Agency For Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AC13920003	A. BUILDING _____ B. WING _____	03/17/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALBA MEDICAL CENTER	4210 PALM AVENUE HIALEAH, FL 33012

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A 000	INITIAL COMMENTS An unannounced complaint investigation survey #2008003261 was conducted on 3-17-08. The following deficiencies were identified during the investigation:	A 000	THE ACTIONS LISTED BELOW WILL BE IMPLEMENTED BY 04-17-2008 AS STATED IN THE STATEMENT OF DEFICIENCIES.	
A 156	Clinic Supplies/equip. Stand.-2nd Trimester Equipment Maintenance. (a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer ' s specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair. (c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair. Chapter 59A-9.0225(7), F.A.C.	A 156	A) MAINTENANCE LOGS HAVE BEEN DEVELOPED TO PROVIDE WRITTEN DOCUMENTATION OF EQUIPMENT TESTING AND CALIBRATIONS. THESE LOGS WILL KEEP RECORDS OF EACH INDIVIDUAL PATIENT MONITORING EQUIPMENT. RECEIVED APR - 4 2008 AHCA HAQ-1 MIAMI B) MAINTENANCE LOGS HAVE ALSO BEEN IMPLEMENTED FOR ANESTHESIA AND SURGICAL EQUIPMENT. C) SURGICAL INSTRUMENTS WILL BE CLEANED AND CHECKED FOR FUNCTION AFTER EACH USE. OUR EMPLOYEE HANDBOOK AND POLICIES AND PROCEDURE MANUAL WILL SERVE AS WRITTEN DOCUMENTATION OF THE PREVENTIVE MAINTENANCE PROGRAM THAT HAS BEEN DEVELOPED AND IMPLEMENTED.	

AHCA Form 3020-0001
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: CLINIC DIRECTOR — (X6) DATE: 04-04-08

STATE FORM 6211 — IGR211 —

Agency For Health Care Administration

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A 156	Continued From Page 1 This Standard is not met as evidenced by: Based on record review and interview the facility failed to develop a written preventive maintenance program and compile a maintenance record indicating history of testing, initiated annually, to insure proper operation, and a state of good repair of the defibrillator used in the care of patients receiving 1st and 2nd trimester abortions in the facility. The findings included: A tour of the facility was conducted on 3-17-08 at 1 pm. The defibrillator was hidden under other equipment. There was no maintenance documentation for the defibrillator in the facility. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was untrained and unable to use the equipment. Correction Date: 4-17-08	A 156		
A 201	Clinic Personnel-2nd Trimester Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. The clinical staff requirements are as follows: Physicians. The clinic shall designate a licensed physician to serve as a medical director. Nursing Personnel. Nursing personnel in the clinic shall be governed by written policies and	A 201	PERSONEL RECORDS FOR ALL EMPLOYEES HAVE BEEN IMPLEMENTED. OUR EMPLOYEE HANDBOOK AND POLICY PROCEDURE MANUAL INCLUDES A LIST OF ALL JOB DUTIES AND RESPONSIBILITIES FOR WHICH EACH EMPLOYEE IS GOVERNED BY.	

Ana Sanchez 04-04-08

Agency For Health Care Administration

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A 201	Continued From Page 2 procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established. Chapter 59A-9.023(1),(2),and (3), F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility failed to provide adequately trained personnel capable of providing appropriate service and supervision to the patients including a position description for each position delineating duties and responsibilities and maintaining personnel records for all employees performing or monitoring patients receiving 1st and 2nd trimester abortions in the facility. The findings included: Review of the employee file for the medical assistant revealed that the medical assistant had worked in the facility for 5 years. There was no evidence in the file of training of assistance with 2nd trimester abortions, no job deecription, and no orientation to the facility. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was untrained and unable to use any of the equipment in the procedure room. There was no nurse available to assist the physician with the procedure. Correction Date: 4-17-08	A 201		

Dina Lindsey 04-04-08.

