMBER:				(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED
		008137		B. WING		12/19/2012
NAME OF PR	OVIDER OR SUPPLIER		STREET ADDRE	SS, CITY, STATE	ZIP CODE	
WHOLE W	OMANS HEALTH OF BE	AUMONT	440 18TH ST BEAUMONT,			
(X4) ID PREFIX TAG	X (EACH DEFICIENCY MUST BE PRECEDED BY FULL			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTS (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE COMPLETE
A317	sterile field. During the tour of the staff #2 observed in the procedure rooms approaches with water son the sterile package available for patient of procedures had been An interview with the at 4:30 PM confirmed	ming into contact with facility on 12/18/2012 he sterilization area and proximately twenty (20) tain or discoloration no es. These pouches were care use. Six surgical	with d peel ted re	A317		
A 320	(d) Policies and procidisinfection, sterilization supplies. (5) Equipment and si Effective sterilization performing correct magnets packaging, arranger and storage. The foll included in the writte subsection to provide measures. (A) Equipment. A lice provide sterilization of the requirements of the requirements of the control of critical items.	edures for decontamination, and storage of sterilization procedures of instruments depending the first of items in the sterilization procedures shall need to fitems in the sterilization defective sterilization ensed abortion facility sequipment adequate to this paragraph for sterilization of court, the sterilization of court,	ation, rile Is on ilizer, I be In this shall meet ization	A 320	A320 The Administrator will be resporensuring follow through of Infect Standards 139.49 (d)(5)(A) Corrective Action and Monitorin A317, A126.	tion Control 03-04-13

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WING 008137 12/19/2012 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIED 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID Ю (XS) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX REGULATORY OR LISC IDENTIFYING INFORMATIONS . TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY A 320 Continued From page 14 A 320 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

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prevent physical damage.

FORM APPROVED Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION DENTIFICATION NUMBER COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) (EACH DEFICIENCY MUST BE PRECEDED BY FULL) COMPLETE PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) A 320 Continued From page 15 A 320 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 peal pauches 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

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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.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/O		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	008137		B. WING		12/19/2012	
NAME OF PROVIDER OR SUPPLIER		STREET ADDRE	SS, CITY, STAT	E, ZIP CODE		
WHOLE WOMANS HEALTH OF B	EAUMONT	440 18TH ST BEAUMONT,				
PREFIX (EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FU LSC IDENTIFYING INFORMATI		ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION ACH CORRECTIVE ACTION SHOULD BE SS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	
A 320 Continued From page	e 16		A 320			
To receive a dry load in a load. The repressurveyor that the fact trays in the sterilizer correctly. Review of the autocoments (6/5/2012 -1 had been ran with melaced in a peel polinstruments also plassame load. It was delog that staff members loads in the small at	f only 2 pouches could light and the instrument of the sterilize the s	oriate ents 6 loads ments in the clave ad ran 8/2012 eet #7, ng or peel rds action, erile zer , the	A 328	The Administrator will be responsensuring proper follow through of Control protocols, including accurlabeling of autoclaved instrument. Staff training will be facilitated to the sterilization protocol, and protocinclude: 1) Date and time 2) Load # 3) Autoclave 4) Type of pack (1st tri pack pack, D&E, etc) 5) Staff Initials In order to ensure compliance, the Administrator will inspect the protocomplete for the staff responsitive sterilization, and successful commontude. Random spot checks we continue to take place from this forward.	Infection rate s. address per labeling c., Lam he roper al packs the of 6 on form will ole for pliance will will	03-04-13

