

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  AC13910054	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  08/10/2010
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NAME OF PROVIDER OR SUPPLIER  A WOMAN'S WORLD MEDICAL CENTER, INC.	STREET ADDRESS, CITY, STATE, ZIP CODE 503 SOUTH 12TH STREET FORT PIERCE, FL 34950
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A 000	INITIAL COMMENTS  Abortion Center Re-licensure survey was conducted 8/10/2010. A Woman's World Medical Center, Inc. had deficiencies found at the time of the visit.	A 000		
A 100	Physical Plant Req.-2nd Trimester  The following are minimum standards of construction and specified minimum essential physical plant requirements which must be met when providing second trimester abortions.  (1) Consultation room(s) with adequate private space specifically designated for interviewing counseling, and medical evaluations;  (2) Dressing rooms designated for staff and patients;  (3) Handwashing station(s) equipped with a mixing valve and wrist blades and located in each patient exam/procedure room or area;  (4) Private procedure room(s) with adequate light and ventilation for abortion procedures;  (5) Post procedure recovery room(s) equipped to meet the patient's needs;  (6) Emergency exits wide enough to accommodate a standard stretcher or gurney;  (7) Cleaning and sterilizing area(s) adequate for the cleaning and sterilizing of instruments;  (8) Adequate and secure storage area(s) for the storage of medical records and necessary equipment and supplies; and	A 100		

HCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Candace M Dye* TITLE: *Administrator* (X6) DATE: *8/20/10*

STATE FORM 6888 9Z0J11 If continuation sheet 1 of 11

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A 100	<p>Continued From page 1</p> <p>(9) If not otherwise required by the Florida Building Code, at least one general use toilet room equipped with a hand washing station.</p> <p>Chapter 59A-9.022, F.A.C.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview it was determined the clinic did not ensure the consultation area adequately provided a private space for interviewing, counseling, and conducting medical evaluations.</p> <p>The findings include:</p> <p>During initial tour of the clinic with an Administrative Assistant, conducted on 08/10/2010 beginning at approximately 9:15 AM, the Administrative Assistant was asked to point out the consultation room. At this time she brought this surveyor to a room with one wall with a reception window, 2 full walls, and a countertop as the fourth wall that joins the small hallway. This small hallway contains a doorway to the procedure room (that is directly next to the consultation area); then a restroom; a lab and kitchen at the end of the hallway and a doorway to the recovery room is on the opposite side of the hallway from the restroom. There are two desks in the center of the room (that face each other) that are separated by tall bookshelves in the consultation area. In addition there is a chair next to each desk with a tall bookshelf on the other side of the chair. Any patient "buzzed" in from the waiting room would have the ability to see patient's receiving counselling in these areas.</p>	A 100	<p>As of 8/15/2010 each patient will have all of their medical evaluations: consult, ultrasound, lab work, and counseling done in the exam room. The exam room is an enclosed room with 4 walls and 1 door for privacy for patients. This has been discussed with the Medical Director and he agrees that all patients will have their evaluations done in the exam room with 4 walls and 1 door. If the consult room is occupied the patient will need to sit back in the lobby and wait until the room is available. The protocol manual has been updated.</p>	8/15/10

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A 100	Continued From page 2  Any patient that utilized the hallway, to go to the rest room, procedure room, or recovery room has the potential to hear a patient in the counseling area. This requirement notes a consultation room with adequate private space is a minimum standard for the physical plant of an abortion clinic. This area is not an enclosed room and provides the potential for a patient to be seen or overheard by other patients. During interview with the Administrator, conducted on 08/10/2010 at approximately 11:35 AM, she stated this consultation area has not been a concern in the past and that all patients have to be "buzzed" in. When asked if a patient could be in the counseling area when other patients would be in the recovery area, restroom, or in the procedure room, she replied, yes.	A 100  A100	Each patient will have counseling in the exam/procedure room. A single room with 1 door. Which will be closed during counseling. No one else will have access to this room except the office staff and the doctor.	8/15/10
A 158	Clinic Supplies/equip. Stand.-2nd Trimester Equipment Maintenance.  (a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.  (b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the	A 158		