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A 202	Continued From Page 3	A 202		
A 202	Clinic Personnel-2nd Trimester Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control. In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide: (a) Infection control, to include at a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members. (b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires; (c) Confidentiality of patient information and records, and protecting patient rights; (d) Licensing regulations; and (e) Incident reporting. Chapter 59A-9.023,(4) and (5), F.A.C.	A 202	OUR EMPLOYEE HAND BOOK AND POLICY AND PROCEDURES MANUAL WILL SERVE AS WRITTEN ORIENTATION FOR EACH EMPLOYEE TO FAMILIARIZE THEMSELVES WITH THE FACILITY ITS POLICIES AND PROCEDURES FIRE SAFETY, BIO MEDICAL WASTE, SAFETY MEASURES, PATIENT CONFIDENTIALITY, PATIENT RIGHTS. LICENSING, INCIDENT REPORTING. AND MEDICAL EMERGENCIES. EACH EMPLOYEE IS TO READ THIS MANUAL ONCE A YEAR AND SIGN STATING THAT THEY HAVE READ AND FAMILIARIZED THEMSELVES WITH THE FACILITIES. POLICIES. AND PROCEDURES OUR MEDICAL DIRECTOR WILL BE PROVIDING IN SERVICE TRAINING TO PERSONNEL WITHIN THEIR AREAS OF COMPETENCY. AN-IN SERVICE TRAINING LOG WILL BE IMPLEMENTED FOR EACH AREA OF TRAINING.	

Dina Hinds 02-04-08

Agency For Health Care Administration

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A 202	Continued From Page 4 This Standard is not met as evidenced by: Based on record review and interview the facility failed to provide a written orientation program for the staff at the beginning of employment and at least annually thereafter to insure and maintain their understanding of their duties and responsibilities, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients and proper use of fire extinguishers, confidentiality of patient information and incident reporting. The findings included: Review of the employee file for the medical assistant revealed that the medical assistant had worked in the facility for 5 years. There was no evidence in the file of annual in-service training of the employee to insure and maintain their understanding of their duties and responsibilities, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients, proper use of fire extinguishers, confidentiality of patient information and incident reporting. Review of the documentation in the facility failed to produce a policy and procedure manual for 1st and 2nd trimester abortions, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients and proper use of fire extinguishers, confidentiality of patient information and incident reporting. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was not given any in-service in the facility. Correction Date: 4-17-08	A 202		

Dina Lindsay 04-04-08

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A 202	Continued From Page 5	A 202		
A 250	Clinic Policies/Procedures-2nd Trimester An abortion clinic providing second trimester abortions shall have written policies and procedures to implement policies and to assure that quality patient care shall relate specifically to the functional activities of clinic services. These written procedures shall apply to second trimester abortions and shall be available and accessible to clinic personnel and shall be reviewed and approved annually by the clinic's medical director. These clinic policies and procedures shall include but not be limited to the following: (1) Patient admission; (2) Pre- and post-operative care; (3) Physician ' s orders; (4) Standing orders with required signatures; (5) Medications, storage and administration; (6) Treatments; (7) Surgical asepsis; (8) Medial asepsis; (9) Sterilization and disinfection; (10) Documentation: Medical records and facility records; (11) Patient discharge; (12) Patient transfer; (13) Emergency measures; (14) Incident reports; (15) Personnel orientation; (16) Inservice education record; (17) Anesthesia; (18) Equipment and supplies: availability and maintenance; (19) Volunteers; and (20) Visitors. Chapter 59A-9.024, F.A.C.	A 250	AN EMPLOYEE HAND BOOK AND POLICY AND POLICY AND PROCEDURES MANUAL WILL BE DEVELOPED AND IMPLEMENTED THIS MANUAL WILL INCLUDE THE FACILITIES POLICIES AND PROCEDURES TO ! PATIENT ADMISSION PRE AND POST OPERATIVE CARE, PHYSICIANS ORDERS, MEDICATION, STORAGE AND ADMINISTRATION, TREATMENTS, SURGICAL AND MEDICAL PROTOCOLS, STERILIZATION AND DISINFECTION, DOCUMENTATION OF MEDICAL AND FACILITY RECORDS, PATIENT DISCHARGE AND TRANSFER, EMERGENCY MEASURES, INCIDENT REPORTING, PERSONNEL ORIENTATION AND IN SERVICE TRAINING MAINTENANCE LOGS AND VISITORS	

