



# WHOLE WOMAN'S HEALTH OF McALLEN, LLC

Transforming Healthcare, One Woman at a Time

A249

*TAC 139.49 (d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards.*

*(J)Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling in a manner that does not compromise the packaging of the product.*

*(i) Sterilize items shall be transported so as to maintain cleanliness and sterility to prevent physical damage.*

*(ii) Sterilized items shall be stored in a well ventilated, limited access areas, with controlled temperature and humidity.*

*(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised for storage.*

Whole Woman's Health of McAllen complies with this requirement by storing sterile packs, and pouches in a cabinet on the clean side of the pathology room with a clear designation between the clean and dirty areas. All pouches and packs were in perfect condition, properly stacked and stored in the clean designated area, after steam sterilizing peel pouches the appearance of the paper changes to a wrinkled look due to the paper reacting to steam. This does not mean the pouches were crushed, or compromised.

Whole Woman's Health of McAllen, LLC does not agree with deficiencies A201 and A249 listed in the attached report and we assert that we are in full compliance.

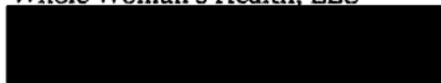
If further information is required, please do not hesitate to contact me.

Respectfully,



Corporate Vice President

Whole Woman's Health, LLC



802 South Main Street • McAllen, Texas 78501 • ph: 956.686.2137 • fax: 956.686.2149

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# WHOLE WOMAN'S HEALTH OF McALLEN, LLC

Transforming Healthcare, One Woman at a Time

[REDACTED]  
Corporate Vice President  
Whole Woman's Health, LLC

January 5, 2016

Larrie Collier, Manager  
Health Facility Compliance San Antonio Group  
2303 SE Military Drive, Bldg.514  
San Antonio, TX 78223

**Re: Challenge to Statement of Deficiencies for Facility License#008036**

Dear Mr. Collier,

Thank you for taking the time to review our concerns regarding deficiencies A201, and A249 on the deficiency report received on December 8<sup>th</sup>, 2015.

Attached you will find a complete plan of correction for all tags listed on the deficiency report.

Please do not hesitate to contact me with any questions, Thank you for your time.

Respectfully,

[REDACTED]  
[REDACTED] Corporate Vice President  
Whole Woman's Health, LLC  
[REDACTED]

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  008038	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  11/10/2015
NAME OF PROVIDER OR SUPPLIER  WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(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 entrance conference was held with the facility clinical coordinator and another facility staff member on the morning of 11/10/15. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.  Continued licensure is recommended, with an approved plan of correction.  An exit conference was held with the facility clinical coordinator and another administrative staff on the evening of 11/10/15. Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000		
A 126	TAC 139.41(a) Policy Development and Review  (a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:	A 126	A126 The Clinic Administrator will be responsible for the conduct of the facility, and for the implementation, enforcement and monitoring of the written policies governing the facility.  The clinic Administrator has placed a purchase order for small red biohazard bags, as well as small biohazard stickers as a backup option for storing pathological waste in the biohazard freezer.	12/28/15

SOD - State Form  
LABORATORY

LABORATORY IDENTIFICATION NUMBER  
LABORATORY IDENTIFICATION NUMBER

TITLE

(X6) DATE

STATE FORM

6899

RNH011

If continuation sheet 1 of 7

LABORATORY IDENTIFICATION NUMBER: [REDACTED] NUTRITIVE'S SIGNATURE: [REDACTED] TITLE: LUN, Clinic Administrator DATE: 01/06/2016

Texas Department of State Health Services

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A 126	<p>Continued From page 1</p> <p>This Requirement is not met as evidenced by: Based on a review of policies, tour of the facility, and interview the facility failed to enforce written policies governing the facility's total operation, to provide health care in a safe and professionally acceptable environment.</p> <p>Findings included:</p> <p>Facility procedure entitled, "Procedure for pathology" stated in part, "10. The staff member will dispose of the POC into a small biohazard bag. When that bag is full or at the end of a session (whichever comes first), the staff member will place that bag into another Ziploc and put it into the path lab freezer."</p> <p>During a tour of the facility on 11/10/15 it was observed that the freezer that the biohazard freezer contained approximately 5 unlabeled plain Ziploc bags containing POC (products of conception). The POC was not in a labeled biohazard bag.</p> <p>In an interview on 11/10/15, staff member #2 confirmed that all POC should be placed in a biohazard bag prior to being placed in a Ziploc bag and stored in the designated freezer.</p>	A 126	<p>An In Service will be facilitated to reiterate to staff that when working pathology, the POC should be placed in a small red biohazard bag to be stored in the freezer, even though all the small bags will be placed in a large biohazard bag and container to be transported out of the building. In the event the clinic has to use zip lock bags, a biohazard sticker will be placed on the outside of the bag in order to properly identify the bag before placing it inside the biohazard freezer.</p> <p>In order to monitor compliance with this requirement, the clinic administrator will conduct randomized tracers on staff working in the pathology lab, findings will be discussed during the quality assurance meetings.</p>	
A 197	<p>TAC 139.48(1)(A) Physical &amp; Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows.</p>	A 197	<p>A197</p> <p>The Clinic Administrator will be responsible for ensuring all physical and environmental requirements are accurately followed.</p>	01/04/15

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STREET ADDRESS, CITY, STATE, ZIP CODE  
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MC ALLEN, TX 78501**

