

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 03/01/2012
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 000	INITIAL COMMENTS Survey Introduction Department surveyors visited the licensed abortion or reproductive health clinic operated by New Woman All Women Health Care ("the Clinic"), located at 1001 17th Street South, Birmingham, Alabama to conduct an on-site annual survey and to conduct a complaint investigation. The complaint alleged that the Clinic had a breach in protocol on January 21, 2012, resulting in two patients being transferred out via ambulance to a local hospital. The complaint further alleged that the Clinic has no wheelchair/gurney access and that the current State Board of Health rules require corridors and doors to be wide enough for stretchers and that all facilities must comply with ANSI 117.1, which requires buildings and facilities to be accessible and to be usable by the physically handicapped. During the course of the Department's investigation into these allegations surveyors interviewed the Emergency Medical Service Personnel, all clinic staff working on the date of the incident, the physician and clinic nursing supervisor. The Department surveyors observed clinic staff provide patient care, took measurements of the clinic's corridors and the wheelchair and gurney used on the day of the incident and reviewed the medical records for all of the patients that received treatment on January 21, 2012. The clinic's video surveillance camera footage from the incident was reviewed as well. During the course of the interviews with the Emergency Medical Service Personnel it was	L 000			

Health Care Facilities

TITLE

(X6) DATE

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

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L 000	Continued From page 1 verified by the Department surveyors that at no point during their visit did they attempt to enter the Clinic with a gurney and were unable to do so. The width of the gurney measures at 25 inches and it has the ability to make sharp turns, if needed. The surveyors measured the width of the corridors inside the clinic and they were 48 inches wide. There was more than enough clearance for the gurney to enter the building and make any turns necessary to get to the patient recovery room. There are four entrances and exits from the Clinic. Review of the medical records for the two patients that were transported via ambulance on January 21, 2012 revealed they both received an unknown excessive amount of the drug Vasopressin. This was a medication error on the part of the Registered Nurse that the Clinic physician and Clinic Administrator identified. The medication error was identified and the Clinic called 911. Both of the patients were transported to a local hospital for evaluation and monitoring. The Registered Nurse that made the medication error has had disciplinary action taken against her by the Clinic. Medical records and interviews with clinical staff at the Clinic did not indicate the patients were in immediate danger. Medical record reviews from the local treating hospital did not indicate the patients were in immediate danger. The onsite visit did result in citations.	L 000			
L 100	ALABAMA LICENSURE DEFICIENCIES	L 100			

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L 100	Continued From page 2	L 100		
	<p>420-5-1-.02 Administration (1)(a) Governing Authority. Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is organized, equipped, staffed and administered in a manner to provide adequate care for each patient admitted.</p> <p>The requirements of this rule were not met as evidenced by:</p> <p>Based on interview, review of medical records and review of policy and procedures it was determined the governing body failed to ensure:</p> <ol style="list-style-type: none"> 1. The clinic staff was properly trained to provide safe quality patient care. Refer to 420-5-1-.02(5)(a)(b) 2. The clinic had policies and procedures related to medication errors and the administration of medications, including administration of intravenous medications. Refer to 420-5-1-.03(7)(b) 3. Employee Identifiers # 5 and # 12, physicians, had documentation they were qualified to perform abortions in their personnel files. Refer to 420-5-1-.02(d)(2) 4. The physician documented in the medical record legibly. Refer to 420-5-1-.02(8)(b) 5. The recovery room medical assistant was documenting the condition of the patient prior to discharge. Refer to 420-5-1-.02(8)(a)(b) 			

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L 100	Continued From page 3	L 100			
	<p>6. Complete and accurate documentation of the administration of medications given to patients was included in the medical record. Refer to 420-5-1-.02(8)(a)(b)</p> <p>7. The Registered Nurse (RN) administered and prepared medications accurately per a signed physician's order. Refer to 420-5-1-.03(7) (b)</p> <p>8. All patient used equipment had a record of routine inspection and maintenance. Refer to 420-5-1-.04 (5)(b)(c)</p> <p>9. The on-call nurse returned patient calls, documented the correct dates on the on-call reports, completed the on-call record and notified the physician of patient problems. Refer to 420-5-1-.03 (d)(e)</p> <p>Findings include:</p> <p>On 2/01/12 at 4:50 PM the surveyors reviewed the policy and procedure manual and could not find policies for medication errors or the administration of medications.</p> <p>On 2/03/12 at 10:50 AM, in an interview with Employee Identifier (EI) # 1, the Administrator, was asked if the clinic had policies and procedures for addressing medication errors. Employee Identifier # 1 stated, " No. " EI # 1 was asked if the clinic had a policy and procedure for the administration of medications and responded she did not think so. Employee Identifier # 1 did say the clinic had standing orders for the administration of certain medications and looked through the policy and procedure manual. No policy for the administration of medications was found by EI # 1.</p> <p>Employee Identifier # 1 was asked who was responsible for the overall management of the clinic and stated, "Me. The Governing Authority."</p>				

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L 100	Continued From page 4	L 100		
	<p>420-5-1-.02 Administration.</p> <p>(5) Personnel.</p> <p>(a) Each abortion clinic shall utilize personnel to provide services who have appropriate training and qualifications for the services that they provide.</p> <p>(b) Personnel Files. There shall be a personnel file for each employee which shall include:</p> <p>1. Job Description. A written job description that describes the duties and responsibilities, position title, authority, and qualifications for each employee.</p> <p>3. Orientation. There shall be a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include at a minimum, fire and disaster safety, medical emergencies, infection control, and patient confidentiality. There shall be documentation of completion of this orientation maintained in the personnel file.</p> <p>The requirements of this rule were not met as evidenced by:</p> <p>Based on review of personnel files and interviews, it was determined that the Clinic failed to have the following information in the personnel files:</p> <p>1. A written job description for 3 of 7 employee files reviewed.</p> <p>2. Documentation of orientation for 5 of 7 employee files reviewed</p> <p>3. Documented patient care responsibilities</p>			

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L 100	Continued From page 5 included in the employee's job description. This had the potential to affect all patients served. Findings include:	L 100		
	1. Employee Identifier (EI) # 3, the Registered Nurse who worked on 1/21/12 when two patients were transferred out of the Center by ambulance, with a date of hire of 10/28/11 failed to have a written job description and failed to have a comprehensive orientation completed for a Registered Nurse in her personnel folder. Employee Identifier # 3 worked independently providing direct patient care on 1/21/12 when an unknown excessive amount of the drug Vasopressin was administered to two patients, Medical Record (MR) # 2 and MR # 3. These two patients were transported out of the clinic via ambulance and sent to Hospital # 1 for evaluation and additional monitoring. On 2/01/12 at 10:45 AM, Employee Identifier # 2, the Registered Nurse Supervisor of the clinic was interviewed. During this interview EI # 2 was asked what her responsibilities were related to training the other nursing staff. Employee Identifier # 2 stated that EI # 3 worked with EI # 2 a " few days to see how we did things. She (EI # 3) followed me around, watched me counsel, I watched her counsel and watched her draw up meds. " Employee Identifier # 2 stated that EI # 3 worked with her on clinic and non-clinic days. Employee Identifier # 2 was asked if she oriented EI # 3, the Registered Nurse that worked on 1/21/12, and she stated, " She worked with me. " Employee Identifier # 2 was asked if anyone else in the clinic oriented EI # 3 and EI # 2 stated, "I don't know beyond myself."			

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L 100	Continued From page 6	L 100			
	<p>On 2/02/12 at 4:35 PM, Employee Identifier # 2, the Registered Nurse Supervisor of the clinic was interviewed again. During this interview EI # 2 was asked if she ever observed EI # 3 draw up any medications. Employee Identifier # 2 stated she had observed EI # 3 draw up the drug Toradol. Employee Identifier # 2 was asked if she ever observed EI # 3 draw up the drug Vasopressin and EI # 2 responded, "No."</p> <p>Employee Identifier # 2 had no documentation that EI # 3 had been checked off to function independently as the clinic Registered Nurse.</p> <p>On 2/03/12 at 10:50 AM, Employee Identifier # 1, the Administrator, was interviewed and asked who at the clinic was responsible for all nursing services. Employee Identifier # 1 responded EI # 2, the Registered Nurse (RN) Supervisor. Employee Identifier # 1 was asked who at the clinic was responsible for the orientation of all nurses and EI # 1 responded EI # 2, the RN Supervisor. Employee Identifier # 1 was asked who at the clinic was responsible for assuring that EI # 3, the RN that worked on 1/21/12, was competent to work independently as a Registered Nurse and EI # 1 responded, "I would say (Employee Identifier # 2)." Employee Identifier # 1 was asked if the clinic had any documentation to show that EI # 3 was given an orientation and job skills check-off for her role as a registered nurse and EI # 1 responded, "I thought so." Employee Identifier # 1 reviewed the personnel file for EI # 3 and stated that EI # 3 had read the protocol manual. EI # 1 based this statement on a copy of a document that EI # 3 signed on 6/14/07, prior to EI # 3 obtaining her nursing license and functioning in the role of the clinic nurse. There was no job description and no</p>				

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L 100	Continued From page 7 nursing skills check-off in Employee Identifier # 3's personnel file when reviewed by EI # 1 and the surveyors. On 2/07/12 at 9:00 AM, Employee Identifier # 3, the Registered Nurse who worked independently on 1/21/12 when two patients were transferred out by ambulance after receiving an unknown excessive amount of the drug Vasopressin was interviewed. Employee Identifier # 3 was asked what type of orientation she received at New Woman All Women. Employee Identifier # 3 stated she trained with EI # 2, the RN Supervisor two times on clinic days. Employee Identifier # 3 stated no one else at the clinic oriented her. Employee Identifier # 3 stated she trained with EI # 1, the Administrator, in another clinic out of state for conducting patient counseling. Employee Identifier # 3 was asked if she had worked at the New Woman All Women clinic independently before on clinic days and stated, "Yes." Employee Identifier # 3 was asked what she was told about preparing medications for clinic and EI # 3 stated she misread the label and was drawing up the medications the wrong way. Employee Identifier # 3 stated, "I misread the mark on where to draw up to (the drug Vasopressin)." Employee Identifier # 3 stated the information is usually on the board, but she did not see it. Employee Identifier # 3 confirmed that EI # 2 had pre-drawn up syringes with the drug Vasopressin before the 1/21/12 clinic. Employee Identifier # 3 stated all of the pre-drawn up syringes of Vasopressin had been used and that was why she had to draw up more Vasopressin. Employee Identifier # 3 was asked how she would know what medication to give and the amount to give and EI # 3 responded she knew from when she trained with EI # 2, the RN Supervisor. Employee Identifier # 3 was asked when she became aware	L 100		

