

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: C3704	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/27/2011
NAME OF PROVIDER OR SUPPLIER NEW WOMAN ALL WOMEN HEALTH CAR		STREET ADDRESS, CITY, STATE, ZIP CODE 1001 17TH STREET SOUTH BIRMINGHAM, AL 35205		
(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
L 100	<p>ALABAMA LICENSURE DEFICIENCIES</p> <p>THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION.</p> <p>This Rule is not met as evidenced by: 420-5-1-.02 Administration (5) Personnel Each abortion clinic shall utilize personnel to provide services who have appropriate training and qualifications for the services that they provide.</p> <p>This rule is not met as evidenced by:</p> <p>Based on review of personnel records and an interview with Employee Identifier (EI) # 1, Clinic Administrator, the clinic failed to assure EI # 2 and EI # 4, Registered Nurses, were trained for the duties they performed in the clinic. This had the potential to affect all patients served.</p> <p>Findings include:</p> <p>A review of EI # 2's personnel record was completed on 7/26/11 by the Health Surveyor. The review of the, "New Employee Training Record" revealed only the name, social security number and address for EI # 2 was completed. The rest of the training form was left blank. The form covered the following topics:</p> <ol style="list-style-type: none"> 1. Informed of job description and its policy and procedure. 2. A general explanation of the epidemiology and symptoms of bloodborne diseases. 3. An explanation of the employer's infection control program. 4. An explanation of the modes of transmission of bloodborne pathogens. 5. An explanation of the appropriate method for 	L 100		

Health Care Facilities

TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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L 100	Continued From page 1 recognizing tasks and other activities that may involve exposure to blood and other potentially infectious material. 6. An explanation of the use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices and personal protective equipment (PPE). 7. Information on types, proper use, location, removal, handling, decontamination and/or disposal of PPE. 8. An explanation of the basis for selection of PPE. 9. Information on Hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated. 10. Information on the appropriate actions to take and persons to contact in an emergency. 11. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available. Also, information on the medical counseling that the employer is providing for exposed individuals. A review of EI # 2's personnel record revealed an attestation that EI # 2 had completed orientation classes as part of her employment at New Women All Women Health Care. The form included the following information: "I have fully read and/or understand the following rules and regulations. **Rules and Regulations set by the Alabama Department of Health. **New Women All Women Health Care Policy and Protocol Manual. **All OSHA (Occupational Safety Health Administration) and CLIA (Clinical Laboratory Improvement Act) Guidelines. **HIPPA Regulations (Health Insurance	L 100		

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L 100	Continued From page 2 Portability and Accountability Act). "I understand I am expected to be able to cross train in several areas of the clinic. "I understand this is a drug free work place. "I also understand I am expected to be caring, compassionate and understanding towards all patients, guests and fellow employees." The form was not signed or dated by EI # 1, Clinic Administrator. A review of EI # 2's form titled, "Counselor qualifications/evacuation" was left blank. The form included the following items that were to be covered with EI # 2: Ability to give a complete description of the abortion procedure, first and second trimester. Ability to give full disclosure of the medical risks associated with abortion, first and second trimester. Reiteration of all the alternatives to pregnancy. Knowledge of the name and qualifications of the physician and/or medical director. Ability to discuss anatomy (with emphasis on the anatomical aspects of pregnancy, birth control, and sexually transmitted diseases). Discussion of available methods of birth control. Ability to make patients comfortable enough to ask questions. Ability to answer questions and willingness to seek answers from another staff member if the counselor does not know the answer. Use of visual aids. Articulation and organization. Empathy and sincerity. Hygienic and other procedures to be observed following discharge from the facility. There were two job descriptions in EI # 2's personnel file, Nursing Supervisor and Qualified	L 100		

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L 100	Continued From page 3 Counselor. A review of EI # 4's personnel record was completed on 7/26/11 by the Health Surveyor. There were two job descriptions in EI # 4's personnel file, Nursing Supervisor and Qualified Counselor. A review of the, "New Employee Training Record" revealed only the name for EI # 4 was completed. The rest of the training form was left blank. The form covered the following topics: Informed of job description and its policy and procedure. A general explanation of the epidemiology and symptoms of bloodborne diseases. An explanation of the employer's infection control program. An explanation of the modes of transmission of bloodborne pathogens. An explanation of the appropriate method for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious material. An explanation of the use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices and personal protective equipment (PPE). Information on types, proper use, location, removal, handling, decontamination and/or disposal of PPE. An explanation of the basis for selection of PPE. Information on Hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated. Information on the appropriate actions to take and persons to contact in an emergency. An explanation of the procedure to follow if an exposure incident occurs, including the method of	L 100		