Dna Kindley 04-04-08

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A 250	Continued From Page 6 This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to provide written policies and procedures that were available and accessible to clinic personnel and were reviewed and approved annually by the clinic's medical director. The findings included: Review of the documentation in the facility failed to reveal a policy and procedure book for the staff to use. Interview with the Receptionist and the medical assistant on 3-17-08 at 1:30 pm confirmed that there was no policy book available in the facility. Correction Date: 4-17-08	A 250		
A 300	Medical Screening/Eval.-2nd Trimester Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. These patient care policies and procedures, for patients undergoing second trimester abortions, shall include but not be limited to the following: (a) Admission criteria and procedures; (b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions; (c) Specific details regarding the pre-operative	A 300	NEW PATIENT RECORDS WILL BE IMPLEMENTED. THESE WILL INDICATE PAST MEDICAL HISTORY, CARE AND SERVICES PROVIDED, THEY WILL ALSO INCLUDE THE PHYSICAL EXAMINATION EN. FACTOR, VERIFICATION OF PREGNANCY ESTIMATION OF GESTATION AGE, ANY ALLERGIES, ULTRASONOGRAPHY TO CONFIRM GESTATION AGE AND A BIMANUAL EXAM. ESTIMATING UTERINE SIZE. PALPATION OF THE ADNEXA AND ANESTHESIA GIVEN. ALL ORIGINAL PRINTS OF ULTRASONOGRAPHY AND ANY OTHER TESTING WILL BE KEPT IN PATIENT RECORDS.	

Dina Kinder 04-04-08

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A 300	Continued From Page 7 procedures performed, to include: 1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications; including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history. 2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure. Chapter 59A-9.025(1), F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records history and physical examination, estimation of gestational age based on a bimanual and ultrasound examination, copies of ultrasounds, and laboratory tests to prove pregnancy before the procedures are completed for 9 of 9 sampled patients. The findings included: Review of the clinical record of sample patient #1 (16 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-24-08.	A 300		

Dina Kindy 04-04-08

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A 300	Continued From Page 8 Review of the clinical record of sample patient #2 (17 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-30-08. Review of the clinical record of sample patient #3 (15 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 2-8-08. Review of the clinical record of sample patient #4 (22 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination before the procedure on 2-12-08. Review of the clinical record of sample patient #5 (22 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 2-27-08. Review of the clinical record of sample patient #6 (20 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-24-08. Review of the clinical record of sample patient #7, #8, #9 revealed that there was no evidence in the record of an ultrasound examination or lab work to prove pregnancy before the procedure on 3-12-08.	A 300		

Ina Lindsey 04-04-08

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A 300	Continued From Page 9 Interview with the medical assistant and the receptionist on 3-17-08 at 1 pm confirmed that the physicians conducted the visits before the procedures and wrote in the charts. Correction Date: 4-17-08	A 300		
A 301	Medical Screening/eval.-2nd Trimester Laboratory Services. (a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, F.S. (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions. Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available. All laboratory test reports shall be placed in the patient ' s medical record. All laboratory test and storage areas, records and reports shall be available for inspection by the agency. If a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician	A 301	RH FACTOR, HEMOGLOBIN AND URINE PREGNANCY TEST WILL BE CONDUCTED PRIOR TO TERMINATION OF PREGNANCY AND THE RESULTS WILL BE INCLUDED IN THE NEW PATIENT RECORD. AN APPLICATION FOR THE CLIA CERTIFICATE HAS BEEN MAILED TO CLIA.	