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L 100	Continued From page 8 she had made a medication error and she stated when Employee Identifier # 4, a clinic physician, came out and asked her if she was drawing up too much medication because this was the second patient that got sick (vomited) after he administered the paracervical block. At this point Employee Identifier # 1, the Administrator, was summoned by EI # 4 and it was discovered that EI # 3 was drawing up 2.0 cubic centimeters of Vasopressin instead of the 0.2 cubic centimeters. The clinic failed to ensure that Employee Identifier # 3, a newly graduated Registered Nurse, was fully oriented to complete her duties as a RN in the clinic. The clinic failed to have documentation of the job description and an employee skills check-off to show that EI # 3 knew the correct procedure for medication preparation. 2. Employee Identifier # 2, Registered Nurse Supervisor, date of hire 7/9/10 failed to have a comprehensive orientation completed for a registered nurse in her personnel folder. Employee Identifier # 2 is the primary Registered Nurse responsible for patient care on most clinic days and takes the after hour calls for the Clinic. EI # 2 had a job description in the personnel file for Nursing Supervisor and Qualified Counselor. The Nursing Supervisor job description included Responsibilities as follows: 1. Act as charge nurse supervising medical staff and patient areas. 4. Provide adequate orientation for new medical personnel. EI # 2 failed to adequately orient EI # 3, the Registered Nurse who worked independently on	L 100			

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L 100	Continued From page 9 1/21/12 when an unknown excessive amount of the drug Vasopressin was administered to two patients that resulted in their transport to Hospital # 1 for evaluation and further monitoring, as directed in the job description of the Registered Nurse Supervisor. Refer to the above interviews with Employee Identifiers # 1, # 2 and # 3 under example 1. 3. Employee Identifier # 7, Medical Assistant in the procedure room had the following job descriptions in her personnel file: Sterile Technician Laboratory Assistant Receptionist Medical Staff Procedure Room. The above job descriptions are not dated or signed to indicate which position EI # 7 worked. The job description for the medical staff procedure room includes the following responsibilities: 1. Act as physician's assistant and patient support person 2. Be proficient with sterile technique 3. Maintain an orderly environment in the procedure room 4. Has all equipment available for the physician, including any emergency drugs and equipment 5. Per physician instruction, assist in any emergency that may arise and get help immediately 6. Chart pertinent patient information 7. Complete daily inventory of procedure room supplies and keep room stocked 8. Clean exam/procedure room at end of each clinic day 9. Cross train for recovery and other patient care	L 100		

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L 100	Continued From page 10 areas 10. Other duties as assigned by the Nursing Supervisor or Clinic Administrator. EI # 7 has been administering injections of Rhogam and Methergine in the procedure room per an interview with EI # 1, Administrator on 2/3/12 at 8:55 AM. This skill is not included in her responsibilities and there is no documentation EI # 7 has been observed or checked-off by the Registered Nurse Supervisor to administer patient injections. 4. Employee Identifier # 6, the Recovery Room Medical Assistant had a date of hire of 3/12/09. The job description in the personnel folder is for the recovery room nurse. The word nurse has been marked through with a black marker as well as the qualifications of a current Alabama Nursing license either RN (Registered Nurse) or LPN (Licensed Practical Nurse) and one year of nursing experience preferred. The responsibilities on the form have not been altered and include items only a licensed individual may complete, for example: Under physician standing orders provides and/or administers medications. Cross trains in procedure room, ultrasound, follow-up exams, counseling and wherever appropriate. The clinic failed to have a job description for duties EI # 6 would perform as the recovery room medical assistant. 5. Employee Identifier # 8, Medical Assistant, date of hire 2/7/11 failed to have a completed orientation form in the personnel file. The form in	L 100			

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L 100	Continued From page 11 the file was signed and dated 2/7/11, the date of hire, but not co-signed by the administrator. An addendum form in the file regarding the Woman's Right to Know Act was blank and the job descriptions for Medical Staff procedure room, Laboratory Assistant and Sterile Technician and Ancillary Medical Support was in the file with no name and no date. 6. Employee Identifier # 11, a Registered Nurse, date of hire 9/24/10, failed to have a comprehensive orientation completed for a registered nurse in her personnel folder. The new employee training record in the personnel folder with her name has no other information, no dates or signatures for when said training occurred. 7. Employee Identifier # 10, Receptionist/ Front Desk, date of rehire per the employee was 8/2011. The date of hire in the file was 6/2011. A review of the personnel file provided to the surveyor 1/31/12 revealed an application dated 6/9/06. The only item in the file dated 2011 to 2012 was an evaluation form that was dated 1/4/12, the date of EI # 10's evaluation. There was not a job description in the personnel file for EI # 10. The above rule violation is a repeat deficiency from the July 27, 2011, recertification survey. 420-5-1-.02 Administration. (d) Physician Qualifications. 1. All physicians performing abortions at the	L 100		

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L 100	Continued From page 12 facility shall be qualified through training and experience in performing abortions and recognizing and managing complications. 2. Before a physician performs any procedure at the facility, the Medical Director shall credential each physician on the basis of his or her qualifications, and a file shall be kept at the facility detailing the qualifications and experience of each physician. This file must, at a minimum, include: i) proof of licensure in Alabama and all other states in which the physician is or has ever been licensed, ii) a record of any adverse actions ever taken against the physician's license in Alabama or any other state, iii) a current resume, iv) a record of staff privileges at any accredited hospital in the United States, v) a report from the National Practitioner Databank and vi) proof of the nature of the physician's training and experience. This file shall be kept current. The medical director shall review the physician's qualifications at the time the physician is hired and at least yearly thereafter. This review shall include direct observation of the physician's clinical skills, and the results of this review shall be placed in the physician's file. All physicians performing abortions at a facility as of February 1, 2007 shall be credentialed within thirty days of this rule becoming effective. This rule is not met as evidenced by: Based on a review of the physician's credentialing file and an interview it was determined that two of two physicians performing procedures at this clinic had not been observed performing abortion procedures by the clinic Medical Director. This had the potential to affect all patients served. Findings include:	L 100			

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L 100	Continued From page 13 On 1/31/12 at 12:30 PM, the file of Employee Identifier # 5, a clinic physician, was reviewed by the surveyor. The only current items in the file were a medical license and a controlled substance form both with an expiration date of 12/31/12. The file failed to include: i) proof of licensure in all other states in which the physician is or has ever been licensed, ii) a record of any adverse actions ever taken against the physician's license in Alabama or any other state, iii) a current resume, iv) a record of staff privileges at any accredited hospital in the United States, v) a report from the National Practitioner Databank and vi) proof of the nature of the physician's training and experience. On 2/02/12 EI # 5 was observed by the surveyor to perform surgical abortion procedures. In an interview with Employee Identifier # 1, the Administrator, on 1/31/12 at 1:00 PM, she confirmed there was no documentation of an observation by the Medical Director of EI # 5 performing medical or surgical abortions and the physician's file was not complete. The recovery room log book was reviewed by the surveyors on 2/28/12. Employee Identifier #12 had performed abortion procedures on 2/06/12, 2/13/12 and 2/27/12. On 2/29/12 at 1:45 PM, the file of Employee Identifier # 12, a clinic physician, was reviewed by the surveyor. The only current items in the file	L 100			

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L 100	Continued From page 14 were a medical license and a controlled substance form both with an expiration date of 12/31/12. The file failed to include: i) proof of licensure in all other states in which the physician is or has ever been licensed, ii) a record of any adverse actions ever taken against the physician's license in Alabama or any other state, iii) a current resume, iv) a record of staff privileges at any accredited hospital in the United States, and v) a report from the National Practitioner Databank. 420-5-1-.03 Patient Care. (2) Policies and Procedures. The facility shall develop and follow detailed written policies and procedures that are consistent with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. This rule is not met as evidenced by: Based on review of the clinic policy and procedure manual, an interview and the Alabama Board of Nursing Administration and Safety standards it was determined the clinic failed to have a policy for addressing medication errors and a policy for medication administration. This had the potential to affect all patients served by this clinic. Findings include:	L 100			

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L 100	Continued From page 15	L 100			
	<p>A review of the policy and procedure manual was conducted by the surveyors on 2/01/12. The surveyors were unable to locate policies and procedures that addressed medication errors and medication administration.</p> <p>On 2/03/12 at 10:50 AM, Employee Identifier (EI) # 1, the Administrator, was interviewed and asked if the clinic had policies and procedures for addressing medication errors and medication administration. Employee Identifier # 1 verified there was no policy for addressing medication errors. Employee Identifier # 1 reviewed the policy and procedure manual for a policy on medication administration and found standing orders for certain medications, but not a policy on the administration of medications by clinic staff.</p> <p>The Alabama Board of Nursing Medication Administration and Safety Rule, 610-X-6-.07, provides:</p> <p>(1) The registered nurse or licensed practical nurse shall have applied knowledge of medication administration and safety, including but not limited to:</p> <p>(l) Calculation of drug dosages.</p> <p>(3) The registered nurse or licensed practical nurse shall exhibit skills when administering medications including but not limited to:</p> <p>(d) Measuring medication dosages. (e) Math calculations. (f) Routes of administration.</p> <p>(4) Documentation of medication administration shall comply with the principles of documentation and include safety precautions of medication administration, controlled drug records per federal and state law, and facility policy.</p>				

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L 100	Continued From page 16 According to Potter and Perry, Fundamentals of Nursing, 6th Edition Copyright 2005, Mosby, Inc. "Medication administration is an essential part of nursing practice, which requires a sound knowledge base in order for medications to be administered safely. Nurses must be prepared to administer medications using a variety of routes. " The clinic failed to develop and implement policies and procedures for all current standards of nursing care related to medications. 420-5-1-.03(7)(b) Pharmaceutical Services. 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 after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered 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. The requirements of this rule were not met as evidenced by:	L 100			

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L 100	Continued From page 17	L 100		
	Based on review of the patient records, interview and review of medication administration documentation it was determined:			
	<p>1. Medication preparation by the Registered Nurse (RN) was an inaccurate dose</p> <p>2. Pitocin was administered intravenously to a patient and the RN failed to document and monitor the patient per manufacturer recommendations</p> <p>3. Medication prepared by the RN failed to have a signed physician's order for the nurse to follow prior to the preparation of the medication.</p> <p>4. The RN failed to administer a medication as ordered.</p> <p>This had the potential to affect all patients served at the clinic.</p> <p>Findings include:</p> <p>According to Potter and Perry, Fundamentals of Nursing, 6th Edition Copyright 2005, Mosby, Inc.</p> <p>"A medication order is required for any medication to be administered by a nurse...If the medication order is incomplete, the nurse should inform the prescriber and ensure completeness before carrying out any medication order."</p> <p>"A medication order is incomplete unless it has the following parts: client's full name, date that the order is written, medication name, dose, route of administration, time and frequency of administration, and signature of physician, nurse practitioner, or physician assistant."</p>			

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L 100	Continued From page 18	L 100			
	<p>Pitocin Official FDA information: Revised 12/2009 JHP Pharmaceutical LLC</p> <p>"Indications and Usage for Pitocin- Antepartum: 3. As adjunctive therapy in the management of incomplete or inevitable abortion...</p> <p>"Precautions/ General: All patients receiving intravenous Oxytocin (Pitocin) must be under continuous observation by trained personnel who have a thorough knowledge of the drug and are qualified to identify complications... Except in unusual circumstance, Oxytocin (Pitocin) should not be administered in the following conditions...any condition in which there is a predisposition for uterine rupture, such as previous major surgery on the cervix or uterus including cesarean section...</p> <p>"Pitocin Dosage and Administration A. Induction or Stimulation of Labor Intravenous infusion (drip method) is the only acceptable method of parenteral administration of Pitocin for the induction or stimulation of labor. Accurate control of the rate of infusion is essential and is best accomplished by an infusion pump. C. Treatment of Incomplete, Inevitable or Elective Abortion Intravenous infusion of 10 units of Pitocin added to 500 ml (milliliter) of a physiologic saline solution or 5% dextrose-in-water solution may help the uterus contract after a suction or sharp curettage for an incomplete, inevitable or elective abortion. ...the injection-to-abortion time may be shortened by infusion of Pitocin at the rate of 10 to 20 milliunits (20 to 40 drops) per minute."</p>				