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L 100	<p>Continued From page 4</p> <p>reporting the incident and the medical follow-up that will be made available. Also, information on the medical counseling that the employer is providing for exposed individuals.</p> <p>A review of EI # 4's personnel record revealed an attestation that EI # 4 had completed orientation classes as part of her employment at New Women All Women Health Care. The form included the following information:</p> <p>"I have fully read and/or understand the following rules and regulations. **Rules and Regulations set by the Alabama Department of Health. **New Women All Women Health Care Policy and Protocol Manual. **All OSHA (Occupational Safety Health Administration) and CLIA (Clinical Laboratory Improvement Act) Guidelines. **HIPPA Regulations (Health Insurance Portability and Accountability Act). "I understand I am expected to be able to cross train in several areas of the clinic. "I understand this is a drug free work place. "I also understand I am expected to be caring, compassionate and understanding towards all patients, guests and fellow employees."</p> <p>The form was not signed or dated by EI # 1, Clinic Administrator.</p> <p>A review of EI # 5's personnel record was completed on 7/26/11 by the Health Surveyor. There was no job application and no job description in EI # 5's personnel record.</p> <p>A review of the, "New Employee Training Record" revealed only the front side of the form for EI # 5 and each area was dated 6/22. The back of the</p>	L 100		

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L 100	<p>Continued From page 5</p> <p>form held the information of who had conducted the training and was to have been completed but there was no back side of the form in the personnel record.</p> <p>A review of the Laboratory Personnel Evaluation form in the personnel file was signed by EI # 5 but not by the Technical Director of the lab. A form related to a person's proficiency in performing laboratory procedures in the facility was in the personnel record but had no information completed not even a name on the form.</p> <p>On 7/26/11 at 2:05 PM, EI # 1 was interviewed and asked who was responsible for assuring all new staff are trained prior to working independently in the clinic and that all staff check-offs are documented? EI # 1 stated, the Assistant Director to the Administrator, EI # 3. EI # 1 was shown the personnel record for EI # 2, EI # 4 and EI # 5 confirmed the documentation was not completed for their training.</p> <p>420-5-1-.04 Physical Environment (5) Equipment and Supplies Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the facility integral to patient care to assure satisfactory operation thereof.</p> <p>This rule is not met as evidenced by:</p> <p>Based on observation and an interview with Employee Identifier (EI) # 1, Clinic Administrator, the clinic failed to assure that all medical equipment had annual preventive maintenance performed. This had the potential to affect all patients served.</p>	L 100		

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L 100	Continued From page 6 Findings include: On 7/25/11 at 1:30 PM a tour of the clinic revealed the following patient used equipment had not had the annual preventive maintenance (PM) performed, the last preventive maintenance completed was 3/25/11. Patient Exam Room 1 1. Two portable standing lights 2. Exam table 3. GE ultrasound machine 4. Suction machine Patient Exam Room 2 1. Two portable standing lights 2. Exam table 3. GE ultrasound machine 4. Suction machine 5. Datascope Passport (used to assess blood pressure and has the ability to run an EKG) 6. Two portable floor fans Patient Exam Room 3 1. Ultrasound machine 2. Exam table 3. AED (Automated External Defibrillator) Patient Laboratory Area 1. American Dimensional Rotator 2. Scales Work Room 1. Two Delta XL Sterilizers In an interview on 7/25/11 at 10:30 AM, Employee Identifier (EI) # 1, Clinic Administrator, called the preventive maintenance company on and confirmed the PMs had not been completed at	L 100		

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L 100	Continued From page 7 the clinic. 420-5-1-.04 Physical Environment (5) Equipment and Supplies (d) Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. Each facility shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The facility shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for such removal. This rule is not met as evidenced by: Based on observations of the medical supplies and medications available for patient use the clinic failed to assure there were no expired items available for patient use. This had the potential to affect all patients served. Findings include: On 7/26/11 at 9:55 AM, the Health Surveyors were accompanied by Employee Identifier (EI) # 2 and observed the medication storage area. Included in the medications available for patient use was a vial of Bacteriostatic Water 0.9 % Sodium Chloride 30 milliliter (ml) vial. The vial was opened and had no date or initials of when or whom opened the used vial.	L 100			