Ina Hendley 04-04-08.

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A 301	Continued From Page 10 assistant shall, at the request of the patient and before the abortion procedure is performed, review the ultrasound evaluation results with the patient, including an estimate of the probable gestational age of the fetus. A test for anemia shall be performed. Chapter 59A-9.025(2), (4), (5), (6), (7), and (8) F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records Rh factor testing and anemia testing before procedures were performed for 8 of 9 (all except #4) Review of the clinical records of sampled patients #1, #2, #3, #5, #6, #7, #8, #9 revealed that there was no evidence of laboratory tests to indicate the Rh factor, if necessary or anemia testing in the records. Interview with the medical assistant on 3-17-08 at 1 pm confirmed that the physicians conducted the visits before the procedures and wrote in the charts. Correction Date: 4-17-08	A 301		
A 400	Recovery Rm Stand.-2nd Trimester Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions: (1) Following the procedure, post procedure	A 400	(1) THE RECOVERY ROOM WILL BE SUPERVISED AT ALL TIMES BY THE MEDICAL ASSISTANTE. THE MEDICAL DIRECTOR WILL PROVIDE IN SERVICE TRAINING. IN THIS AREA.	

Ina Lindsey 04-04-08

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A 400	Continued From Page 11 recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants. (2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic. (3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient refuses the Rho (D) immune globulin, refusal Form 3130-1002, January 2006, " Refusal to Permit Administration of Rh(D)	A 400	THE PHYSICIAN WILL BE AVAILABLE TO DISCHARGE EACH PATIENT AND ALL EMPLOYEE'S HAVE COMPLETED C.P.R. COURSE. 2) HOSPITILIZATION WILL BE ARRANGED BY THE FACILITY IF ANY COMPLICATIONS OCCUR BEYOND THE MEDICAL CAPABILITIES OF THE STAFF. OUR EMERGENCY KIT IS READILY AVALIABLE IN CASE OF A MEDICAL EMERGENCY 3) THE PHYSICIAN WILL DISCUSS WITH EACH PATIENT THE RHO(D) IMMUNE GLOBULIN AND WILL ENSURE THAT IT IS OFFERED TO THE PATIENT IN THE IMMEDIATE POST OPERATIVE PERIOD OR THAT IT WILL BE AVALIABLE FOR 72 HOURS FOLLOWING THE COMPLETION OF THE TERMINATION OF PREGNANCY IF THE PATIENT REFUSES THE RHO(D) IMMUNE GLOBULIN THE (AHCA REFUSAL FORM) 3130-1002 WILL BE SIGNED BY THE PATIENT AND WILL REMAIN IN HER MEDICAL RECORDS.	

Ina Lindsey 04-04-08

Agency For Health Care Administration

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALBA MEDICAL CENTER	4210 PALM AVENUE HIALEAH, FL 33012

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A 400	Continued From Page 12 Immunoglobulin ", herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient' s medical record. (4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone,"with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis. (5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period. Chapter 59A-9.027, F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility staff failed to provide vital signs and patient condition before and after the procedures in the facility for 11 of 11 sampled patients. The findings included: Review of 11 clinical records from 3-10-08 (1 procedure), 3-14-08 (1 procedure), 3-15-08 (9 procedures), revealed that none had any documentation of the pre-procedure or recovery	A 400	4) A NEW POST OPERATIVE FORM WILL BE DEVELOPED AND IMPLEMENTED TO BE GIVEN TO EACH PATIENT IN REGARDS TO POST-OPERATIVE INSTRUCTIONS. A 24 HOUR NUMBER IS PROVIDED IN THIS FORM IN CASE OF EMERGENCIES. 5) OUR EMPLOYEE HANDBOOK AND POLICY AND PROCEDURES MANUAL, WILL SPECIFY THE MINIMUM LENGTH OF TIME FOR RECOVERY AS WARRANTED BY THE PROCEDURE TYPE AND GESTATION.	