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L 100	Continued From page 19	L 100			
	<p>1. Medical Record (MR) # 1 presented to the clinic on 11/7/11 for her first visit. The patient's blood pressure on this visit was 148/93 and her weight of 230 pounds was recorded.</p> <p>The patient's pregnancy history included two cesarean sections, one in 1995 and the second in 1997. The medical history included surgery 11/2010 for removal of the right ovary. The history also noted that she was a diabetic. The ultrasound performed on the first day established a gestational age of 16 weeks 2 days.</p> <p>Medical Record # 1 returned 11/11/11 for a surgical procedure. The physician, Employee Identifier (EI) # 4, documented the use of 20 ml of 1% Xylocaine plus 5 units of Vasopressin as a paracervical block. The procedure was attempted with difficulty and EI # 4 documented on the surgical procedure note to see written documentation below. The physician documented at 1:30 PM unreadable information, it was written over pre-printed lines on the paper for recovery room documentation. EI # 4 documented the following information that was legible: "(P) plan, will give Pit (Pitocin) 10 units/ 500 ml of NS (normal saline) then reassess in 60 minutes to see if contractions will bring down."</p> <p>EI # 2, the RN Supervisor documented, "1340 (1:40 PM) IV (intravenous) 20 g (gauge) started LAC (left antecubital) 500 cc (cubic centimeters) NS (Normal Saline) hung with 10 units Pitocin running at 75 cc per hr (hour). Patient tolerated without distress."</p> <p>EI # 4, the physician documented, "1430 (2:30 PM) able to complete D&E (dilation & evacuation)</p>				

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L 100	Continued From page 20 with forceps/suction." Medical Record # 1 documented on her comment sheet following her surgical procedure on 11/11/11, "I wish it could have been more private... I needed to be more relaxed." In an interview on 2/3/12 at 9:35 AM with EI # 1, the Administrator, it was confirmed the patient did not have any documented monitoring while the Pitocin was administered. EI # 1 was asked if the clinic had a policy for administration of IV Pitocin and she stated, "No." On 2/10/12 at 9:52 AM, Employee Identifier # 4, the Physician, was interviewed by phone and asked about the monitoring of this patient that received IV Pitocin and what, as the physician would he expect from staff. Employee Identifier # 4 responded MR # 1 was taken to the recovery room and should have had her blood pressure checked. EI # 4 went on to say the patient was not actively bleeding so the type of monitoring would be different than one of a patient that was bleeding. Mosbys Nursing Drug Reference 2008, 21st Edition list the following items as nursing considerations for the nurse who is administering Pitocin to assess for: 1. Blood Pressure 2. Pulse 3. Watch for changes that may indicate hemorrhage 4. Respiratory rate, rhythm, depth; notify prescriber of abnormalities 5. Length, intensity, duration of contractions; notify prescriber of contractions lasting over one minute... 6. Signs and symptoms of water intoxication;	L 100		

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L 100	Continued From page 21 confusion, anuria, drowsiness, headache. There was no documentation of where the patient was located while she received the IV Pitocin. There was no documentation how the rate of the infusion of Pitocin was controlled. There was no documentation of how much of the IV Pitocin was infused, no monitoring of the patient's vital signs, contractions, bleeding, signs and symptoms of water intoxication or pain level during and after the infusion. 2. Medical Record # 2 presented to the clinic 1/20/12 for her first visit, the medical history included an allergy to Latex. Medical Record # 2 returned on 1/21/12 for a surgical procedure. The physician, EI # 4 documented the use of 20 ml of 1% Xylocaine plus 5 units of Vasopressin as a paracervical block. EI # 4 documented, "the patient tolerated the procedure not well, after paracervical block vomited ? secondary to (unable to read documentation written across lines on the form). Vital stable O2 (oxygen) sat (saturation) 95%. Has latex allergy found out after (unable to read documentation written across lines on the form)." The recovery room documentation at 9:15 AM revealed the blood pressure was 136/118, a second blood pressure documented with no time by the entry was recorded as 136/118. EI # 4 documented on the bottom of the procedure form, "2nd(second) similar case nurse was drawing up more than 0.2 ml (Vasopressin) unsure how much." The patient was transferred to Hospital # 1 by emergency services for observation.	L 100			

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L 100	Continued From page 22 Employee Identifier # 3, the Registered Nurse working on 1/21/12, was mixing Vasopressin with 1% Xylocaine for the physician's use in the paracervical block. EI # 3 had drawn up the Xylocaine in the 20 ml syringe and then drew up the Vasopressin according to a phone interview with EI # 4 on 2/10/12 at 9:52 AM. The most current typed "drawing up medication" piece of paper hanging on the wall at the nurse's station instructs the nurse to draw up Lidocaine 10cc to 20cc using sterile technique and Vasopressin 0.2 cc is drawn up in a tuberculin syringe using sterile technique. The most current process is not signed by the physician as an order. A review of the Governing Body meeting minutes dated 5/21/11 documented the protocol manual was, " reviewed and deemed acceptable. The use of Vasopressin on every patient was discussed and further dialogue will continue amongst the physicians. " The minutes were signed by the Medical Director. A review of the current clinic pre-operative medication protocol lists Lidocaine 1% 10-20 cc injected paracervically by MD (Medical Doctor). There is no listing of the drug Vasopressin on the protocol. The protocol is signed by the Medical Director. On 2/10/12 at 9:52 AM, Employee Identifier # 4, the physician who performed procedures on 1/21/12, was interviewed by phone and asked if the Registered Nurses at the clinic usually drew up the Lidocaine and Vasopressin for the physicians. Employee Identifier # 4 responded that he and the Medical Director late last year began using Vasopressin with all patients and the	L 100			

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L 100	Continued From page 23 protocol was changed. EI # 4 did not remember when the protocol was changed, but that the nurses would draw up the medications correctly or the physician would draw up the medication in the procedure room. EI # 4 also stated that the nurses had been mixing the two medications in a large syringe for the past 3 to 4 months. 3. Medical Record # 3 presented to the clinic on 1/20/12 for her first visit. Medical Record # 3 returned 1/21/12 for a surgical procedure. The physician, EI # 4 documented the use of 20 ml of 1% Xylocaine plus 5 units of Vasopressin as a paracervical block. EI # 4 documented, "the patient tolerated the procedure not well, vomited, vitals okay, suspect secondary > (greater than) dose Vasopressin. Nurse inadvertently drew up more than 0.2 ml, unsure how much will discuss with Medical Director of clinic. *Patient to be transferred to ED (Emergency Department) for observation." On 2/07/12 at 9:00 AM, Employee Identifier # 3, the Registered Nurse who worked on 1/21/12 and administered the wrong dose of the medication Vasopressin, was interviewed. Employee Identifier # 3 was asked to explain what happened on 1/21/12 and during her statement she stated she drew up too much of the Vasopressin into the syringe with the Lidocaine. Documented on the bottom of the procedure record dated 1/21/12 was: Methergine 0.2 mg (milligrams) IM (intramuscular) right at 9:52 AM. During an interview on 2/07/12 at 9:00 AM, EI # 3 the RN confirmed she did not administer the injection and was written up by EI # 1, the Administrator. EI # 1 placed the RN, EI # 3 on 90	L 100			

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L 100	Continued From page 24 days probation on 1/26/12 for: " a. Mistakenly drawing up more than 0.2 cc of Vasopressin which resulted in two patients being overdosed and then hospitalized. b. Failing to give an injection of Methergine which was ordered by the MD (medical doctor)." The clinic failed to have an approved standing order or current protocol signed by the Medical Director for the use of the drug Vasopressin. The clinic failed to assure that EI # 3 was competent to work independently on clinic days for medication administration. The clinic failed to have policies and procedures for the administration of medications and the use of IV Pitocin. The above rule violation is a repeat deficiency from the July 27, 2011, recertification survey. 420-5-1-.02 Administration. (8) Records and Reports. (a) Medical Records to be kept. An abortion facility shall keep adequate records, including procedure schedules, histories, results of examinations, nurses' notes, records of tests performed and all forms required by law. (b) Authentication of Records. All records shall be legibly written, dated, and signed in an indelible manner with the identity of the writer indicated. (c) Filing of Records. All patient medical records shall be filed in a manner which will facilitate easy retrieval of any individual's record. The requirements of this rule were not met as evidenced by: Based on observation, review of medical records, interviews, Alabama Board of Medical Examiners and Medical Licensure Commission Rule and the	L 100			

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L 100	Continued From page 25 Alabama Board of Nursing Standards of Practice it was determined the clinic failed to ensure: 1. Medical record documentation was legible. 2. Medical record documentation was accurate for dates of ultrasound images, complete expiration dates provided for lot numbers of drugs and accurate dates for phone calls received by the on-call nurse. 3. Medication additions and changes to pre-printed medication dosage amounts were initialed and dated by the licensed practitioner who made said changes. 4. Advance documentation of patient care had not been documented prior to the care being rendered by clinic staff. 5. Late entries made in the medical record were documented as late entries with the initials of the individual who made the late entry and the date the late entry was made, at a minimum. 6. Medical records contained documentation of pelvic examinations that were to be done for the medical procedures. 7. Medical records were filed in an organized manner, easily retrievable and complete. This had the potential to affect all patients served by this abortion clinic. Findings include: Alabama Board of Medical Examiners, Medical Licensure Commission Rule 545-X-4-.09, Minimum Standards for Medical Records, provides: "Adequate records are necessary to ensure continuity of care, not only by the physician who maintains a particular record, but by other medical professionals. Therefore, every physician licensed to practice medicine in Alabama shall	L 100			

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L 100	Continued From page 26 maintain for each of his or her patients, a record which, in order to meet the minimum standard for medical records, shall: (1) be legible, and written in the English language; (4) indicate the date any professional service was provided; (5) contain pertinent information concerning the patient's condition; (6) reflect examinations, vital signs, and tests obtained, performed, or ordered and the findings or results of each; (8) indicate the medications prescribed, dispensed, or administered and the quantity and strength of each; (9) reflect the treatment performed or recommended; (10) document the patient's progress during the course of treatment;" Alabama Board of Medical Examiners, Medical Licensure Commission Rule 545-X-4-.06, Unprofessional Conduct, provides: "Unprofessional conduct shall mean the commission or omission of any act that is detrimental or harmful to the patient of the physician or detrimental or harmful to the health, safety, and welfare of the public, and which violates the high standards of honesty, diligence, prudence and ethical integrity demanded from Alabama. Furthermore, without limiting the definition of unprofessional conduct in any manner, the Commission sets out the below as examples of unprofessional conduct: (11) Failing or refusing to maintain adequate records on a patient or patients." Alabama Board of Nursing, Standards of Practice Rule 610-X-6-.06, Documentation Standards,	L 100			