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		008137		B. WING		12/19/	2012
NAME OF PRO	VIDER OR SUPPLIER		STREET ADDRE	SS, CITY, STAT	E, ZIP CODE		
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A 339	12/18/2012 at approx pouches in the sterilizer removed from the autidate and time sterilizer and autoclave. An interview with the at 5:00 PM confirmed documentation on the autoclave load. 139.49(d)(5)(H)(ii) Interview autoclave load. (d) Policies and procedisinfection, sterilizate supplies. (5) Equipment and sterilizate supplies. (ii) Medication or mandeteriorate with the produced according to the recommendations. This Requirement is Based on record reviate interview, the facility medications were reareas. The facility all documentation of the opened and accesse impossible to determ beyond the safe use United States Pharm	he sterilization room on imately 4:00 PM the peration room that were be toclave were not labeled, sterilizing load number of the sterilization of 12/18 of there was missing elitems coming from the fection Control Standard edures for decontamination, and storage of sterilization procedures. Iterilization procedures the sterilization procedures of the sterilization procedures of the sterilization procedures. Iterilization procedures of the shall be the manufacturer in the manufacturer in the manufacture of the sterilization procedures of the sterilization procedures of the shall be the manufacturer in the manufacture of the manufacture of the manufacture of the medication is of date as defined by the nacopeia	being d with ber, 1/2012 de	A 339	A339 The Administrator will be responsensuring the Medication Therapy being followed. Training will be conducted by the Medical Services on Medication Therapy as well as evaluate the coff the staff working with medication of the staff working with medication of the clinical inspection evaluation of the clinics Infection and Patient Care within 60 days or report.	Protocol is Director of Therapy competency ions. ce with this ical Services in, and Control	03-04-13
	Chapter 797, Pharm	eia (USP 2008), Gener laceutical Compoundin , requires multidose via	g/				uursonagereneovenseeren eaapopoigipagiinaaliinaa

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PRINTED: 01/09/2013 FORM APPROVED Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE AAR 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 (X4) IO SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (XS) COMPLETE EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY A 339 Continued From page 18 A 339 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, 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 340 139.49(d)(5)(H)(iii) Infection Control Standards A 340 (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A 340 (5) Equipment and sterilization procedures. (H) Maintenance of sterility. The Administrator will be responsible for (iii) All packages shall be inspected before use. If insuring compliance with Infection Control a package is torn, wet, discolored, has a broken 03-04-13 Standards 139.49 (d)(5)(H)(iii) seal, or is damaged, the item may not be used. The item shall be returned to sterile processing Corrective Action, See A317, and A326.

for reprocessing.

instruments.

This Requirement is not met as evidenced by: Based on observation and interview the facility failed to maintain the sterility of the surgical

Observed during the tour on 12/18/2012 staff #7

Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CUA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION DENTIFICATION NUMBER: COMPLETED A BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (XS) (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLETE DATE TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) A 340 Continued From page 19 A 340 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 slain or discoloration noted on the sterile packages. A review of the of the steam sterilizer operation quide 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 351 139.49(d)(5)(L)(ii) Infection Control Standards A 351 (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

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operation for pressure, temperature, and time at desired temperature and pressure. A record shall

Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION CROSS-REFERENCED TO THE APPROPRIATE TAG DATE **DEFICIENCY** A 351 Continued From page 20 A 351 be maintained either manually or machine generated and shall include: (I) the sterilizer identification: (II) sterilization date and time: (III) load number; A351 (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); The Clinic Administrator will be responsible (V) identification of operator(s); for ensuring all sterilization practices are (VI) results of biological tests and dates compliant with Infection Control Standards. performed; and; (VII) time-temperature recording charts from Training will be facilitated by the Director of Medical Services in order to address the each sterilizer(if not provided on sterilizer proper documentation of sterilization recording charts). 03-04-13 practices on the Autoclave log. Note: Whole Woman's Health did not report This Requirement is not met as evidenced by: an increase of patient infection Based on observation, record review, and complications during the time period noted interview the facility failed to document the date on this deficiency report (06-05-12 to 12-18and time of sterilizer load, sterilizing load number, 12) or the type of sterilizer on 40 of 112 loads. In order to monitor compliance with Review of the autoclave load log for the last 6 Infection Control Standards the months (6/5/2012 -12/18/2012) revealed 40 of Administrator will conduct an audit of the 112 loads had missing documentation (date and Autoclave Log every day after sterilization is time of sterilizer load, sterilizing load number, or complete for a period of 6 months. At this time an evaluation form will be completed the type of sterilizer). for the staff responsible for sterilization, and successful compliance will conclude. 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 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

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION Ю (X5) COMPLETE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION TAG DATE DEFICIENCY) A 422 A 422 A422 A 423 A 423 SOD - State Form STATE FORM 6899