Ina Lindsey 04-04-08

Agency For Health Care Administration

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A 400	Continued From Page 13 period following the procedures. There was no documentation of the discharge time, the patients condition, the accompanying family member or post procedure medication given. Interview with the medical assistant on 3-17-08 at 4 pm confirmed that the physician was due to come in at 3:30 pm on the day of the complaint investigation to complete the records. Correction Date: 4-17-08	A 400		
A 450	Post Proc. F/up Care-2nd Trimester Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion: (1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests. (2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted. (3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency. Chapter 59A-9.028, F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility	A 450	(1) A POST ABORTION FOLLOW UP VISIT WILL BE PROVIDED FOR EACH PATIENT. AT THIS TIME A MEDICAL EXAM AND A REVIEW OF ALL LABORATORY WILL BE REVIEWED WITH THE PATIENT. (2) A URINE PREG. TEST WILL BE CONDUCTED TO RULE OUT A CONTINUING PREGNANCY IF THE SUSPICION THAT A CONTINUATION OF PREGNANCY ARISES THE PATIENT WILL BE EVALUATED BY THE PHYSICIAN. (3) OUR POST OPERATIVE INSTRUCTION SHALL FOR THE EDUCATION OF THE PATIENT DURING THE POST-PROCEDURE CARE ALSO INCLUDE SPECIFIC INSTRUCTIONS IN CASE OF AN EMERGENCY THANK YOU FOR YOUR ASSISTANCE IN THIS MATTER, PLEASE FEEL FREE TO CONTACT ME, IF ANY OTHER MATTERS ARE IN QUESTION,	

04-04-08

Agency For Health Care Administration

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A 450	Continued From Page 14 providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests and a urine pregnancy test obtained at the time of the follow-up visit to rule out continuing pregnancy for 4 of 4 sampled patients. The findings included: Review of the clinical records of sampled patients #1, #2, #3, #4 revealed that there was no evidence of a follow-up visit in the record. Interview with the medical assistant on 3-17-08 at 1 pm confirmed that the patients were not encouraged to return to the facility. Correction Date: 4-17-08	A 450		

Ina Kaufman 04-04-08

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

CHARLIE CRIST
GOVERNOR

HOLLY BENSON
SECRETARY

March 25, 2008

Dora Hernandez, Administrator
Alba Medical Center
4210 Palm Avenue
Hialeah, FL 33012

Dear Ms. Hernandez,

On 3-17-08, Arlene Schweitzer, RNC representing this office conducted an unannounced survey to investigate complaint # 2008003261 filed against Alba Medical Center.

The allegation that the facility failed to operate within the scope of practice was unable to be confirmed. However, the Medical Center must operate within the regulations set forth by the legislature.

Enclosed is your "Statement of Deficiencies and Plan of Correction" (State Form) listing the Deficiencies discussed with you and/or your representatives upon the completion of the survey.

Please complete a "**Plan of Correction"** (PoC) for the deficiencies shown on the "Statement of Deficiencies and Plan of Correction," including the date corrective action was accomplished or is anticipated to be accomplished. **Also, please sign and date all forms on the bottom and return them to this office within ten (10) calendar days of receipt of this letter.** Failure to submit a reply within this time may jeopardize your licensure/certification status. All corrections must be made by 4-17-08.

Plan of Correction (PoC)

A PoC for the deficiencies must be submitted on the State Form enclosed. Your PoC must contain the following:

- What corrective action(s) will be implemented to correct the deficient practice;
- Who will correct the deficient practice and when the deficient practice will be corrected;
- What systemic changes/measures will be put into place to ensure that the deficient practice does not recur; and,
- What on-going monitoring/quality assurance will be conducted to ensure the deficient practice will not recur, who will be responsible for the on going monitoring.