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L 100	Continued From page 27	L 100			
	<p>provides:</p> <p>(2) Documentation of nursing care shall be:</p> <p>(d) Timely.</p> <p>(i) Charted at the time or after the care, including medications, is provided. Charting prior to care being provided, including medications, violates principles of documentation.</p> <p>(ii) Documentation of patient care that is not in the sequence of the time the care was provided shall be recorded as a "late entry" including a date and time the late entry was made as well as the date and time the care was provided.</p> <p>(e) 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>(f) Corrections to a record by a licensed nurse shall have the name or initials of the individual making the correction.</p> <p>Medical Record findings:</p> <p>The Mifeprex Authorization Consent form stated under item number seven, "I agree to a vaginal and/or abdominal ultrasound, which is required to date my pregnancy accurately. I also understand that the ultrasound is one of many diagnostic tools used during the course of my medical abortion, and that the ultimate determination of my length of pregnancy will rely on the physician's final diagnosis. I also understand that I will have a pelvic exam today by the physician that will assist in this diagnosis." A review of medical records for 3 of 9 patients that had a Mifeprex Authorization Consent form revealed there was no documentation the physician performed a pelvic examination.</p> <p>1. Medical Record (MR) # 1, presented to the clinic on 11/7/11 for her first visit. The patient's</p>				

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L 100	Continued From page 28 blood pressure on this visit was 148/93 and her weight of 230 pounds recorded. The ultrasound performed on the first day established a gestation of 16 weeks 2 days.	L 100			
	MR # 1 returned 11/11/11 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. The procedure was attempted with difficulty and EI # 4 documented on the surgical procedure note to see written documentation below. The physician documented at 1:30 PM unreadable information, it was written over pre-printed lines on the paper for recovery room documentation. The recovery room vital signs were documented on a separate sheet of paper but the medical assistant failed to document the condition of the patient on discharge, the discharge instructions and medications provided to the patient. Methergine 0.02 mg (milligrams) given IM (intramuscular) at 3:40 PM was documented but, the signature of who administered the injection was not legible. In an interview with Employee Identifier (EI) # 1, the Administrator at 9:35 AM on 2/3/12, confirmed the writing was not legible and no signature with the identity of the writer was available on the injection area of the note. 2. Medical Record (MR) # 2 had a surgical				

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L 100	Continued From page 29 procedure on 1/21/12. This patient's surgical procedure portion of her medical record was forwarded to the Department prior to the arrival of Department surveyors for the on-site investigation. The surgical procedure form sent to the Department failed to document a completed date for the day 1 visit, no year was listed. The form documented on day 2 Employee Identifier (EI) # 2's name as the Registered Nurse (RN). There was no fetal age in weeks documented in the surgical procedure section of the note that was to be completed by the physician. During the on-site investigation on 1/31/12, EI # 1 the Administrator, gave the surveyors MR # 2 for review. During the review of the medical record on-site the surveyors identified the addition of Employee Identifier # 3's name on the form as the RN on day 2 and the number "10" had been added to the fetal age in weeks section of the surgical procedure note. The medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 4, the physician, wrote all over the bottom part of the procedure form, which was not legible as it was written on top of pre-printed information. The surgical procedure had a time of 10:10 AM documented. The time the patient entered the recovery room was documented as 9:15 AM. A blood pressure was recorded at 9:15 AM as 136/118 and a second blood pressure of 136/118 was written with no time. The patient discharge note was documented by the medical assistant in the recovery room, EI # 6, at 9:45 AM,	L 100			

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L 100	Continued From page 30 "Ambulatory d/ced (discharged) in no distress." The patient was actually transferred by ambulance to a local hospital at 10:33 AM, per the ambulance run report, for an unknown excessive dose of Vasopressin.	L 100			
	<p>In an interview on 2/03/12 at 10:30 AM, EI # 1, the Administrator, confirmed there had been additional documentation added to the patient's surgical procedure report note that was sent to the Department. EI # 1 stated she instructed EI # 3, the RN, to sign the form since she was the RN on duty and EI # 1 also stated she added the number "10" to the blank section for fetal weeks. EI # 1 confirmed the recovery room assistant, EI # 6, documented the time in and out on the form and discharge condition prior to the patient leaving the clinic.</p> <p>On 2/01/12 at 10:45 AM, Employee Identifier # 2, the RN Supervisor, was interviewed and confirmed she did not work on day 2, 1/21/12. EI # 3, a RN, worked this day.</p> <p>3. MR # 3 presented to the clinic 1/20/12 for her first visit.</p> <p>MR # 3 returned on 1/21/12 for a surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>The physician, EI # 4 continued to write all over the side and bottom part of the procedure form, which was not legible as it was written on top of pre-printed information.</p>				

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L 100	Continued From page 31 The patient entered the recovery room at 9:50 AM. A blood pressure was recorded at 9:50 AM and 10:05 AM, a third time entry of 10:35 AM was written, but no blood pressure results were documented. The patient discharge was documented by the medical assistant with no time, "Ambulatory d/ced (discharged) in no distress." The patient was transferred by ambulance to a local hospital at 10:40 AM for an unknown excessive dose of the drug Vasopressin. The only nurse signature on the form for 1/21/12 was by EI # 2, Registered Nurse Supervisor who did not work on 1/21/12. There were no initials to document who had administered the pre-op medications at 9:20 AM. Documented at the bottom of the procedure form was: Methergine 0.02 mg (milligrams) IM (intramuscular) right at 9:52 AM. On 2/07/12 at 9:00 AM, during an interview EI # 3, the RN confirmed she did not administer the injection. EI # 3 was written up by EI # 1, Administrator. EI # 1 placed the RN, EI # 3, on 90 days probation on 1/26/12 for: "a. Mistakenly drawing up more than 0.2 cc of Vasopressin which resulted in two patients being overdosed and then hospitalized. b. Failing to give an injection of Methergine which was ordered by the MD (medical doctor)." A review of the medical record onsite on 2/1/12 revealed a second nurse, Employee Identifier # 3, had signed the form that she had administered the medications. EI # 1 stated on 2/2/12 at 4:15 PM that she had asked the nurse, EI # 3, to go	L 100			

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L 100	Continued From page 32 back and sign the form after it was sent to the surveyors on 1/26/12. EI # 1 confirmed the recovery room assistant documented the time in and out on the form and discharge condition prior to the patient leaving the clinic.	L 100			
	<p>The physician, EI # 4 documented in the surgical procedure section of the form an ultrasound was completed and viewed by the patient. On review of the ultrasound pictures in the medical record there were three ultrasound pictures dated 1/20/12 between 10:51 AM and 10:54 AM. Another ultrasound picture in the medical record was dated 1/22/12 at 00:44:39.</p> <p>In an interview with Employee Identifier (EI) # 1, Administrator on 2/2/12 at 4:15 PM, EI #1 confirmed it was true none of the ultrasounds were dated 1/21/12, the date of the surgical procedure by the physician.</p> <p>4. MR # 4 presented to the clinic on 1/17/12 for her first visit. The patient's blood pressure, documented on a separate form dated 1/18/12, was 130/98 and her pulse was 111. The hematocrit was 32 with a note written by EI # 2, Registered Nurse Supervisor, "Over the counter iron." and initialed by EI # 2 out to the side of form.</p> <p>The patient returned 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>EI # 2 signed the form on day 2, 1/21/12 even</p>				

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L 100	Continued From page 33 though she was not working 1/21/12. EI # 3, Registered Nurse signed under EI# 2's name as the nurse for 1/21/12. The physician documented a time which was not legible on the surgical procedure section of the form.	L 100			
	<p>The recovery room section documents the patient was present from 8:15 AM until 9:45 AM. The condition of the patient and her discharge was not documented as the vital signs for 9:15 AM through 9:45 AM were written over the notes section of the form where the medical assistant in the recovery room writes condition and mode of discharge.</p> <p>In an interview 2/2/12 at 4:15 PM with EI # 1, the Administrator she confirmed it was difficult to read the form. When asked why EI # 2 signed the form when she was off she stated, "To make it easier on herself."</p> <p>5. MR # 5 presented to the clinic on 1/10/12 for her first visit.</p> <p>MR # 5 returned 1/21/12 for a surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. A second Registered Nurse initialed by the pre-op medications as having administered them but no signature was present on the form to identify the licensed nurse.</p> <p>The physician documented a time which was not</p>				

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L 100	Continued From page 34 legible on the surgical procedure section of the form. In an interview 2/3/12 at 8:55 AM with EI # 1, Administrator she confirmed she could not tell what time the procedure was completed. EI # 1 stated that she thought it was 8:05 AM as that was the time the patient went to the recovery room. 6. MR # 6 presented to the clinic on 1/17/12 for her first visit. MR # 6 returned on 1/21/12 for a surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. A second Registered Nurse initialed by the pre-op medications as having administered them but no signature was present on the form to identify the licensed nurse. The form indicated MR # 6 received Rhogam and Methergine 0.02 mg IM. The form does not document who administered the injections, the Methergine has a time of 7:20 AM with no signature and the Rhogam appears to have a time of 9:21 AM written over to be 7:21 AM. In an interview 2/3/12 at 8:55 AM with EI # 1, the Administrator, she confirmed EI # 7 administered the injections. EI # 7 was the medical assistant working in the room with the physician during the	L 100			

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L 100	Continued From page 35 procedure for MR # 6. EI # 1 stated, "She has been giving injections for years." 7. MR # 7 presented to the clinic on 1/17/12 for her first visit.	L 100			
	<p>The patient returned on 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under the first nurse for 1/21/12. The physician documented a time which was not legible on the surgical procedure section of the form.</p> <p>The recovery room section documents the patient was present from 8:55 AM until 9:05 AM. The condition of the patient and her discharge was not legible.</p> <p>In an interview 2/3/12 at 8:55 AM with EI # 1, the Administrator, confirmed she could not tell what time the procedure was completed. EI # 1 stated that she thought it was 8:55 AM as that was the time the patient went to the recovery room. EI # 1 stated that she thought EI # 6 had documented the patient left the recovery room at 9:25 AM and confirmed it looked like 9:05 AM.</p> <p>8. MR # 8 presented to the clinic 1/12/12 for her first visit.</p> <p>The patient returned 1/21/12 for the surgical</p>				

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L 100	Continued From page 36 procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under the first nurse for 1/21/12. The form indicated MR # 8 received Rhogam IM. The form does not document who administered the injections, the Rhogam has a time of 7:32 AM with no signature. In an interview 2/3/12 at 8:55 AM with EI # 1, the Administrator, she confirmed EI # 7 administered the injections. EI # 7 was the medical assistant working in the room with the physician during the procedure for MR # 8. EI # 1 stated, "She has been giving injections for years." 9. MR # 9 presented to the clinic 1/10/12 for her first visit. The patient returned 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under EI# 2's name as	L 100			

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L 100	Continued From page 37 the nurse for 1/21/12. The physician documented a time which was not legible on the surgical procedure section of the form. In an interview 2/3/12 at 9:15 AM with EI # 1, Administrator she confirmed she could not tell what time the procedure was completed. EI # 1 stated that she thought it was 8:45 AM as that was the time the patient went to the recovery room. 10. MR # 10 presented to the clinic on 1/5/12 for her first visit. The patient returned 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under EI# 2's name as the nurse for 1/21/12. The physician documented a time which was not legible on the surgical procedure section of the form. The patient was pre-medicated with Ibuprofen 800 mg and Diazepam 10 mg by mouth at 7:00 AM. The patient had a documented gestational age of the fetus of 11 weeks. According to the recovery room record and EI # 1 the patient was through with her procedure at 7:35 AM. In an interview 2/3/12 at 9:15 AM with EI # 1, Administrator she confirmed she could not tell what time the procedure was completed. EI # 1	L 100			