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A 156	<p>Continued From page 3</p> <p>manufacturer ' s specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair.</p> <p>(c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair.</p> <p>Chapter 59A-9.0225(7), F.A.C.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review it was determined the clinic did not ensure the written maintenance program was implemented, specifically related to testing equipment (not less than annually) to ensure proper operation and a state of good repair.</p> <p>The findings include:</p> <p>During tour of the clinic, conducted with an Administrative Assistant on 08/10/2010 beginning at 9:15 AM, the following equipment was located, for use, on the premises: a centrifuge; 2 autoclaves; an ultrasound; a suction machine; a small refrigerator, a small freezer, and a defibrillator. Each of these items did not contain a sticker that noted inspections. The Administrative Assistant stated she was not aware of the requirement to inspect equipment on an annual basis. Review of the policy and procedure related to equipment maintenance indicated equipment will be maintained according to the manufacturer's instructions and preventative maintenance and calibration will be recorded on appropriate control logs. During subsequent interview with the Administrator,</p>	A 156  A156	As of 8/15/10 each of the following equipments will have an individual log stating date of service, purpose of service, approximate date of next service and a signature of the service person, with their company name. This shall include the centrifuge, dry heat sterilizers, ultrasound, vacuum aspiration machine, small refrigerator, deep freezer and the defibrillator. These equipments shall be inspected no less than once a year for proper operation and to insure they are working properly according to manufacturer specifications. This will be evaluated at each annual meeting with the staff and Medical Director to insure the maintenance on the equipment has been implemented. This deficiency was completed on 8/19/10 by medical equipment technician, Brian Lawrie, BMET.	8/19/10

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A 156	Continued From page 4 conducted on 08/10/2010 at approximately 10:20 AM, she confirmed that the above noted equipment had not been inspected and logs of inspections have not been maintained.	A 156		
A 202	Clinic Personnel-2nd Trimester  Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control.  In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide: (a) Infection control, to include at a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members. (b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires; (c) Confidentiality of patient information and	A 202  A202	Each employee and contracted employees have an employee file that will contain the following: Date of Hire, start date and rate of pay at start along with raises and the dates given.  Employee orientation will include:  *Job Descriptions for every employee *Clinic Policies and Procedures *Fire Safety Rules & Evacuation Plan for staff and Patients *Medical Emergency Protocol *Infection Control *Patient Confidentiality *Counseling of Patients *Record Keeping *Incident Reporting *Licensing Regulations	9/1/10

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A 202	<p>Continued From page 5</p> <p>records, and protecting patient rights; (d) Licensing regulations; and (e) Incident reporting.</p> <p>Chapter 59A-9.023,(4) and (5), F.A.C.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview it was determined the clinic did not ensure each staff member has documentation of an orientation; a job description; and required annual inservice trainings for 7 of 7 employees and contractors.</p> <p>The findings include:</p> <p>During personnel record review and interview with the Administrator, conducted on 08/10/2010 beginning at approximately 11:00 AM, she stated some staff do not have personnel files and for others she has only maintained a copy of current licensure. There was no documented evidence of a job description; orientation; or annual inservice training related to fire safety, infection control, confidentiality, licensing regulations, and incident reporting for the following employees and/or contractors:</p> <p>Contractor #1: contracted since 1985 Contractor #2: contracted since 1997 Contractor #3: contracted since 2005 Employee #4: employed since 02/27/2010 Employee #5: employed since 1997 Employee #6: employed since November 2004 Employee #7: employed since April 1991</p> <p>The Administrator stated that she did not have any knowledge of the requirement to maintain job descriptions, orientation records, or annual inservice training records for employees and contractors.</p>	<p>A 202</p> <p>A202</p> <p>Cont'd</p>	<p>Administrator will include documentation of orientation at hire and documentation of review or orientation annually in February of each year after.</p> <p>This standard has been included in the policies and Procedures protocol manual. The review of orientation has been added to the agenda for the Annual Staff Meeting that is held in February every year. The attendants will sign a meeting attendance log with the date of the event and a copy will be placed in each employees permanent file.</p>	<p>9/1/10</p>

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A 301	Continued From page 6	A 301		
A 301	<p>Medical Screening/eval.-2nd Trimester</p> <p>Laboratory Services.</p> <p>(a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, F.S.</p> <p>(b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.</p> <p>Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available.</p> <p>All laboratory test reports shall be placed in the patient ' s medical record.</p> <p>All laboratory test and storage areas, records and reports shall be available for inspection by the agency.</p> <p>If a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall, at the request of the patient and before the abortion procedure is performed, review the ultrasound evaluation results with the patient, including an estimate of the probable gestational age of the fetus.</p> <p>A test for anemia shall be performed.</p>	A 301		