Please send all your correspondence to the Miami Address located at the bottom right hand corner of this letter.

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

Area Office 11
8355 NW 53rd Street
Manchester Building
Miami, FL 33166

Please mail the plan of correction to:

R. Steve Emling, Field Office Manager, Area 11
Agency for Health Care Administration, HQA
8355 NW 53rd Street Miami, FL 33166
Phone: (305) 499-2165 Fax: (305) 499-2190

Certain documents may be made available for public disclosure as required by law.

In order to obtain feedback regarding your survey, a web-based interactive survey satisfaction questionnaire has been placed on the Agency's website at www.fdhc.state.fl.us/Publications. You may access the "Quality Assurance Survey Satisfaction Questionnaire" through the link under the Forms heading on this webpage. Your feedback is encouraged and valued, as our goal is to ensure a satisfactory and professional survey process.

Thank you for the assistance provided to the surveyor at the time of the survey. Should you have any questions, please contact me at 305-499-2165.

Sincerely,

for R. Steve Emling
Field Office Manager, Area 11
Division of Health Quality Assurance

Enclosures: State Form
Cc: Hospital Unit

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

CHARLIE CRIST
GOVERNOR

HOLLY BENSON
SECRETARY

AREA OFFICE 11

Guidelines for the Development of Plans of Correction (POC)

The Plan of Correction (POC) is intended to correct any systemic regulatory non-compliance found during the survey process and remediate any specific non-compliance that may have been identified for the individuals receiving services from the facility.

A POC for the deficiencies must be submitted by 10 days after the facility receives its State Form and CMS-2567. Failure to submit an acceptable Plan of Correction within the required time frame may result in the imposition of remedies 20 days after due date for submission.

Your Plan of Correction must contain the following:

1. What corrective action(s) will be accomplished for those patients found to have been affected by the deficient practice;

2. How you will identify other patients having the potential to be affected by the same deficient practice and what corrective action will be taken;

3. What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur; and,

4. How the corrective action(s) will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place.

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A 000	INITIAL COMMENTS An unannounced complaint investigation survey #2008003261 was conducted on 3-17-08. The following deficiencies were identified during the investigation:	A 000		
A 156	Clinic Supplies/equip. Stand.-2nd Trimester Equipment Maintenance. (a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer ' s specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair. (c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair. Chapter 59A-9.0225(7), F.A.C.	A 156		

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A 156	Continued From Page 1 This Standard is not met as evidenced by: Based on record review and interview the facility failed to develop a written preventive maintenance program and compile a maintenance record indicating history of testing, initiated annually, to insure proper operation, and a state of good repair of the defibrillator used in the care of patients receiving 1st and 2nd trimester abortions in the faclity. The findings included: A tour of the facility was conducted on 3-17-08 at 1 pm. The defibrillator was hidden under other equipment. There was no maintenance documentation for the defibrillator in the facility. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was untrained and unable to use the equipment. Correction Date: 4-17-08	A 156		
A 201	Clinic Personnel-2nd Trimester Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. The clinical staff requirements are as follows: Physicians. The clinic shall designate a licensed physician to serve as a medical director. Nursing Personnel. Nursing personnel in the clinic shall be governed by written policies and	A 201		

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A 201	Continued From Page 2 procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established. Chapter 59A-9.023(1),(2),and (3), F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility failed to provide adequately trained personnel capable of providing appropriate service and supervision to the patients including a position description for each position delineating duties and responsibilities and maintaining personnel records for all employees performing or monitoring patients receiving 1st and 2nd trimester abortions in the facility. The findings included: Review of the employee file for the medical assistant revealed that the medical assistant had worked in the facility for 5 years. There was no evidence in the file of training of assistance with 2nd trimester abortions, no job description, and no orientation to the facility. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was untrained and unable to use any of the equipment in the procedure room. There was no nurse available to assist the physician with the procedure. Correction Date: 4-17-08	A 201		