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L 100	Continued From page 38 stated that she thought it was 7:35 AM as that was the time the patient went to the recovery room. The time documented the patient entered the recovery room was 8:35 AM. Written over the 8:35 AM time was 7:35 AM. The discharge time was documented as 8:05 AM. 11. MR # 12 presented to the clinic on 1/17/12 for her first visit. The patient returned 1/21/12 for the medical abortion procedure. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. The RU 486 Alternative Protocol section of the note documented Misoprostol 800 mcg (micrograms). The dosage amount of 800 mcg had been lined through and 1600 mcg was written in. There were no initials by this change in dosage amount to indicate who made the dosage change. The physician documented a time which was not legible on the medical procedure section of the form. The discharge note section from the recovery room is not legible. In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to read the form. When asked why EI # 2 signed the form when she was off she stated, "To make it easier on herself." 12. MR # 13 presented to the clinic 1/11/12 for her first visit.	L 100			

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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	Continued From page 39 The patient returned 1/21/12 for the medical abortion procedure. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12.	L 100			
	<p>The RU 486 Alternative Protocol section of the note documented Misoprostol 800 mcg. The dosage amount of 800 mcg had been lined through and 1600 mcg was written in. There were no initials by this change in dosage amount to indicate who made the dosage change.</p> <p>The physician documented a time which was not legible on the medical procedure section of the form.</p> <p>The discharge note section from the recovery room is not legible.</p> <p>In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to read the form. When asked why EI # 2 signed the form when she was off she stated, "To make it easier on herself."</p> <p>13. MR # 14 presented to the clinic on 1/20/12 for her first visit.</p> <p>The patient returned 1/21/12 for the medical abortion procedure. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12.</p> <p>The discharge note section from the recovery room is not legible.</p> <p>In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to</p>				

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L 100	Continued From page 40 read the form. When asked why EI # 2 signed the form when she was off she stated, "To make it easier on herself." 14. MR # 15 presented to the clinic on 1/19/12 for her first visit. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. The physician documented a time which was not legible on the surgical procedure section of the form for 1/21/12. In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to read the form. 15. MR # 17 presented to the clinic on 1/16/12 for her first visit. The patient returned 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under the first nurse for 1/21/12. The discharge note section from the recovery	L 100			

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L 100	Continued From page 41 room is not legible. In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to read the form.	L 100			
	<p>16. MR # 18 presented to the clinic on 1/13/12 for her first visit.</p> <p>The second date on the form has been changed from 1/21/12 to 1/22/12.</p> <p>A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>The physician, EI # 4 documented estimated blood loss that was not legible and the time of the procedure was not legible.</p> <p>The patient entered the recovery room at 7:50 AM and remained until 9:20 AM. The systolic blood pressure reading was checked at 8:05 AM, 8:50 AM and 9:05 AM. There was no blood pressure documented at 9:20 AM. The 9:20 AM was written over and changed to 8:20 AM.</p> <p>The discharge note section from the recovery room record has no comment written in the note section.</p> <p>In an interview 2/3/12 at 8:55 AM with EI # 1, Administrator she confirmed the time of the procedure was 7:50 AM and that it was difficult to read the form.</p> <p>17. MR # 16 presented to the clinic on 1/20/12</p>				

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L 100	Continued From page 42 for her first visit. The patient returned 1/21/12 for the surgical procedure. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. EI # 2 signed the form on day 2, 1/21/12 even though she was not working 1/21/12. EI # 3, Registered Nurse signed under EI# 2's name as the nurse for 1/21/12. In an interview 2/2/12 at 4:15 PM with EI # 1, Administrator she confirmed it was difficult to read the form. The physician, EI # 4 documented in the surgical procedure section of the form an ultrasound was completed and was not viewed by the patient. On review of the ultrasound pictures in the medical record there were two ultrasound pictures one dated 1/20/12 at 11:11 AM and the second ultrasound dated 1/22/12 at 00:22:10. In an interview with Employee Identifier (EI) # 1, Administrator on 2/2/12 at 4:15 PM, EI # 1 confirmed it was true none of the ultrasounds were dated 1/21/12, the date of the surgical procedure by the physician. 18. Medical Record # 20 had a surgical procedure on 12/21/11. A review of the medical record documentation under the surgical procedure section revealed the words, "+ (plus) Vaso 4 U (units)" hand written. There were no initials or date made by the entry to document	L 100			

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L 100	Continued From page 43 who gave the order for this additional medication. The top of the patient procedure form documented MR # 20 was allergic to Doxycycline. The recovery room section of the form, under the standing orders, marked MR # 20 was given Doxycycline 100 milligrams to take home. There was a progress note in the medical record that had no date, no time and no signature of who documented the entry that read as follows: "Patient was asked if she had medication allergies & she answered no. Pt (patient) given standard antibiotic Doxycycline 100 mg to take home. Pt called back saying she's allergic to Doxycycline. (El # 3's name), RN called her pharmacy (Walgreens) on 12/21/2011 @ (at) 11:30 AM & called in Erythromycin 250 mg x (times) 20 with instructions to take 2 caps q (every) 6 hrs (hours) for 1st 24 hrs, then one q 6 hrs until done." The clinic failed to verify drug allergies with MR # 20 prior to her discharge and have dated, timed and a signature of the clinic staff member who made an entry into the MR # 20's clinic record. 19. Medical Record # 22 had a medical abortion procedure on 1/21/12. A review of the medical record documentation listed Employee Identifier # 2 as the RN for this patient's visit. The RU 486 Alternative Protocol section of the note documented the Mifeprex 200 milligram (mg) expiration date as 6/14. However, this date was lined through and the date 11/14 was listed. Misoprostol 800 mcg (micrograms) was listed in this section of the note as well. The dosage amount of the drug, 800 mcg, was lined through and written in was 1600 mcg. There were no initials by this change to indicate who made the	L 100			

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L 100	Continued From page 44 dosage change or who made the change to the expiration date. The time entered on this form for when the medical procedure was completed was not legible.	L 100			
	<p>On 2/01/12 at 10:45 AM, Employee Identifier # 2, the RN Supervisor, was interviewed and confirmed she did not work on day 2, 1/21/12. EI # 3, the RN, worked this day.</p> <p>20. Medical Record # 23 had a medical abortion procedure on 1/21/12. A review of the medical record documentation listed Employee Identifier # 2 as the RN for this patient's visit. The RU 486 Alternative Protocol section of the note documented Misoprostol 800 mcg. The dosage amount of 800 mcg had been lined through and 1600 mcg was written in. There were no initials by this change in dosage amount to indicate who made the dosage change.</p> <p>On 2/01/12 at 10:45 AM, Employee Identifier # 2, the RN Supervisor, was interviewed and confirmed she did not work on day 2, 1/21/12. EI # 3, the RN, worked this day.</p> <p>21. Medical Record # 24 had a medical abortion procedure on 1/21/12. A review of the medical record documentation listed under the day one visit a blood pressure reading that was not legible. The diastolic numbers had been written over and could not be read. The RU 486 Alternative Protocol section of the note documented Mifeprex and the Misoprostol was administered.</p> <p>22. Medical Record # 25 had a surgical procedure on 1/21/12. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5</p>				

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L 100	Continued From page 45 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. Under day 2 Employee Identifier # 2 signed her name as the RN. This RN stated in an interview on 2/01/12 that she did not work on 1/21/12. 23. Medical Record # 26 had a surgical procedure on 1/21/12. A review of the medical record documentation under the surgical procedure section had no legible time documented. The time the patient entered the recovery room was documented as 8:10 AM. Under day 2 Employee Identifier # 2 signed her name as the RN. This RN stated in an interview on 2/01/12 that she did not work on 1/21/12. 24. Medical Record #27 had a surgical procedure on 1/21/12. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. Under day 2 Employee Identifier # 2 signed her name as the RN. This RN stated in an interview on 2/01/12 that she did not work on 1/21/12. The form Certification of Opportunity to View Ultrasound, Appendix A - Page 1 had both options marked (reviewed the ultrasound before the abortion and rejected the opportunity to view the ultrasound before the abortion). The date of 1/17/12 had been lined through and written beside it was the date 1/21/12. There were no initials by the date to indicate who made the change. The time documented in the surgical procedure note was not legible, the time the	L 100			

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L 100	Continued From page 46 patient entered the recovery room was documented as 8:35 AM. On 2/02/12 at 3:30 PM, in an interview with Employee Identifier # 1, the Administrator, was asked about the Appendix A form having both options, reviewed ultrasound and rejected opportunity to review ultrasound marked. EI # 1 stated the form was completed on the patient's first visit and then prior to the procedure the doctor asked again if the patient wanted to view the ultrasound. EI # 1 responded the patient must have said yes when asked by one staff member and no when asked by the other staff member. 25. Medical Record # 28 had a surgical procedure on 1/21/12. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. Under day 2 Employee Identifier # 2 signed her name as the RN. This RN stated in an interview on 2/01/12 that she did not work on 1/21/12. The time documented in the surgical procedure note was not legible, the time the patient entered the recovery room was documented as 8:40 AM. 26. Medical Record # 30 had a medical abortion procedure on 1/21/12. A review of the RU 486 Alternative Protocol documented the Mifeprex expiration date as 01/14, no year was documented. The Misoprostol 800 mcg dosage amount was lined through and written in was 1600 mcg. There were no initials to indicate who made the change in the dosage amount given to the patient.	L 100			

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L 100	Continued From page 47 27. MR # 11 presented to the clinic on 11/22/11 for her first visit. The patient returned 11/30/11 for the surgical procedure. The November to December call log completed by Employee Identifier (EI) # 2, the RN Supervisor, documented MR # 11 called on 12/1/11. Medical Record # 11's procedure date was documented by EI # 2 as 11/30/11. MR # 11 called EI # 2 complaining of pain on 11/31/11(the form was dated wrong). The clinic Patient Call form completed by EI # 2 failed to document a time the call was received or an abortion date, it did document the call came in 11/31/11 (the form was dated wrong). Complaints reported from MR # 11 were from the mother, " Pt in extreme pain on the right side and not bleeding. Spoke with Medical Director and patient sent to Hospital # 1 ED (Emergency Department)." Employee Identifier # 2 failed to notify the hospital she was sending a patient over who had a procedure 11/30/11 and was in extreme pain. On the clinic Patient Call form EI # 2 documented, "Patient called stated she had a clot removed. Doing fine." There was no date or time of this call. The clinic Patient Call form completed by EI # 2 on 12/3/11 at 12:00, had no an abortion date documented. Complaints reported from MR # 11's boyfriend, "Stated he had taken patient to hospital # 2 where they removed a sac, wants to speak to owner. Patient continues to be (nothing further was documented on the form)."	L 100			