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Texas Department of State Health Services STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION (X3) DATE SURVEY IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING 008137 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (XS) PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLETE DATE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) A 423 Continued From page 23 A 423 A 423 A 444 139.56(a) Emergency Services A 444 (a) A ficensed 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, SOD - State Form STATE FORM

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Texas Department of State Health Services FORM APPROVED STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION (X3) DATE SURVEY IDENTIFICATION NUMBER: COMPLETEN A. BUILDING B. WING 12/19/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A WHOLE WOMANS HEALTH OF BEAUMONT BEAUMONT, TX 77703 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) COMPLETE CROSS-REFERENCED TO THE APPROPRIATE TAG DATE DEFICIENCY) A 444 Continued From page 24 A 444 This Requirement is not met as evidenced by: A444 Based on observation, record review, and interview the facility failed to follow their own Whole Woman's Health of Beaumont is Emergency Medical Protocol for a patient transfer compliant with the Department's requirements for Emergency Services to the hospital. 139.56(a) A review of the record titled "Emergency Medical Whole Woman's Health has and follows a Protocol" revealed "Only a physician licensed in written Medical Emergency Protocol, and the the State of Texas can diagnose, treat, and physician has admitting privileges at a local release a patient from care in this office. If the hospital. physician feels that the patient 's care can be managed within the resources of Whole Woman ' Whole Woman's Health of Beaumont s Health, appropriate medical care will be given Medical Emergency Protocol states: "Only a according to acceptable medical standards. If the physician licensed in the state of Texas can physician determines that a patient 's medical diagnose, treat, and release a patient from emergency cannot be managed within the care in this office. (Staff #1 is a Texas resources of this office, the patient will be Licensed physician that diagnosed, treated, and released the patient from our facility) If transported by the physician or via ambulance to the physician feels that the patient's care can an appropriate hospital." be managed within the resources of Whole Woman's Health, appropriate Medical care An interview with the facility physician on will be given according to acceptable medical 12/19/2012 at 10:00 AM revealed a patient had standards. (The physician treated the increase bleeding problem after the abortion patient's post op bleeding onsite, with procedure had been completed. The patient was surgical intervention and medication transferred by private car to the local hospital. therapy according to the standard of care.) If the physician determines that a patient's A review of the record titled "Complication Log" medical emergency cannot be managed for the past year of 2012, revealed no within the resources of this office, the patient will be transported by the physician, or via documentation of a patient having a bleeding complication after an abortion procedure. ambulance to an appropriate hospital. (The physician's judgment was that the patient An interview within the Administrator on was stable, ambulatory, non-emergent, and did not required transfer. The physician 12/19/2012 at 10:30 AM confirmed the patient referred the patient to meet him at the was transferred to the local hospital for a bleeding hospital for observation only.) 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

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A 455	139.57(c)(1)(B) Disch	arge and Follow-up		A 455			
	written policies and pr (1) examination or ref report complications, required by subsection the facility after an ab- policy and procedure (B) documentation of following a patient's	erral of all patients who as identifiedin the list n (a)(1) of this section, ortion procedure. The w shall require:	to vritten		A455 The Administrator will be response ensuring discharge and follow up pare strictly followed. Whole Woman's Health of Beaumoreate a protocol for Physician ider of perioperative complications as a postoperative complications.	orotocols ont will ntification vell as	
	Based on observation interview the facility farabortion complication. An interview with the facility farabortion complication. An interview with the facility farabortion complication. An interview with the facility farabortion complication for the farabortion farabortion.	illed to document a pos t.	nad was		The Director of Medical Services w facilitate training for the staff on the mentioned definitions of complicate. The physician will identify the com and the staff will track them, by util Complication log established in the The Administrator will trend the fit the Medical Director to review and need for case review or performance improvement.	ne above tion. aplications, dizing the efacility.	03-04-13
	A review of the record for the past year of 20 documentation of a pa complication after an Surveyor asked for or facility and the Admin	I titled "Complication Li 112, revealed no atient having a bleeding abortion procedure, courrence reports for th istrator reported that th	og"		The Director of Medical Service, as the Medical Director will monitor t Complications log on a quarterly be during Quality Assurance analysis.	he asis	
	was transferred to the complication. Also co the complication log of	e Administrator on AM confirmed the patie local hospital for a ble nfirmed by the Adminis	eding trator				

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