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L 100	<p>Continued From page 8</p> <p>The laboratory area had two boxes of Vacutainer tubes which had expired. A box of lavender topped tubes expired 2/2011 and a box of red topped tubes expired 5/2011.</p> <p>During a tour of the procedure room # 2 on 7/25/11 at 9:55 AM, the Health Surveyors observed 10 disposable plastic suction tip/curettes 12 mm(millimeter) which expired on 5/2011, 7 curettes 12 mm expired 5/2011 and 1, 13 mm curette expired 5/2011.</p> <p>During a tour of the procedure room # 3 on 7/25/11 at 9:55 AM, the Health Surveyors observed expired drugs in the emergency cart. Aminophylline 500 mg (milligrams)/ 20 ml (milliliter) vial expired 5/2011, Vasopressin 20 u(units)/ml a 10 ml vial expired 6/2011, 500 ml of 5% Dextrose expired 5/2011 and a suture kit which had expired 3/2011. The emergency cart was not locked to prevent unauthorized access.</p> <p>420-5-1-.03 Patient Care (7) Pharmaceutical Services (g) Emergency Kit or Emergency Drugs. The kit or medicine shall be stored in such a manner as to be inaccessible to unauthorized personnel while allowing quick retrieval by authorized personnel.</p> <p>This rule is not met as evidenced by:</p> <p>Based on observation of the Emergency (ER) Kit the clinic failed to assure the kit was locked and inaccessible to patients and unauthorized staff members. This had the potential to affect all patients served.</p> <p>Findings include:</p>	L 100		

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L 100	<p>Continued From page 9</p> <p>On initial tour of the clinic on 7/25/11 at 9:55 AM, Health Surveyors were accompanied by Employee Identifiers (EI) # 1 and # 2. In Patient Exam Room # 3 the ER Kit was observed to be unlocked. EI # 2 was asked where the key was for the ER Kit, but was unable to locate it.</p> <p>On 7/25/11 at 1:35 PM, Health Surveyors observed the ER Kit in Patient Exam Room # 3 and it was still unlocked.</p> <p>(7) Pharmaceutical Services.</p> <p>(b) Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility by patient name after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered professional nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of Medical Examiners and the State Board of Pharmacy.</p> <p>This rule is not met as evidenced by:</p> <p>Based on observation and an interview with</p>	L 100		

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L 100	<p>Continued From page 10</p> <p>Employee Identifier (EI) # 2, the Registered Nurse, the clinic failed to:</p> <ol style="list-style-type: none"> 1. Assure all medications were labeled appropriately 2. Medications were administered in a timely fashion to ensure potency of the drug 3. Prepared by licensed staff as required by standards of practice 4. Documented time medication was administered. <p>This had the potential to affect all patients served by the facility.</p> <p>Findings include:</p> <p>Refer to 420-5-1-.02(8)(a) Records and Reports Alabama Board of Nursing, Standards of Practice Chapter 610-X-6-.06 Documentation Standards (d)(iii) (d) Timely. (i) Charted at the time or after the care, including medications, is provided... (ii) Should the registered nurse or licensed practical nurse add documentation that was omitted, the documentation shall reflect " late entry" including a date and time the late entry was made as well as the date and time the care was provided. (iii) A mistaken entry in the record by a licensed nurse shall be corrected by a method that does not obliterate, white-out, or destroy the entry.</p> <p>Alabama Board of Nursing, Standards of Practice Chapter 610-X-6-.07 Medication Administration and Safety (1)(j) Safety precautions including but not limited to: (i) Right patient (ii) Right medication (iii) Right time</p>	L 100		

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L 100	<p>Continued From page 11</p> <p>(iv) Right dose (v) Right route (vi) Right reason (vii) Right documentation</p> <p>"Stability</p> <p>"Syringes -Toradol- Store at controlled room temperature 15-30 degrees Celsius (59-86 Fahrenheit)- Protect from light. Retain in carton until time of use. Baxter Healthcare Corporation- Package Insert Ketorolac (Toradol).Revised 01/2006</p> <p>On initial tour of the clinic on 7/25/11 at 9:55 AM, Health Surveyors were accompanied by Employee Identifier (EI) # 2. In the recovery room refrigerator the surveyor observed 5 syringes with a date of 7/23/11 as the date it was prepared and xylocaine written on the end of the plunger. There was no strength of the medication and when EI # 2 was asked if she prepared the syringes without a strength, she stated that EI # 6, a medical assistant had prepared the syringes. EI # 6 is not a licensed employee.</p> <p>A review of the locked drug box in the double locked medication closet revealed pre-filled medication cups and pre-filled syringes. There was a total of 37 medication cups with 800 mg of Ibuprofen and 10 mg of Valium sitting uncovered and unlabeled in the box. There was a total of 7 syringes with Toradol prepared, 4 from 7/14/11 and 3 from 7/20/11 in the locked box. EI # 2 confirmed she had pre-filled the medication.</p> <p>Medical record examples:</p>	L 100		