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L 100	Continued From page 48 EI # 2 documented, "Referred to (EI # 1), clinic owner." A progress note was in the medical record dated 12/5/11, no time and no signature was present on the form.	L 100		
	<p>On 2/2/12 at 11:25 AM the surveyor observed a procedure at the clinic. The patient ambulated to the recovery room and her care was assumed by EI # 6, the recovery room medical assistant. EI # 6 documented the time of the patient's arrival and her vital signs, then put times on the form for 15 minute interval vital signs and documented in the notes section of the procedure room form, "Ambulatory D/Ced (discharged) in no distress."</p> <p>In an interview with EI # 1, the Administrator, on 2/2/12 at 4:15 PM, EI # 1 confirmed that EI # 6 documented the discharge and times prior to the patient's actual discharge.</p> <p>A revisit was made to the clinic on 2/28/12 to 3/01/12. Additional medical record reviews revealed continued non-compliance with documentation.</p> <p>28. Medical Record # 31 first presented to the clinic on 11/17/11.</p> <p>A review of the patient call form located in the on-call log book revealed MR # 31 had been discharged home from Hospital # 1. The surveyors requested MR # 31's chart on 2/28/12 and clinic staff was unable to locate the patient record.</p> <p>The surveyors obtained documentation from Hospital # 1 on 3/01/12, that MR # 31 had been referred from the clinic to Hospital # 1 on 11/30/11 for an ectopic pregnancy.</p>			

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L 100	Continued From page 49 On 3/01/12 the surveyors requested MR # 31's record from the clinic staff. The clinic staff was unable to locate the medical record. Survey staff reviewed the laboratory log book for 11/17/11 and recovery room log book. Survey staff requested the medical record for a patient that had a similar first name to MR # 31 and when the record was reviewed it was in fact the patient record for MR # 31. There was a different last name listed on the patient chart than was listed on the patient call sheet, previously reviewed by the surveyor. The clinic failed to assure there was an accurate method for identifying and retrieving patient medical records. 29. MR # 32 was first seen at the clinic on 11/09/11. MR # 32 had a surgical procedure on 11/16/11. The answering service on-call log documented on 11/21/11 at 7:05 PM, MR # 32 called the on-call clinic staff reporting she was "bleeding clots and cramping." There was no documentation the clinic staff returned the phone call to MR # 32 to address her reported problems. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the entry to document who gave the order for this additional medication. The recovery room section of the note documented a 10:45 AM blood pressure reading that had been written over to have a diastolic reading of 88. 30. MR # 33 was first seen at the clinic on 11/18/11.	L 100			

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L 100	Continued From page 50 MR # 33 had a surgical procedure on 11/23/11. The answering service call log documented on 11/28/11 at 5:08 PM, MR # 33 called the on-call clinic staff reporting she had "bad cramps and passing clots." There was no documentation the clinic staff returned the phone call to MR # 33 to address her reported problems. 31. MR #34 was first seen at the clinic on 11/17/11. MR # 34 had a surgical procedure on 11/23/11. The answering service call log documented on 11/24/11 at 12:40 AM, MR # 34 called the on-call clinic staff reporting a temperature of 102.5. The documentation on the patient call sheet, completed by the on-call clinic staff, documented MR # 34 called the clinic on 11/26/11 and her temperature was 101, not 102.5 as reported on the answering service call log. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the entry to document who gave the order for this additional medication. The blood pressure reading documented on 11/17/11 was not legible. 32. MR # 35 was first seen at the clinic on 10/15/11. MR # 35 had a medical procedure on 10/29/11. The Misoprostol 800 mcg dosage amount was lined through and written in was 1600 mcg. There were no initials to indicate who made the change in the dosage amount given to the patient. The answering service call log documented on	L 100			

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L 100	Continued From page 51 10/30/11 at 4:29 PM, MR # 35 called complaining of bleeding very heavy when standing up. There was no documentation the on-call clinic staff returned the phone call to MR # 35.	L 100			
	<p>Documented on the bottom of the telephone check form Employee Identifier # 2, RN Supervisor, wrote, "CVS (telephone number) called in 11-29-11 @ (at) 9:30." There was no documentation what EI # 2 called in for MR # 35 to the CVS or what problems MR # 35 was experiencing.</p> <p>On 12/14/11 the patient call sheet documented MR # 35 called and spoke with EI # 2, no time was documented of when the call was received. This phone call was not documented on the answering service call log that survey staff reviewed. MR # 35 called stating she took the RU 486 on 10/29/11 and her follow up had a faintly positive pregnancy test. EI # 2 documented she told MR # 35 to return to the clinic to see the physician on, "Friday AM 7:00." There was no documentation in the medical record that MR # 35 returned as instructed on Friday.</p> <p>33. MR # 36 first visited the clinic on 2/02/12.</p> <p>MR # 36 had a surgical procedure on 2/04/12. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication.</p> <p>The physician, EI # 4 documented in the surgical procedure section of the form an ultrasound was completed and viewed by the patient. On review of the ultrasound pictures in the medical record</p>				

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L 100	Continued From page 52 there were two ultrasound pictures dated 2/02/12 at 4:31. Another ultrasound picture in the medical record was dated 2/05/12 at 6:06. The surgical procedure was done on 2/04/12.	L 100			
	34. MR # 37 first visited the clinic 1/26/12. MR # 37 had a surgical procedure on 2/11/12. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" hand written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. 35. MR # 38 first visited the clinic 9/21/11. MR # 38 had a surgical procedure on 10/01/11. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the entry to document who gave the order for this additional medication. 36. MR # 39 first visited the clinic on 1/26/12. MR # 39 had a surgical procedure on 1/28/12. There is no date on "Day 2" of the procedure form. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" hand written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. 37. MR # 40 first visited the clinic on 12/12/11. MR # 40 had a medical procedure on 12/16/11.				

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L 100	Continued From page 53 The Misoprostol 800 mcg dosage amount was lined through and written in was 1600 mcg. There were no initials to indicate who made the change in the dosage amount given to the patient.	L 100		
	<p>38. Medical Record # 41 first visited the clinic on 10/26/11.</p> <p>MR # 41 returned to the clinic on 10/29/11 to have a surgical procedure completed. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 5 units Vasopressin" hand written over pre-printed procedure text. There were no initials or date made by the entry to document who gave the order for this additional medication. There is no time documented under the surgical procedure section. The physician, EI # 4, documented he was unable to complete the surgical procedure and EI # 4 converted MR # 41 to a medical procedure.</p> <p>A review of the RU 486 Alternative Protocol documentation revealed the Misoprostol 800 mcg dosage amount was lined through and written in was 1600 mcg. There were no initials to indicate who made the change in the dosage amount given to the patient.</p> <p>A review of the medical record revealed there was no consent form completed for the Misoprostol, RU 486 protocol, in the medical record for MR # 41.</p> <p>Medical Record # 41 returned to the clinic on 11/02/11 to be seen by EI # 13, the Physician. An ultrasound was performed and EI # 13 sent MR # 41 to Hospital # 1 after EI # 13 identified she had an ectopic pregnancy with cardiac activity noted. MR # 41 was seen and treated at Hospital # 1 on</p>			

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L 100	Continued From page 54 11/02/11 and discharged home the same day. The day one section of the procedure record documented MR # 41 was RH positive. A review of the medical record from Hospital # 1 showed MR # 41 was actually RH negative.	L 100			
	The patient call sheet documented on 10/30/11 and 10/31/11 that MR # 41 phoned the on-call clinic staff. On 10/30/11 at 8:56 AM, MR # 41 called with questions about how to take the pills she was given at the clinic. MR # 41 called back on 10/30/11 at 2:27 PM, reporting she was cramping badly and had not passed any blood. The answering service on-call log did not show where MR # 41 called the on-call clinic staff on 10/31/11. There was an 11/01/11 6:45 AM, phone call documented in the answering service on-call log that was reviewed by the surveyors. The patient call sheet, at the bottom of the page, documented on 11/01/11 that MR # 41 had Zofran called in for nausea. There was no time when this call was received by clinic staff or follow up with the patient documented in the medical record. 39. MR #42 was first seen at the clinic on 2/22/12. The day one work up documentation had the RH factor listed as 40, not if the patient was RH negative or positive. The hematocrit was documented as, "POS" (positive) and then written over to read, "Neg." (negative). There was no quantitative value listed for the patient's hematocrit level. There was no initial, date or notation that the documentation, on the day one visit, was an error. At the bottom of the form where staff document medications given after the procedure both options for administration of the				

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L 100	Continued From page 55 Microgram were marked, one as given and one as not given. There was no initial, date or notation that the documentation was an error. 40. MR # 43 is a 17 year old who required parental consent prior to her procedure. The parental consent form in the medical record had the patient's signature on the parent or legal guardian signature line, not the patient's actual parent or legal guardian. The signature line where the patient's name is to be written in was left blank, however the form was signed by the parent of MR # 43. The medical record contained a birth certificate to validate the parental signature was that of MR # 43. A review of the counseling information form in the medical record documented that MR # 43 did not feel that it was her decision to have an abortion, but her mother's decision. The form documented that MR # 43 marked the following questions no: "3. Do you think having this abortion is in your best interest? 4. Are you sure you want to have an abortion? 5. Do you think you will most likely be able to go on with your normal activities without emotional or psychological problems because of the abortion?" The counseling information form ask the question, "Why do you want to have the abortion?" and MR # 43's written response was, "Because my mother want me to." There is no documentation of where any of the clinic staff followed up with MR # 43 to discuss her concerns about having the abortion procedure. On 2/29/12 at 2:00 PM, in an interview with EI # 1, the Administrator, was asked about the responses from MR # 43. EI # 1 stated there should be documented follow up of where the staff talked with the patient and that prior to any procedure	L 100			

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L 100	Continued From page 56 the physician ask the patient if they want to have the procedure. No procedure is done if the patient does not want it. MR # 43 was first seen at the clinic on 9/26/11 and documented to be RH negative. MR # 43 had a surgical procedure on 9/28/11. At the bottom of the patient form where medications are documented after the procedure the drug Microgam was marked as given, but there was no documentation on the route, location, date, time or initial of the person who administered the drug. The answering service log documented that MR # 43 called the on-call clinic staff on 10/02/11 at 4:20 AM, complaining of vomiting and severe cramps. The patient call sheet date and time were written over and there is not legible documentation on when the on-call clinic staff spoke with MR # 43 to discuss her reported problems. The instructions section of the patient call sheet documented on 10/03/11 that MR # 43 was taken to the emergency room, the name of the hospital was not listed, and she was given a shot for nausea and sent home. 41. MR # 44 was first seen at the clinic on 2/02/12. MR # 44 was seen on 2/06/12 for a surgical procedure. The physician, EI # 12 documented in the surgical procedure section of the form an ultrasound was completed and viewed by the patient. On review of the ultrasound pictures in the medical record there were two ultrasound pictures dated 2/02/12 at 2:37. Another ultrasound picture in the medical record was dated 2/07/12 at 1:33. The surgical procedure	L 100			