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A 202	Continued From Page 3	A 202		
A 202	Clinic Personnel-2nd Trimester Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control. In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide: (a) Infection control, to include at a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members. (b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires; (c) Confidentiality of patient information and records, and protecting patient rights; (d) Licensing regulations; and (e) Incident reporting. Chapter 59A-9.023,(4) and (5), F.A.C.	A 202		

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A 202	Continued From Page 4 This Standard is not met as evidenced by: Based on record review and interview the facility failed to provide a written orientation program for the staff at the beginning of employment and at least annually thereafter to insure and maintain their understanding of their duties and responsibilities, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients and proper use of fire extinguishers, confidentiality of patient information and incident reporting. The findings included: Review of the employee file for the medical assistant revealed that the medical assistant had worked in the facility for 5 years. There was no evidence in the file of annual in-service training of the employee to insure and maintain their understanding of their duties and responsibilities, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients, proper use of fire extinguishers, confidentiality of patient information and incident reporting. Review of the documentation in the facility failed to produce a policy and procedure manual for 1st and 2nd trimester abortions, infection control precautions, general sanitation, personal hygiene such as hand washing, use of masks and gloves, fire protection, to include evacuating patients and proper use of fire extinguishers, confidentiality of patient information and incident reporting. Interview with the medical assistant on 3-17-08 at 1 pm revealed that he/she was not given any in-service in the facility. Correction Date: 4-17-08	A 202		

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A 202	Continued From Page 5	A 202		
A 250	Clinic Policies/Procedures-2nd Trimester An abortion clinic providing second trimester abortions shall have written policies and procedures to implement policies and to assure that quality patient care shall relate specifically to the functional activities of clinic services. These written procedures shall apply to second trimester abortions and shall be available and accessible to clinic personnel and shall be reviewed and approved annually by the clinic's medical director. These clinic policies and procedures shall include but not be limited to the following: (1) Patient admission; (2) Pre- and post-operative care; (3) Physician ' s orders; (4) Standing orders with required signatures; (5) Medications, storage and administration; (6) Treatments; (7) Surgical asepsis; (8) Medial asepsis; (9) Sterilization and disinfection; (10) Documentation: Medical records and facility records; (11) Patient discharge; (12) Patient transfer; (13) Emergency measures; (14) Incident reports; (15) Personnel orientation; (16) Inservice education record; (17) Anesthesia; (18) Equipment and supplies: availability and maintenance; (19) Volunteers; and (20) Visitors. Chapter 59A-9.024, F.A.C.	A 250		

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A 250	Continued From Page 6 This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to provide written policies and procedures that were available and accessible to clinic personnel and were reviewed and approved annually by the clinic's medical director. The findings included: Review of the documentation in the facility failed to reveal a policy and procedure book for the staff to use. Interview with the Receptionist and the medical assistant on 3-17-08 at 1:30 pm confirmed that there was no policy book available in the facility. Correction Date: 4-17-08	A 250		
A 300	Medical Screening/Eval.-2nd Trimester Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. These patient care policies and procedures, for patients undergoing second trimester abortions, shall include but not be limited to the following: (a) Admission criteria and procedures; (b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions; (c) Specific details regarding the pre-operative	A 300		

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A 300	Continued From Page 7 procedures performed, to include: 1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications; including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history. 2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure. Chapter 59A-9.025(1), F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records history and physical examination, estimation of gestational age based on a bimanual and ultrasound examination, copies of ultrasounds, and laboratory tests to prove pregnancy before the procedures are completed for 9 of 9 sampled patients. The findings included: Review of the clinical record of sample patient #1 (16 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-24-08.	A 300		

