

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 12/02/2010
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 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-.03 Patient Care. (8) Infection Control. (d) Investigation of Infections. 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: (i) Any report by a patient of severe cramps; (ii) Any report by a patient of passage of a blood clot as large or larger than three centimeters, or one and one fourth inches, in diameter (the approximate size of a fifty cent piece); (iii) Any report by a patient that she has passed tissue; (iv) Any report by a patient of foul-smelling discharge; (v) Any report by a patient that she has soaked two or more sanitary pads in one hour; (vi) Any report by a patient of a body temperature of 100 degrees Fahrenheit</p>	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 or more; (vii) Any diagnosis of perforation of the uterus; and (viii) Any hospitalization of a patient for adverse conditions resulting from a procedure performed at the facility. This rule is not met as evidence by: Based on review of the center's Infection Control Committee minutes, policy and review of medical records it was determined the center failed to assure that the surveillance log book was maintained for all events required. This had the potential to affect all patients served. Findings include: Center Policy: Post Operative Emergency Protocol "All patient complaints warranting referral to the back up physician or emergency room will be appropriately documented in the clinic's problem chart logbook." A review of the Infection Control Committee minutes for the calendar year 2010 documented there no infections in the center. A review of Medical Record (MR) # 1 revealed she had a procedure on 3/17/10. On 3/24/10 it was documented on the telephone check form that the patient had a temperature ranging from 99 to 103, had been to the emergency department (ED)with vomiting and a temperature and cramping that moved up her abdomen. MR # 1 was sent to the hospital and the physician from the center spoke with the ED about concerns that MR # 1 may have appendicitis or a massive infection.	L 100		

Alabama Department of Public Health

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L 100	Continued From page 2 A review of MR # 2 revealed she had a procedure on 5/22/10. On 5/24/10 it was documented on the telephone check form that the patient had pain when she urinated and a sharp pain and burning sensation. In addition, MR # 2 stated pain when having a bowel movement. On 5/25/10 the center phoned to check on MR # 2 and was informed she was in the hospital having emergency surgery, dilation and curettage, because "something was left." The center Registered Nurse documented the patient was very upset and that the patient already had an infection when she went to the ED. There was no documentation in the center's surveillance log book for these two patients with clinical signs of infection. 420-5-1-.03 Patient Care. (7) Pharmaceutical Services. (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	L 100		

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L 100	<p>Continued From page 3</p> <p>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. Abortifacient medications shall be prescribed only by a physician. Abortifacient medications shall be administered only by a physician or by a nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse, under the direct supervision of a physician. For the purposes of this subsection, a physician is directly supervising the administration of an abortifacient medication when he [or she] is in the building and the administration is performed within the physician ' s sight or pursuant to the physician ' s written instructions concerning a specific patient given after the examination of the patient.</p> <p>This rule is not met as evidence by:</p> <p>Based on observation of stored medications the center failed to assure that the current standard of practice for the storage of medications in syringes was followed. This had the potential to affect all patients served by the center.</p> <p>Findings include:</p> <p>USP (United States Pharmacopeia) 797 Pharmaceutical Compounding-Sterile Preparations "4. For a low-risk level preparation, in the absence of passing a sterility test (see Sterility Tests {71}), the storage periods cannot exceed the following time periods: before administration,</p>	L 100		

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L 100	Continued From page 4 the CSPs (Compounded Sterile Products) are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), for not more than 14 days at a cold temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25 (degrees) and -10 (degrees). Observations: On 11/30/10 at 10:45 AM, the surveyors observed 1% Lidocaine drawn up and stored in the medication closet. There was one 10 cc (cubit centimeter) syringe without a date on it of when the medication was drawn up. In addition to this syringe the following syringes filled with Lidocaine were noted to be stored past the time standard in the USP: 2, 10cc syringes dated 8/25/10 2, 10cc syringes dated 8/30/10 one 10cc syringe dated 11/20/10 one 20cc syringe dated 10/28/10 one 20cc syringe dated 11/17/10 5, 20cc syringes dated 11/23/10 There was also an opened vial of Benadryl without a date of when the vial was opened. 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	L 100		

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L 100	Continued From page 5 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 was not met as evidence by: Based on observation and an interview the center failed to assure that all medications and supplies available for patient use were not expired. This had the potential to affect all patients served. Findings include: On initial tour of the facility on 11/30/10 at 9:25 AM, the surveyors observed the following expired medication, Methergine 0.2 milligrams. Three syringes were expired with the following dates: 9/18/10, 10/06/10 and 11/05/10. Observations of supplies in exam room # 2 revealed 8 expired disposable currettes, size 6. Observations of supplies in the private exam room revealed the following expired supplies: Disposable Currettes: Size 9: 23 expired on 2/2009 2 expired on 8/2010 Size 10: 12 expired on 9/2008 14 expired on 2/2010 Size 13: one expired on 1/10/2003 2 expired on 4/04/2004	L 100		

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L 100	Continued From page 6 Size 15: 10 expired on 10/20/2003 6 expired on 8/2009 There were also four boxes of Exel Safelet catheters, 22 gage, that expired on 10/08/2007. 420-5-1-.04 Physical Environment. (5) Equipment and Supplies. (a) Testing and Diagnostic Equipment. All testing and diagnostic equipment shall be maintained in good working order at all times. If equipment is obsolete or permanently unusable because of irreparable damage or malfunction to the equipment or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be returned to use until repaired and tested to ensure proper operation. This rule was not met as evidence by: Based on observation and an interview the center failed to assure that all equipment not in good working order was separated and clearly tagged as temporarily unusable. This affected one of	L 100		