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L 100	Continued From page 57 was done on 2/06/12. 42. MR # 45 was first seen at the clinic on 1/25/12. The day one laboratory documentation noted MR # 45 was RH positive. On 1/26/12 MR # 45 returned to the clinic to have a surgical procedure. The time documented when she entered the recovery room had been written over. There was no initial, date or notation that the time entry was an error. The surgical pathology report documented in the comment section that there was an absence of definite chorionic villi or fetal tissue. MR # 45 was called and on 2/02/12 was seen again in the clinic for a second surgical procedure to be completed. The documentation on the second surgical procedure form listed MR # 45 as RH negative. There was no documentation MR # 45 was given Microgam or Rhogam. Under the physician pre-op medication section of the second surgical procedure note the drug Vicodin 5/500 mg times two was lined through and hand written in was "X (times) 1." There was no initial, date or time to document who made the change in the dosage amount of the drug. The physician, El # 5, documented in the surgical procedure section of the form an ultrasound was completed and not viewed by the patient. On review of the ultrasound pictures in the medical record there was one ultrasound picture dated 1/25/12, one ultrasound picture dated 1/27/12 and there were three ultrasound pictures dated 2/02/12. The first surgical procedure was done on 1/26/12 and the second surgical procedure was done on 2/02/12. 43. MR # 46 was first seen in the clinic on 10/17/11.	L 100			

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L 100	Continued From page 58 MR # 46 returned to the clinic on 10/19/11 to have a surgical procedure completed. Under the physician pre-op medications was hand written in the drug Misoprostol 800 mcg. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the above entries to document who gave the order for the additional medications. The answering service call log documented on 11/20/11 at 4:56 PM, MR # 46 called the on-call clinic staff reporting heavy bleeding with blood clots. The patient call sheet was dated 11/20/11, but there were two different times documented for when the call was received. At the bottom of the patient call sheet it was documented on 11/21/11 that MR # 46 was doing "great," there was no time documented of when this call was received. The answering service call log documented 11/21/11 at 11:48 PM, MR # 46 called the on-call clinic staff experiencing problems. There was no documentation in the medical record of the 11/21/11 patient call reporting problems and no follow up call made to MR # 46. 44. MR # 48 was first seen at the clinic on 10/11/11. MR # 48 returned to the clinic on 10/22/11 to have a surgical procedure completed. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the entry to document who gave the order for this additional medication.	L 100			

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L 100	Continued From page 59 The answering service on-call log documented MR # 48 called the on-call clinic staff on 10/25/11 at 7:07 AM, to report MR # 48 had a severe headache and a fever of 100.9. There was no patient call sheet completed for this phone call and no documentation the patient problems were followed up on. 45. MR # 49 was first seen at the clinic on 11/7/11. MR # 49 returned to the clinic on 11/23/11 to have a surgical procedure completed. A review of the medical record documentation under the surgical procedure section revealed the words, "plus 4 units Vasopressin" hand written. There were no initials or date made by the entry to document who gave the order for this additional medication. The physician, EI # 13, documented in the surgical procedure section of the form an ultrasound was completed and viewed by the patient. On review of the ultrasound pictures in the medical record there was one ultrasound picture dated 11/07/11 and two ultrasound pictures dated 11/24/11. The surgical procedure was done on 11/23/11. The answering service call log documented MR # 49 called the on-call clinic staff on 11/27/11 at 3:24 AM, reporting severe bleeding and cramps. The patient call sheet dated 11/27/11 at 3:24 AM, instructed the patient to reduce her activity and if the bleeding did not decrease to call the clinic back. The patient report of cramps was not addressed by the on-call clinic staff. A review of the medical records for 20 of 47 patients revealed the clinic had completed a chart	L 100			

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L 100	Continued From page 60 review checklist. The clinic staff drew a line down the list of items that were to be reviewed on the chart review checklist. The chart review checklist documented the patient chart had been reviewed for completeness by clinic staff.	L 100			
	<p>The clinic failed to assure that timely, accurate, legible and complete documentation was completed by all staff members who are responsible for patient care.</p> <p>420-5-1-.03 Patient Care. (1) Patient Care. All patient care must be rendered in accordance with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. As with any surgical procedure, the physician performing the procedure is responsible for the procedure and for ensuring that adequate follow-up care is provided. In order to facilitate continuity of patient care, the facility physician shall contact and communicate with any physician rendering care for complications arising from the abortion as soon as he [or she] is informed of the existence of such complications. The facility shall develop and follow a policy and procedure for communication with outside physicians, such as emergency room physicians, so that all facility nurses and staff cooperate with any physician rendering care for complications arising from an abortion.</p> <p>The requirements of this rule were not met as evidenced by:</p> <p>Based on review of medical records and interview it was determined the clinic failed to document communication with outside physicians related to</p>				

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L 100	Continued From page 61 transfer of patients with complications from abortion procedures completed at this clinic. This had the potential to affect all patients served by this clinic.	L 100			
	Findings include: 1. Medical Record (MR) # 1 presented to the clinic on 11/7/11 for her first visit. MR # 1 returned 11/11/11 for the surgical procedure. The patient's pregnancy history included two cesarean sections one in 1995 and the second in 1997. The medical history included surgery 11/2010 for removal of the right ovary. The history also noted that she was a diabetic. The ultrasound performed on the first day established a gestation of 16 weeks 2 days. The November to December call log listed MR # 1 as calling on 11/18/11 and the on-call nurse recorded the procedure as having been done 11/14/11. MR # 1 complained of pain. The Patient Call form failed to document a time the call was received or an abortion date. Complaints recorded, "Having pains all day and now they are unbearable. Feels like contractions. Has taken Motrin not helping." Instructions from the on-call nurse EI # 2, the Registered Nurse Supervisor, "Consider going to ED (Emergency Department) and be seen (at Hospital #1). Patient states she would feel better to be seen. Gave patient number to call if MD (Medical Doctor) had any questions." The on-call nurse failed to notify the physician who did the procedure and failed to notify the hospital she was sending a patient over who had				

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L 100	Continued From page 62 a difficult procedure and received Intravenous Pitocin at the clinic on 11/11/11. 2. MR # 2 presented to the clinic 1/20/12 for her first visit. MR # 2 returned 1/21/12 for a surgical procedure. The incident report information received 1/23/12 by fax from Employee Identifier(EI) # 1, Administrator documented EI # 4, physician, "Spoke with the physicians at (Hospital # 1) on several occasions to follow up on our patients." There was no documentation of any conversation with (Hospital # 1) physicians regarding the patient's transfer. 3. MR # 3 presented to the clinic on 1/20/12 for her first visit to the clinic. MR # 3 returned 1/21/12 for a surgical procedure. The physician, EI # 4 documented the use of 20 ml of 1% Xylocaine plus 5 units of Vasopressin as a paracervical block. EI # 4 documented, "the patient tolerated the procedure not well, vomited, vitals okay, suspect secondary > (greater than) dose Vasopressin. Nurse inadvertently drew up more than .2 ml, unsure how much will discuss with Medical Director of clinic. * Patient to be transferred to ED (emergency department) for observation." The incident report information received 1/23/12 by fax from Employee Identifier(EI) # 1, Administrator documented EI # 4, physician, "Spoke with the physicians at Hospital #1 on several occasions to follow up on our patients." There was no documentation of any conversation with Hospital # 1 physicians regarding the	L 100			

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L 100	Continued From page 63 patient's transfer. 420-5-1-.03 Patient Care. (d) Post-Operative Policies and Procedures: A facility must develop and follow written policies and procedures detailing the sequence of post-operative care. The facility must have a 24 hour answering service that immediately refers all calls related to post abortion problems to a qualified registered nurse, nurse practitioner, physician assistant, or physician. If a registered nurse, nurse practitioner, or physician assistant will be the initial medical contact, clear protocols must be developed and approved by the medical director, all facility physicians, and any outside covering physicians to establish when a physician will be contacted, which physician will be initially contacted, how the outside covering physician will be contacted if immediate care is needed, and how the patient will be contacted and receive the physician's instructions. (e) Call Records: In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the registered nurse, nurse practitioner, physician assistant, or physician. The call record should include the patient's name, time and date of call, a brief description of the reason for the call, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient's medical record. The requirements of this rule were not met as evidenced by: Based on review of clinic policy, medical records and interview it was determined the on-call nurse failed to return calls to patients with reported	L 100		

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L 100	<p>Continued From page 64</p> <p>problems and failed to document the correct dates of calls and complete the on-call records. The on-call nurse failed to report calls the physician related to increased pain and bleeding or to notify the hospital a patient had been directed to go to the emergency room. This had the potential to affect all patients served.</p> <p>Findings include:</p> <p>During the third on-site visit on 2/29/12 at 2:00 PM, Employee Identifier # 1, the Administrator, informed the survey staff that in January 2012 the clinic staff was unable to locate the on-call book that contained documentation from the on-call answering service and a copy of the patient call sheet follow ups that were completed from September 2011 through January 2012. EI # 1 went on to say that she and EI # 14, the Assistant Administrator, re-created the on-call log book with the documentation from the answering service and the patient call forms from the medical records.</p> <p>Clinic Policy: Problem Calls From Patients</p> <p>1. All calls are recorded and then charted/documented in the patient's chart. See problem sheet. Calls are then documented in the comp (complications) log.</p> <p>8. Calls received after the nursing department is closed for the day are referred to the nurse on call. Calls received after the clinic is closed are referred to the nurse on call.</p> <p>Clinic Policy: Contact & Communication With Physicians For Emergencies</p> <p>"When the RN (Registered Nurse) on call has a</p>	L 100			

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L 100	Continued From page 65 situation requiring the necessity of contacting the covering Physician, optimally the physician who performed the abortion is contacted. Otherwise The Medical Director is called."	L 100			
	<p>Standing Orders for Post Abortion Problems</p> <p>A. Excessive Bleeding: soaking more than 1 maxi pad in 1 hour 1. Fill the Methergine RX (prescription) (Methergine 0.2 mg #12) for bleeding and take 1 every 4 hours for 6 doses. Instruct patient the medication will make her cramp. 2. If cramping is severe take 2 Aleve than 1 every 12 hours. Patient may alternate Aleve with Extra Strength Tylenol or follow standing orders for cramps. 3. If conditions have not improved in four hours or if increasing in severity, send the patient to the nearest emergency room.</p> <p>B. Excessive Bleeding: Soaking more than 4 pads in an hour.</p> <p>C. Blood Clots: the size of a 50 cent piece or larger or lots of little clots 1. Follow the same instructions for excessive bleeding.</p> <p>D. Cramps: 1. Patient make take Aleve sig 1 q (every) 8-12 hrs (hours) if no contraindications. Patient may take Extra Strength Tylenol sig 1-2 q 4-6 hrs. Aleve may be alternated with Tylenol. 2. Patient is to call the clinic 1 hr after taking medication. If condition has not improved the MD is contacted for further instruction. 3. Patient is instructed to use a hot water bottle or heating pad.</p>				

