2/26/08

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
	AC13910012	A. BUILDING _____ B. WING _____	01/22/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EPOC CLINIC, INC	809 VIRGINIA DRIVE ORLANDO, FL. 32803

(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 000	INITIAL COMMENTS Relicensure survey was conducted on 01/22/08. Deficient practices were identified and cited at A150, A158, A202, A250 and A400.	A 000		
A 150	Clinic Supplies/Equip. Stand.-2nd Trimester Each abortion clinic providing second trimester abortions shall provide the following essential clinic supplies and equipment: (a) A surgical or gynecological examination table(s); (b) A bed or recliner(s) suitable for recovery; (c) Oxygen with flow meters and masks or equivalent; (d) Mechanical suction; (e) Resuscitation equipment to include, at a minimum, resuscitation bags and oral airways; (f) Emergency medications, intravenous fluids, and related supplies and equipment; (g) Sterile suturing equipment and supplies; (h) Adjustable examination light; (i) Containers for soiled linen and waste materials with covers; and (j) Appropriate equipment for the administering of general anesthesia, if applicable. Chapter 59A-9.0226(1), F.A.C.	A 150 ✓	~~SEE ATTACHED~~ Expired items have been removed. Administrator has been reoriented with policies and procedures for expired medications or other medical devices and this practice will be re-evaluated on a monthly basis to assure compliance by Administrative Director. Administrator and staff have been reoriented with policies and procedures, including and as defined in 59A-9.0225 which require the availability of IV fluids. IV Fluid Inventory Logs which have always been in place for this purpose will be monitored. Immediate correction has been verified by Administrative Director and will be evaluated on a monthly basis.	2/7/08

AHCA Form 3020-0001
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE ✓ TITLE (X6) DATE

STATE FORM UHXK11 If continuation sheet 1 of 11

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A 150	Continued From Page 1 This Standard is not met as evidenced by: Based on observation and interview, the facility failed to ensure stored patient medications had not expired and intravenous (IV) fluids were available for patient use. Findings: During the initial tour of the facility on 01/22/08 at 9:20 a.m. the following was observed. Stored in the supply room, 3 boxes containing numerous individually wrapped osmotic cervical dilators were observed. One box expired on 06/06 and 2 boxes expired on 05/06. One box of Lamina Tents contained 7 individually wrapped cervical dilators with no date of expiration identified. One folied wrapped package of Dilapan cervical dilator was observed with the expiration date of 07/06. Furthermore, during the initial facility tour, no IV fluids were observed. The administrator was interviewed on 01/22/08 at 9:20 a.m. She confirmed the boxes and package of cervical dilators identified above had expired. She stated these items were not being administered to the patients and failed to discard them. The administrator was asked about the availability of IV fluids. She stated the IV fluids had expired on 01/06/08 and were discarded. She confirmed 2nd trimester procedures were performed since 01/06/08 without IV fluids available for patient use.	A 150		

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A 158	Continued From Page 2	A 158		
A 158	Clinic Supplies/equip. Stand.-2nd Trimester Equipment Maintenance. (a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the 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. This Standard is not met as evidenced by: Based on review of policies and procedures (P&Ps) and interview, the facility failed to have a written preventative maintenance program for patient monitoring equipment, surgical	A 158	~~SEE ATTACHED~~ The facility has always had written Policies and Procedures for preventive maintenance of all instruments and equipment. Administrator failed to locate and provide appropriate documentation. In addition to in-house practices, maintenance and monitoring is performed annually by a professional medical maintenance company and documentation is available. Administrative Director will assure that maintenance monitoring records documentation is readily available at all times.	2/7/08

2/4/08

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A 156	Continued From Page 3 equipment and failed to ensure the ultrasound machine, nebulizer, pulse oximeter and oxygen gauge were checked and tested annually. Findings: Documented evidence was not found in the facility's P&Ps to reflect a preventative maintenance program was developed and implemented for the patient monitoring equipment and surgical equipment. Documented evidence was not found to indicate the ultrasound machine, nebulizer, pulse oximeter and oxygen gauge were checked and/or tested annually to ensure proper functioning and state of good repair. The administrator was interviewed on 01/22/08 at approximately 11 a.m. and stated the ultrasound machine and nebulizer were purchased and received on 01/22/07. She confirmed the equipment identified above were not checked annually to ensure the equipment was functioning properly.	A 156		
A 202	Clinic Personnel-2nd Trimester Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control. In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and	A 202	~~SEE ATTACHED~~ All employees have received the in-service training as required by 59A-9.023. Appropriate documentation has been performed. Administrative Director will monitor monthly. The services of Total Medical Compliance have been retained for additional training for safety measures including	2/7/08 cont'd

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A 202	Continued From Page 4 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. This Standard is not met as evidenced by: Based on review of the policies and procedures (P&Ps) and interview, the facility failed to have a written orientation program for new employees, failed to provide documented evidence that 3 of 3 new employees received an orientation program (#1, 2 & 3), failed to provide a written planned in-service training program including the program contents for 3 new employees at the beginning of employment (#1, 2 & 3), and failed to provide annually in-service education for 2 of 2 employees (#4 & 5). Findings:	A 202	fire, and infection control on an annual basis. Medical Director has specified policies for medical emergencies.	