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A 301	<p>Continued From page 7</p> <p>Chapter 59A-9.026(2), (4), (5), (6), (7), and (8) F.A.C.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review it was determined the clinic did not ensure when a person who is not a physician performs an ultrasound examination, that this person shall have documented evidence of completion of a course in the operation of ultrasound equipment.</p> <p>The findings include:</p> <p>During tour of the clinic, conducted with an Administrative Assistant on 08/10/2010 beginning at 9:15 AM, the ultrasound was observed in the procedure room. When asked who performs the ultrasound testing, this Administrative Assistant replied that she does and the other Administrative Assistant does. When asked about training on the ultrasound equipment, she stated that the physician showed them how to use it. She then stated the physician still conducts an ultrasound test on each patient. When asked why she or the other Administrative Assistant conduct an ultrasound examination, she replied to confirm a pregnancy and to take fetal measurements and call the physician with these measurements. Review of personnel records for these 2 Administrative Assistants did not reveal any documentation related to training. They did not even have personnel records to review. During interview with the Administrator, conducted on 08/10/2010 at approximately 11:00 AM, she stated the 2 Administrative Assistants do not have personnel files. She confirmed that these to staff members conduct ultrasound testing prior to the arrival of the physician. When asked why the</p>	<p>A 301</p> <p>A301</p>	<p>As of 8/10/10 ultrasounds will be performed by the medical doctor before each abortion per state requirements. Any staff member who have had a course in ultrasound technique will have documentation of a completed course in there permanent file. As of 8/10/10 only the Medical Doctors are performing the ultrasounds. The protocol book has been updated.</p>	<p>8/10/10</p>



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A 301	Continued From page 8  need for 2 ultrasound tests for each patient, she replied these 2 staff members conduct the first ultrasound test to determine gestational age, so the clinic knows what to charge each patient. She stated charges are different for different gestational ages and they need to know that information so they can tell the patient how much money to bring on the day of the procedure. She confirmed that these 2 staff members do not have any course completion or certifications to perform ultrasound testing.	A 301		
A 350	Abortion Procedure-2nd Trimester  Any abortion clinic which is providing second trimester abortions must be in compliance with the following standards relative to second trimester abortion procedures:  (1) A physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be available to all patients throughout the abortion procedure.  (2) The abortion procedure will be performed in accordance with obstetric standards and in keeping with established standards of care regarding the estimation of gestational age of the fetus.  (3) Anesthesia service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.  (4) Prior to the administration of anesthesia, patients shall have a history and physical examination by the individual administering	A 350		



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A 350	<p>Continued From page 10</p> <p>in the recovery room. During interview with the Administrator, conducted on 08/10/2010 at approximately 11:35 AM, she acknowledged the documentation does not reflect monitoring of vital signs. She stated vitals are taken prior to the procedure and prior to discharge. She stated the physician checks with each patient prior to the physician leaving. When asked if the physician checks vitals, she replied, no he just asks them how they are feeling.</p> <p>During initial tour of the clinic with an Administrative Assistant, conducted on 08/10/2010 beginning at approximately 9:15 AM, she was asked where the blood pressure cuffs were located during the observation of the recovery room. She replied that they had participated in a health clinic over the weekend and that the blood pressure cuffs were in the Administrator's truck. When asked who takes the blood pressures in the recovery room, she replied that she does or the Administrator does (neither are licensed or certified professionals that are qualified to assess a patient's condition and to determine if a patient is stable in the recovery room).</p>	A 350  A350	<p>Vital signs will be monitored and documented by a licensed medical professional in the recovery room at the start of the recovery period and again before the patient is discharged.</p> <p>Blood Pressure cuffs, both adult and large size are kept in the surgery room and the recovery room at all times.</p> <p>The protocol manual has been updated to reflect these changes.</p>	8/14/10



CHARLIE CRIST  
GOVERNOR

*Better Health Care for all Floridians*

THOMAS W. ARNOLD  
SECRETARY

August 10, 2010

Administrator  
A Woman's World Medical Center, Inc.  
503 S. 12th Street  
Fort Pierce, FL 34950

Dear Administrator:

This letter reports the findings of a state licensure survey conducted on August 10, 2010 by a representative of this office. Attached is the provider's copy of the State Form 3020, which indicates the deficiencies that were identified on the day of the visit.

Please provide a plan of correction to this Field Office, in accordance with enclosed instructions, for the identified deficiencies **within ten calendar days of receipt of this faxed report**. You will not receive a copy of this report in the mail, you will only receive this faxed report. **All deficiencies shall be corrected no later than September 10, 2010.**

The Quality Assurance Questionnaire has long been employed to obtain your feedback following survey activity. This form has been placed on the Agency's website at <http://ahca.myflorida.com/Publications/Forms.shtml> as a first step in providing a web-based interactive consumer satisfaction survey system. You may access the questionnaire through the link under Health Facilities and Providers on this page. Your feedback is encouraged and valued, as our goal is to ensure the professional and consistent application of the survey process.

Thank you for the assistance provided to the agency's representative. Should you have any questions please call this office at (561) 381-5840.

Sincerely,

Arlene Mayo-Davis  
Field Office Manager

AMD/hl  
Enclosure

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Headquarters  
2727 Mahan Drive  
Tallahassee, FL 32308  
<http://ahca.myflorida.com>



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