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L 100	<p>Continued From page 7</p> <p>three ultrasound machines in the center.</p> <p>Findings include:</p> <p>On initial tour of the facility on 11/30/10 at 9:55 AM, the surveyors observed in the private exam room a GE RT3200 Advantage I ultrasound machine without a current preventive maintenance label. The center administrator was asked about the ultrasound machine and stated it was not working and a part had been ordered for it.</p> <p>There was no signage on the ultrasound machine to indicate it was out of order and unavailable for patient use.</p> <p>420-5-1.03(8)2 Infection Control</p> <p>2. There shall be procedures to govern the use of sterile and aseptic techniques in all areas of the facility.</p> <p>The requirements of this rule were not met as evidenced by:</p> <p>Based on observation it was determined that the Center failed to have procedures for use in the recovery room related to infection control and aseptic technique for patient care and protection. The staff failed to wash their hands and clean equipment between patients. This had the potential to affect all patients served in the Center.</p> <p>Findings include:</p> <p>The Centers for Disease Control and Prevention, Volume 51 published 10/25/02, Guidelines for Hand Hygiene in Health-Care Settings.</p>	L 100			

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L 100	<p>Continued From page 8</p> <p>Recommendations: These recommendations are designed to improve hand-hygiene practices of HCWs (health care worker) and to reduce transmission of pathogenic microorganisms to patients and personnel in healthcare settings.</p> <p>Recommendations:</p> <p>1. Indications for handwashing and hand antisepsis.</p> <p>C. Decontaminate hands before having direct contact with patients.</p> <p>F. Decontaminate hands after contact with a patient's intact skin (e.g. when taking a pulse or blood pressure...)</p> <p>I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient.</p> <p>J. Decontaminate hands after removing gloves.</p> <p>On 12/01/10 at 10:25 AM, the surveyor was present in the Center's recovery room to observe post-operative patient care. Recovery Room (RR) chair # 5 was observed to have splits in the back of the chair with white stuffing visible.</p> <p>On 12/01/10 at 10:25 AM the surveyor observed a patient, Patient Identifier (PI) # 1, in the recovery room. PI # 1 had her vital signs taken at 10:25 AM. After PI # 1 had her vital signs taken the medical equipment was not cleaned but placed on the desk in the sitting area off to the side of the RR.</p> <p>At 10:45 AM, a second patient, PI # 2, entered the recovery room ambulatory. The RR staff person, Employee Identifier (EI) # 2 applied the same blood pressure cuff used on PI # 1 to PI # 2. The blood pressure cuff had been used on PI # 1 and had not been cleaned nor had EI # 2 washed her hands between the two patients after</p>	L 100		

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L 100	<p>Continued From page 9</p> <p>she had touched the patients with her bare hands.</p> <p>At 10:48 PM, a third patient, PI # 3, was brought to the recovery room. EI # 1, the Administrator, then applied the blood pressure cuff that had been used on PI # 1 and # 2 to the new patient. The blood pressure cuff had not been cleaned.</p> <p>At 10:55 PM, the Registered Nurse (RN), EI # 3 came into the RR and picked up the same blood pressure cuff and rechecked PI # 2's blood pressure. The cuff had not been cleaned.</p> <p>The surveyor observed the activities in the recovery room from 10:25 AM until 11:00 AM, patients came into the RR and were discharged from the RR during this time. The surveyor did not observe the staff which included the RN, Administrator and the RR staff clean any equipment or wash their hands between patient contact.</p> <p>420-5-1-.04(5)(b) Equipment and Supplies</p> <p>(b) 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. This schedule shall cover at least the following equipment:</p> <p>(c) The facility must maintain a record for all equipment containing the following information: manufacturer, make, and model of the equipment; date of purchase of the equipment; any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to</p>	L 100		

Alabama Department of Public Health

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L 100	<p>Continued From page 10</p> <p>service; date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by clinic personnel; the names and qualifications of the company and technician performing the tests, maintenance, or repairs; and the results of any tests, maintenance, or repairs. In addition, all manufacturer literature and information must be maintained in this record. If any of this information is not available for equipment purchased prior to October 2006, the fact of the missing information shall be noted in the equipment record, and, if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.</p> <p>The requirements of this rule were not met as evidenced by:</p> <p>Based on observations, review of emergency equipment logs and interviews it was determined that the Center failed to ensure equipment was in operable condition for use. This had the potential to affect all patients served.</p> <p>Findings include:</p> <p>During a tour of the facility 11/30/10 at 9:30 AM, the Emergency Crash Cart Monthly Check form was observed located on the Emergency Cart with the AED (Automated External Defibrillator). The Registered Nurse (RN) had documented for the months of January, February, March, April and May 2010, " AED tested, O2(oxygen) tanks OK." The months of June, July, August, September, October and November had initials under the signature line but no other information.</p> <p>During an interview with the Administrator,</p>	L 100		

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L 100	Continued From page 11 Employee Identifier (EI) # 1, 11/30/10 at 10:20 AM, the surveyor asked if the AED had been tested during the months of June through November. EI # 1 stated that she was sure it had but the regular RN had not been there and it wasn't documented. The Center had continued to perform surgical procedures without prior testing of the defibrillator to ensure it was properly functioning in case of an emergency.	L 100		