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L 100	Continued From page 66 E. Elevated Temperature: Call physician anytime temp goes above 100 Medical Record Findings: 1. Medical Record (MR) # 1 presented to the clinic on 11/7/11 for her first visit. The patient returned 11/11/11 for the surgical procedure. The November to December call log completed by Employee Identifier (EI) # 2, the RN Supervisor, listed MR # 1 called on 11/18/11. Medical Record # 1's procedure date was documented by EI # 2 as 11/14/11. MR # 1 called EI # 2 complaining of pain. The clinic Patient Call form completed by EI # 2 failed to document a time the call was received or an abortion date. Complaints reported from MR # 1 were: "Having pains all day and now they are unbearable. Feels like contractions. Has taken Motrin not helping." Instructions from the on-call nurse EI # 2, Registered Nurse Supervisor, documented on 11/14/11, "Consider going to ED (Emergency Department) and be seen (at Hospital #1). Patient states she would feel better to be seen. Gave patient number to call if MD (Medical Doctor) had any questions." Employee Identifier # 2 failed to notify the physician who did the procedure and failed to notify the hospital she was sending a patient over who had a difficult procedure and received Intravenous Pitocin at the clinic 11/11/11. On the clinic Patient Call form EI # 2 documented	L 100			

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L 100	Continued From page 67 on 11/17/11, "Called doing better went to (Hospital #1). Had D&C (Dilatation and Curettage) on Sunday night (11/13/11)." Medical Record # 1's surgical procedure was completed on Friday, 11/11/11. Sunday was 11/13/11. The clinic Patient Call form documented MR # 1 called EI # 2 on 11/14/11, which would have been after MR # 1 was seen at Hospital # 1 and had a D&C. Employee Identifier # 2 failed to accurately document in the medical record the correct date she received the patient call and the correct date the patient received follow up treatment. 2. MR # 4 presented to the clinic on 1/17/12 for her first visit. The patient returned 1/21/12 for the surgical procedure. The January call log listed MR # 4 called on 1/21/12 with complaints of excessive bleeding. A review of the medical record revealed no documentation of a patient phone call complaining of excessive bleeding on 1/21/12. In an interview with EI # 2, Registered Nurse Supervisor on 2/2/12 at 7:50 AM, the surveyor requested any additional on call forms that were not filed for January. EI # 2 stated, "I guess it's all filed on charts.(referring to the clinic Patient Call forms)" EI # 2 was asked 2/2/12 at 8:00 AM, if any documentation was completed regarding the call from MR # 4 on 1/21/12. EI # 2 stated that she	L 100			

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L 100	Continued From page 68 called EI # 1, Administrator but did not know who the call was from and did not have a telephone number to return the patient phone call. The surveyor reviewed the on-call information from the answering service 2/3/12 at 10:10 AM. The answering service documented MR # 4's call on 1/21/12 with the patient's name and telephone number. EI # 2 failed to return a call to Medical Record # 4 who was having excessive bleeding and failed to notify the physician of the call. Employee Identifier # 2 failed to document the phone call from Medical Record # 4. Employee Identifier # 4, the physician who performed the surgical procedure on 1/21/12, was later contacted by Hospital # 1's physician and was told Medical Record # 4 was placed in the Intensive Care Unit. 3. MR # 11 presented to the clinic on 11/22/11 for her first visit. The patient returned 11/30/11 for the surgical procedure. The November to December call log completed by Employee Identifier (EI) # 2, the RN Supervisor, listed MR # 11 called on 12/1/11. Medical Record # 11's procedure date was documented by EI # 2 as 11/30/11. MR # 11 called EI # 2 complaining of pain on 11/31/11 (the form was dated wrong). The clinic Patient Call form completed by EI # 2 failed to document a time the call was received or an abortion date, it did document the call came in 11/31/11 (the form was dated wrong). Complaints reported from MR # 11 were from the mother, " Pt in extreme pain on the right side and not	L 100			

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L 100	Continued From page 69 bleeding. Spoke with Medical Director and patient sent to Hospital # 1 ED (Emergency Department)." Employee Identifier # 2 failed to notify the hospital she was sending a patient over who had a procedure 11/30/11 and was in extreme pain. On the clinic Patient Call form EI # 2 documented, "Patient called stated she had a clot removed. Doing fine." There was no date or time of this call. The clinic Patient Call form completed by EI # 2 on 12/3/11 at 12:00, had no an abortion date. Complaints reported from MR # 11's boyfriend, "Stated he had taken patient to hospital # 2 where they removed a sac, wants to speak to owner. Patient continues to be (nothing further was documented on the form)." EI # 2 documented, "Referred to (EI # 1), clinic owner." A progress note was in the medical record dated 12/5/11, no time and no signature was present on the form. 4. MR # 32 was first seen at the clinic on 11/09/11. MR # 32 had a surgical procedure on 11/16/11. The answering service on-call log documented on 11/21/11 at 7:05 PM, MR # 32 called the on-call clinic staff reporting she was "bleeding clots and cramping." There was no documentation the clinic staff returned the phone call to MR # 32 to address her reported problems. 5. MR # 33 was first seen at the clinic on 11/18/11.	L 100			

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L 100	Continued From page 70 MR # 33 had a surgical procedure on 11/23/11. The answering service on-call log documented on 11/28/11 at 5:08 PM, MR # 33 called the on-call clinic staff reporting she had "bad cramps and passing clots." There was no documentation the clinic staff returned the phone call to MR # 33 to address her reported problems. 6. MR #34 was first seen at the clinic on 11/17/11. MR # 34 had a surgical procedure on 11/23/11. The answering service on-call log documented on 11/24/11 at 12:40 AM, MR # 34 called the on-call clinic staff reporting a temperature of 102.5. The documentation on the patient call sheet, completed by the on-call clinic staff, documented MR # 34 called the clinic on 11/26/11 and her temperature was 101, not 102.5 as reported on the answering service call log. There was no documentation the physician was notified per clinic standing orders. 7. MR # 35 was first seen at the clinic on 10/15/11. MR # 35 had a medical procedure on 10/29/11. The answering service call log documented on 10/30/11 at 4:29 PM, MR # 35 called complaining of bleeding very heavy when standing up. There was no documentation the on-call clinic staff returned the phone call to MR # 35. Documented on the bottom of the telephone check form Employee Identifier # 2, RN Supervisor, wrote, "CVS (telephone number) called in 11-29-11 @ (at) 9:30." There was no documentation what EI # 2 called in for MR # 35	L 100			

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L 100	Continued From page 71 to CVS or what problems MR # 35 was experiencing. On 12/14/11 the patient call sheet documented MR # 35 called and spoke with EI # 2, no time was documented of when the call was received. This phone call was not documented on the answering service call log that survey staff reviewed. MR # 35 called stating she took the RU 486 on 10/29/11 and her follow up had a faintly positive pregnancy test. EI # 2 documented she told MR # 35 to return to the clinic to see the physician on, "Friday AM 7:00." There was no documentation in the medical record that MR # 35 returned as instructed on Friday. 8. MR # 41 first visited the clinic on 10/26/11. MR # 41 returned to the clinic on 10/29/11 to have a surgical procedure completed. The patient call sheet documented on 10/30/11 and 10/31/11 that MR # 41 phoned the on-call clinic staff. On 10/30/11 at 8:56 AM, MR # 41 called with questions about how to take the pills she was given at the clinic. MR # 41 called back on 10/30/11 at 2:27 PM, reporting she was cramping badly and had not passed any blood. The answering service on-call log did not show where MR # 41 called the on-call clinic staff on 10/31/11. There was an 11/01/11 6:45 AM, phone call documented in the answering service on-call log that was reviewed by the surveyors. The patient call sheet, at the bottom of the page, documented on 11/01/11 that MR # 41 had Zofran called in for nausea. There was no time when this call was received by clinic staff or follow up with the patient documented in the medical record. 9. MR # 43 was first seen at the clinic on 9/26/11 and documented to be RH negative.	L 100			

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L 100	Continued From page 72 MR # 43 had a surgical procedure on 9/28/11. The answering service log documented that MR # 43 called the on-call clinic staff on 10/02/11 at 4:20 AM, complaining of vomiting and severe cramps. The patient call sheet date and time were written over and there is not legible documentation on when the on-call clinic staff spoke with MR # 43 to discuss her reported problems. The instructions section of the patient call sheet documented on 10/03/11 that MR # 43 was taken to the emergency room, the name of the hospital was not listed. MR # 43 was given a shot for nausea at the hospital and sent home. 10. MR # 46 was first seen in the clinic on 10/17/11. MR # 46 returned to the clinic on 10/19/11 to have a surgical procedure completed. The answering service call log documented on 11/20/11 at 4:56 PM, MR # 46 called the on-call clinic staff reporting heavy bleeding with blood clots. The patient call sheet was dated 11/20/11, but there were two different times documented for when the call was received. At the bottom of the patient call sheet it was documented on 11/21/11 that MR # 46 was doing "great," there was no time documented of when this call was received. The answering service call log documented 11/21/11 at 11:48 PM, MR # 46 called the on-call clinic staff experiencing problems. There was no documentation in the medical record of the 11/21/11 patient call reporting problems and no follow up call made to MR # 46. 11. MR # 48 was first seen at the clinic on 10/11/11.	L 100			

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L 100	<p>Continued From page 73</p> <p>MR # 48 returned to the clinic on 10/22/11 to have a surgical procedure completed. The answering service on-call log documented MR # 48 called the on-call clinic staff on 10/25/11 at 7:07 AM, to report MR # 48 had severe headache and a fever of 100.9. There was no patient call sheet completed for this phone call and no documentation the patient problems were followed up on. There was no documentation the physician was notified per clinic standing orders for the elevated temperature.</p> <p>12. MR # 49 was first seen at the clinic on 11/7/11.</p> <p>MR # 49 returned to the clinic on 11/23/11 to have a surgical procedure completed.</p> <p>The answering service call log documented MR # 49 called the on-call clinic staff on 11/27/11 at 3:24 AM, reporting severe bleeding and cramps. The patient call sheet dated 11/27/11 at 3:24 AM, instructed the patient to reduce her activity and if the bleeding did not decrease to call the clinic back. The patient report of cramps was not addressed by the on-call clinic staff. The clinic failed to assure documentation was accurate for times, completion of medical record forms and that Hospital # 1 was informed of a patient referral after a surgical procedure.</p> <p>The above rule violation is a repeat deficiency from the July 27, 2011, recertification survey.</p> <p>420-5-1-.04 Physical Environment (5) Equipment and Supplies. (b) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the</p>	L 100			

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L 100	Continued From page 74 facility integral to patient care to assure satisfactory operation thereof. (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 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. This rule is not met as evidenced by: Based on observation and an interview the clinic failed to assure that all patient used equipment had a record of routine inspection and maintenance for the portable centrifuge in the laboratory and three Omron Blood Pressure cuffs in the recovery room. This had the potential to affect all patients served by the clinic. Findings include:	L 100			

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L 100	Continued From page 75 On 1/31/12 at 11:00 AM, during a tour of the clinic in the patient recovery room there were two Omron Blood Pressure (BP) cuffs located on the top shelf with no maintenance label. There was a third Omron BP cuff on the same shelf that had a maintenance label with the date 10/2007 as the due date for a preventive maintenance. The preventive maintenance had not been completed. On 1/31/12 at 11:10 AM, Employee Identifier (EI) # 6, the Recovery Room Medical Assistant, was interviewed and verified the BP cuffs were used to obtain BP readings on patients in the recovery room. Employee Identifier # 1, the Administrator, was informed about the lack of maintenance labels on the blood pressure cuffs and stated she recently purchased them. Employee Identifier # 1 was asked for documentation to show the blood pressure cuffs were recently purchased and none was provided to the surveyors. The above rule violation is a repeat deficiency from the July 27, 2011, recertification survey.	L 100			