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A 202	Continued From Page 5 The P&Ps were reviewed and a written orientation program was not found. The personnel files for new employees #1, #2 and #3 with respective hire dates of 09/28/07, 10/03/07 and 04/30/07 were reviewed. Documented evidence was not found to indicate these employees received an orientation program which included review of the P&Ps, fire safety, other safety measures and medical emergencies. Employees #1 and #2 also failed to receive infection control in-service education during orientation. The administrator was interviewed on 01/22/08 at approximately 2:30 p.m. and stated new employees reviewed the facility P&Ps which included fire safety, other safety measures and medical emergencies but was unable to provide documented evidence. She confirmed she failed to have a written orientation program and confirmed employees #1 and #2 failed to receive infection control education during orientation. The P&Ps were reviewed regarding a written in-service training program including each program's course content. Written in-service training program was not found. Written in-service training program was not found to reflect the training new employees would receive at the beginning of employment and annually thereafter. The personnel file for employee #4, hired on 01/16/07, was not available at the facility. Review of the facsimile in-service programs signed by the employee on 01/16/07 and 07/17/07 revealed annual in-service education regarding fire protection, patient confidentiality, state licensure regulations and incident reporting	A 202		

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A 202	Continued From Page 6 was not provided. The personnel file for employee #5 hired on 04/07/08 was reviewed. Documented evidence was not found to indicate this employee received annual in-service training regarding fire protection, patient confidentiality and state licensure regulations. The administrator was interviewed on 01/22/08 at approximately 2:45 p.m. and confirmed the findings.	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) Medical asepsis; (9) Sterilization and disinfection; (10) Documentation: Medical records and facility records; (11) Patient discharge; (12) Patient transfer;	A 250	~~SEE ATTACHED~~ The facility has provided all employees with the requirements of 59A-9 and the specific standards of 59A-9.0225 related to second trimester abortions. Medical Director has approved the P&P's and appropriate documentation has been prepared. All employees have received orientation and in-service training and appropriate documentation has been prepared. Administrative Director will re-evaluate on a monthly basis.	2/7/08

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A 250	Continued From Page 7 (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. This Standard is not met as evidenced by: Based on review of the clinic and patient care policies and procedures (P&Ps) and interview, the facility failed to provide documented evidence that the P&Ps were reviewed and approved by the medical director. Findings: The P&Ps for the clinic and patient care were reviewed and documented evidence was not found to indicate the medical director had reviewed and approved these P&Ps. The administrator was interviewed on 01/22/08 at approximately 12:40 p.m. She provided documented evidence that the medical director reviewed and approved the laboratory P&Ps. She confirmed that documented evidence was not found to reflect the clinic and patient care P&Ps were reviewed and approved by the medical director.	A 250		
A 400	Recovery Rm Stand.-2nd Trimester Each abortion clinic which is providing second trimester abortions shall comply with the	A 400	Both the forms and the Policies and Procedures have been revised to reflect the minimum recovery	2/7/08 cont'd

RS SRC mo Dr 2/4/08

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A 400	Continued From Page 8 following recovery room standards when providing second trimester abortions: (1) Following the procedure, post procedure 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	A 400	standards for this requirement. Administrative Director will monitor on a monthly basis. All of the above corrections have been reviewed and authorized by the Medical Director. Administrative Director will review monthly to assure compliance. All documentation is available to support compliance of the aforementioned.	

MB Dir 2/4/08

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A 400	Continued From Page 9 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) 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 interview and review of policies and	A 400		

MD BIR 2/4/08

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A 400	Continued From Page 10 procedures (P&Ps), second trimester medical records for 5 of 5 patients (#1, 2, 7, 8 & 9), the facility failed to include/indicate the recovery room minimum length of time dependent upon the second trimester procedure type and gestational period. Findings: The P&Ps were reviewed and documented evidence pertaining to the recovery room minimum length of time for second trimester procedures was not found. Review of the second trimester procedures signed consent forms for patients #1, #2, #7, #8, and #9 failed to indicate the minimum length of time these patients would spend in the recovery room. The administrator was interviewed on 01/22/08 at approximately 3:35 p.m. She confirmed that a P&P was not written regarding the minimum length of time a second trimester patient would spend in the recovery room. She confirmed the consent form identifying a second trimester procedure did not include the recovery room minimum length of time dependent upon the type of procedure performed and gestational period.	A 400		

AHCA
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

CHARLIE CRIST
GOVERNOR

ANDREW C. AGWUNOBI, M.D.
SECRETARY

January 28, 2008

Administrator
EPOC Clinic, Inc.
609 Virginia Drive
Orlando, FL 32803

RE: Relicensure Survey

Dear Administrator:

This letter confirms the findings of an annual licensure survey conducted at your agency on 01/22/08 by Donna Barton, Registered Nurse Specialist of this office.

Enclosed is a copy of the Statement of Deficiencies and Plan of Correction State Form, which indicates the deficiencies that were discussed with you upon completion of the survey. Please provide a plan of correction, sign, date and return to this office within ten (10) calendar days of receipt.

The Quality Assurance Questionnaire has long been employed to obtain your feedback following survey activity. This form has been placed on the agency's website at www.fdhc.state.fl.us/Pubilications, as a first step in providing a web-based interactive consumer satisfaction survey system. You may access the questionnaire through the link under Forms on this page. Your feedback is encouraged and valued, as our goal is to ensure the professional and consistent application of the survey process.

Please call this office at 407-316-4859, if we may be of any further assistance.

Sincerely,

for Theresa de Guzman

Joel M. Libby
Field Office Manager
Division of Health Quality Assurance

JML/cid

Enclosure: State Form
Instructions for Plan of Correction