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A 197	<p>Continued From page 2</p> <p>(1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;</p> <p>This Requirement is not met as evidenced by: Based on observation and an interview with staff, the facility failed to have a safe and sanitary environment that was maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings were:</p> <p>During a tour of the facility on 11-10-15, the following observations were made:</p> <ul style="list-style-type: none"> <li>- The vinyl cover on the exam table in the sonograph room contained tears, which can harbor bacteria and prevent the exam table from being completely cleaned.</li> <li>- Examination of the medications in the emergency cart revealed 2 vials of Calcium Gluconate 10 % injectable 10 ml with an expiration date of 10/15, 1 bag of Lactated Ringers 500 ml IV with an expiration date of 5/2015, 1 ET Tube with brown discoloration/staining visible on the packaging, and 1 suction tubing with a torn/open packaging. The expired medications and damaged supplies were available for patient use.</li> </ul> <p>The above was confirmed in an interview, with staff #2 during a tour of the facility on 11-10-15.</p>	A 197	<p>The creases on the vinyl cover on the exam table in the sonogram room will be repaired. This exam table won't be in use until the creases have been fixed.</p> <p>Due to a clerical error expired medications were kept with current medications in the crash cart, those have now been removed and properly discarded. Staff has received training on how to evaluate the need to replace medical supplies that do not have expiration dates, the ET and suction tubing have been removed from the cart, and have been replaced by new ones.</p> <p>In order to ensure compliance with the physical and environmental requirements mandated by the state, the clinic administrator will conduct a physical walk through of the facility to inspect the appearance and functionality of all equipment. Findings will be addressed during the quality assurance meetings.</p>	

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A 201	Continued From page 3	A 201		
A 201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements  The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments);  This Requirement is not met as evidenced by: Based on a tour of the facility, the facility failed to store hazardous cleaning solutions and compounds in a secure manner. Failure to do so increases the risk of harm to patients.  Findings were:  During a tour of the facility on 11-10-15, the unlocked laundry room contained items including disinfectant spray, air freshener spray, germicidal wipes, all-purpose spray cleaner and bleach.  The above was confirmed in an interview, with staff #2 on 11-10-15 during a tour of the facility.	A 201	A201  The Clinic administrator will be responsible for ensuring the physical and environmental requirements for the facility are followed accurately.  The Clinic will install locks on the laundry closet cabinets, and ensure all cleaning products are locked during patient care hours.  A staff in service will be facilitated on 01-15-16 to ensure all staff is aware of ensuring these products are to be locked during patient care.  The clinic Administrator will ensure compliance with this requirement by conducting random walk through of the facility. Findings will be addressed during quality assurance meetings.	01/15/16
A 249	TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards  J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall	A 249		

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A 249	<p>Continued From page 4</p> <p>ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.</p> <p>(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.</p> <p><b>FINDINGS:</b></p> <p>During a tour of the facility on 11/10/15, multiple peel pouches were observed stored on a counter in the pathology room. Approximately 10 peel packs were crushed and compressed, the adhesive seal across the bottom of these peel packs was observed to be wrinkled with small gaps present, presenting a risk for contamination. The tacking of the packs also presented a risk of the packaging being punctured.</p> <p>An interview with Staff #3 on 11/10/15, confirmed the above findings.</p>	A 249	<p>A249</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.</p> <p>The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, will reorganize the area and designate storage space on the clean side cabinets to carefully stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.</p> <p>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.</p> <p>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings.</p>	01/15/16

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A 356 A 356	<p>Continued From page 5</p> <p>TAC 139.56(b)(c) Emergency Services</p> <p>(b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).</p> <p>(c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.</p> <p>This Requirement is not met as evidenced by: Based on a review of personnel files and an interview with staff, the facility failed to ensure that all direct care personnel were competent in and maintained current certification in cardiopulmonary resuscitation (CPR), as there was no documented evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. This presents a risk, as staff may not be competent to respond in a medical emergency.</p> <p>Findings included:</p> <p>A review of personnel files revealed that 3 of 6 direct staff members at facility (#1, 2, and 4) obtained cardiopulmonary resuscitation (CPR) through an online resource that contained no evidence of hands-on skills practice, an in-person assessment and/or demonstration of CPR skills. In an interview, on 11/10/15, staff member #2 confirmed that the online course did not contain hands-on skills practice, an in-person assessment and/or demonstration of CPR skills.</p>	A 356 A 356	<p>A356</p> <p>The Clinic Administrator will be responsible for ensuring all personnel complies with emergency services requirements.</p> <p>All staff members will receive Cardiopulmonary resuscitation (CPR) training by January 4, 2016.</p> <p>Documented evidence of hands on skills practice and in person assessment will be placed in personnel files. The Clinic Administrator will ensure compliance with this requirement by conducting monthly audits of the personnel files, and scheduling the proper recertification as needed.</p>	01/04/16



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A 356	Continued From page 6  Review of the Health & Safety Institute and the National Safety Council website found at <a href="http://news.hsi.com/onlineonlycpr">http://news.hsi.com/onlineonlycpr</a> reveals that, "No major nationally recognized training program in the United States endorses certification without practice and evaluation of hands-on skills. According to the Occupational Safety and Health Administration (OSHA) online training alone does not meet OSHA first aid and CPR training requirements."	A 356		