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L 100	<p>Continued From page 12</p> <p>1. Medical Record (MR) # 11042206 received Methergine 0.2 mg IM (intramuscular) in her right leg 4/23/11. There was no time the medication was administered on the Recovery Room record.</p> <p>2. MR # 11072201 received Methergine 0.2 mg IM in her right leg 7/23/11. There was no time the medication was administered on the Recovery Room record.</p> <p>3. MR # 11032805 received Methergine 0.2 mg IM in her right leg 5/27/11. There was no time the medication was administered on the Recovery Room record.</p> <p>EI # 2 confirmed she had not documented a time of medication administered on 7/25/11 at 2:30 PM.</p> <p>420-5-1-.03 Patient Care (8) Infection Control (d) Investigation of Infections.</p> <p>1. Reports of infections observed during any follow-up or return visit of the patient shall be made and kept as a part of the patient's medical record. Each facility shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least quarterly by the facility's medical director. The facility's medical director may specify certain patient complaints, such as mild cramps, which, in his professional opinion and judgment, do not warrant being recorded in the logbook. The logbook shall in all events contain documentation of the following: Any report by a patient of a body temperature of 100 degrees Fahrenheit or more;</p>	L 100		

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L 100	Continued From page 13 This rule was not met as evidenced by: Based on record review, review of the surveillance logbook and an interview with Employee Identifier (EI) # 1, Clinic Administrator, the clinic failed to follow up on a patient who had a reported fever of 102 degrees Fahrenheit. This affected Patient Identifier (PI) # 111990 and had the potential to affect all patients served. Findings include: The medical record for PI #111990 was reviewed and revealed she had a surgical abortion on 5/27/11. The surveillance logbook was reviewed on 7/25/11 and revealed PI # 111990 called the clinic on 5/29/11 at 2:04 reporting light bleeding, a fever of 102 and "aching." EI # 2, Registered Nurse, documented PI # 111990 was instructed to take Motrin, "could be flu." The medical record had no other documentation of a follow up to PI # 111990. On 7/25/11 at 3:15 PM, EI # 1, Clinic Administrator, was interviewed about PI # 111990's record. EI # 1 confirmed there was no follow up made, but that there should have been.	L 100			
L 200	ALABAMA LICENSURE DEFICIENCIES This Rule is not met as evidenced by: 420-5-1-.03 Patient Care. (4) Admission and Examination Procedures. (d) Laboratory Tests.	L 200			

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: C3704	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 07/27/2011
NAME OF PROVIDER OR SUPPLIER NEW WOMAN ALL WOMEN HEALTH CAR			STREET ADDRESS, CITY, STATE, ZIP CODE 1001 17TH STREET SOUTH BIRMINGHAM, AL 35205		
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L 200	<p>Continued From page 14</p> <p>2. If a prophylactic course of antibiotic medications is not administered or dispensed to a patient in connection with the abortion procedure, then an abortion shall not be performed until the results from the gonorrhea culture have been obtained or a waiver of such treatment is signed by the patient. In the case of a medical emergency, as defined in these rules, laboratory tests are not required prior to the procedure.</p> <p>This rule is not met as evidenced by:</p> <p>Based on an interview with the Clinic Administrator and the Registered Nurse, the clinic failed to give patients prophylactic antibiotics following their procedures, instead prescriptions were given to be filled. This had the potential to affect all patients served.</p> <p>Findings include:</p> <p>During the initial tour of the clinic on 7/25/11 at 9:15 AM, Employee Identifier (EI) # 2, the Registered Nurse explained to the Health Surveyors that patients were no longer given Doxycycline post procedure. Patients were now given a prescription to take to Publix, who will fill the prescription for free, or to Wal-Mart who will fill the prescription for 4 dollars.</p> <p>On 7/26/11 at 2:05 PM, EI # 1, Clinic Administrator, was asked about the prescriptions given now and not the prophylactic antibiotic and shown the state licensure rule requiring Abortion or Reproductive Health Centers to dispense or administer these drugs if no gonorrhea culture was obtained. EI # 1 agreed and stated the clinic would now administer or dispense the</p>	L 200			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: C3704	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/27/2011
NAME OF PROVIDER OR SUPPLIER NEW WOMAN ALL WOMEN HEALTH CAR		STREET ADDRESS, CITY, STATE, ZIP CODE 1001 17TH STREET SOUTH BIRMINGHAM, AL 35205		
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L 200	Continued From page 15 prophylactic antibiotics.	L 200		