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A 300	Continued From Page 8 Review of the clinical record of sample patient #2 (17 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-30-08. Review of the clinical record of sample patient #3 (15 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 2-8-08. Review of the clinical record of sample patient #4 (22 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination before the procedure on 2-12-08. Review of the clinical record of sample patient #5 (22 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 2-27-08. Review of the clinical record of sample patient #6 (20 weeks) revealed that there was no evidence in the record of history and physical examination, estimation of gestational age based on a bimanual examination or lab work to prove pregnancy before the procedure on 1-24-08. Review of the clinical record of sample patient #7, #8, #9 revealed that there was no evidence in the record of an ultrasound examination or lab work to prove pregnancy before the procedure on 3-12-08.	A 300		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 300	Continued From Page 9 Interview with the medical assistant and the receptionist on 3-17-08 at 1 pm confirmed that the physicians conducted the visits before the procedures and wrote in the charts. Correction Date: 4-17-08	A 300		
A 301	Medical Screening/eval.-2nd Trimester Laboratory Services. (a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, F.S. (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions. Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available. All laboratory test reports shall be placed in the patient ' s medical record. All laboratory test and storage areas, records and reports shall be available for inspection by the agency. If a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician	A 301		

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	AC13920003	A. BUILDING _____ B. WING _____	03/17/2008

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A 301	Continued From Page 10 assistant shall, at the request of the patient and before the abortion procedure is performed, review the ultrasound evaluation results with the patient, including an estimate of the probable gestational age of the fetus. A test for anemia shall be performed. Chapter 59A-9.025(2), (4), (5), (6), (7), and (8) F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records Rh factor testing and anemia testing before procedures were performed for 8 of 9 (all except #4) Review of the clinical records of sampled patients #1, #2, #3, #5, #6, #7, #8, #9 revealed that there was no evidence of laboratory tests to indicate the Rh factor, if necessary or anemia testing in the records. Interview with the medical assistant on 3-17-08 at 1 pm confirmed that the physicians conducted the visits before the procedures and wrote in the charts. Correction Date: 4-17-08	A 301		
A 400	Recovery Rm Stand.-2nd Trimester Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions: (1) Following the procedure, post procedure	A 400		

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A 400	Continued From Page 11 recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants. (2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic. (3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient refuses the Rho (D) immune globulin, refusal Form 3130-1002, January 2006, " Refusal to Permit Administration of Rh(D)	A 400		

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A 400	Continued From Page 12 Immunoglobulin ", herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient' s medical record. (4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis. (5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period. Chapter 59A-9.027, F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility staff failed to provide vital signs and patient condition before and after the procedures in the facility for 11 of 11 sampled patients. The findings included: Review of 11 clinical records from 3-10-08 (1 procedure), 3-14-08 (1 procedure), 3-15-08 (9 procedures), revealed that none had any documentation of the pre-procedure or recovery	A 400		

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A 400	Continued From Page 13 period following the procedures. There was no documentation of the discharge time, the patients condition, the accompanying family member or post procedure medication given. Interview with the medical assistant on 3-17-08 at 4 pm confirmed that the physician was due to come in at 3:30 pm on the day of the complaint investigation to complete the records. Correction Date: 4-17-08	A 400		
A 450	Post Proc. F/up Care-2nd Trimester Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion: (1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests. (2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted. (3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency. Chapter 59A-9.028, F.A.C. This Standard is not met as evidenced by: Based on record review and interview the facility	A 450		

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A 450	Continued From Page 14 providing 1st and 2nd trimester abortions failed to maintain a complete medical record for each patient that records a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests and a urine pregnancy test obtained at the time of the follow-up visit to rule out continuing pregnancy for 4 of 4 sampled patients. The findings included: Review of the clinical records of sampled patients #1, #2, #3, #4 revealed that there was no evidence of a follow-up visit in the record. Interview with the medical assistant on 3-17-08 at 1 pm confirmed that the patients were not encouraged to return to the facility. Correction Date: 4-17-08	A 450		