Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 000	INITIAL COMMENTS An unannounced complaint investigation was conducted on 04/19-20/2013. Based on the investigative findings, violations of the rules were identified. The investigation continued to collect data to validate the findings related to the administration of an injectable medication administered to patients orally for Medical Abortion Procedures (MABP). The investigative findings revealed an imminent threat to the health and safety of patients. Investigative findings revealed the administration orally of an injectable form of Methotrexate for Medical Abortion Procedures. Manufacturer's packet insert, Medical Affairs for Fresenius KABI (manufacturer of Methotrexate), Assistant Director Education Carolina Poison Center and Medical Advisor for the Division of Health Service Regulation do not recommend the administration of injectable Methotrexate to be given orally to patients. The facility ' s failure to administer the medication according to the manufacturer's recommendation could affect the absorption of the medication. Therefore, the patient would not receive the intended dosage of medication ordered by the physician for the medical abortion procedure.	E 000		
E 131	.0302 PERSON IN AUTHORITY 10A NCAC 14E .0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on protocol review, medical record reviews,observation, staff and physician interviews, review of medication package insert information and interviews with medication	E 131		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 131	Continued From page 1	E 131		

manufacturers and poison control, the facility's governing authority failed to ensure medication administered for medical abortion procedures was administered according to the manufacturers recommendations.

Findings include:

Review of a clinic "MAB (medical abortion procedure) Protocol" (not dated) revealed "For Medical Abortion patients who had an ultrasound confirming an intrauterine pregnancy of less than seven weeks: Patient is to be given 3 cc or 4 cc (depending on BSA body surface area) of Methotrexate orally in the office on day one. Use the BSA formula to determine the appropriate dosage. ..."

1. Closed medical record review of Patient #9 revealed a 21 year-old female that presented to the clinic on 02/16/2013 for a medical abortion procedure. Review of the record revealed the patient was less than 5 weeks gestation by ultrasound. Review revealed the patient was administered Methotrexate 75 mg (3 cc) orally at 1040 and was discharged home. Review revealed the patient returned to the clinic for a follow up appointment on 03/13/2013 and had a positive pregnancy test. Review revealed a surgical abortion procedure was completed on 03/13/2013. Review revealed a follow up appointment was completed on 04/04/2013 and an ultrasound revealed no intrauterine pregnancy.

2. Open medical record review of Patient #1 revealed a 33 year-old female that presented to the clinic on 04/19/2013 for a medical abortion procedure. Review of the record revealed the patient was 5 weeks gestation by ultrasound. Review revealed the patient was administered

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 131	Continued From page 2 Methotrexate 100 mg (4 cc) orally at 1350 and was discharged home. Review revealed the patient was scheduled for a follow up appointment on 05/13/2013. Observation on 04/19/2013 at 1600 during tour of the medication area revealed a 10 ml (milliliter) vial of Methotrexate injection 25 mg (milligrams) per ml (250 mg). Review of the box containing the Methotrexate revealed "contains preservative" (written in red). Interview with a registered nurse during the tour revealed the Methotrexate injectable is administered orally without diluting the medication after determining the appropriate dosage using a formula that was posted on a cabinet door. The nurse stated the medication is drawn up with a syringe and injected into a cup for drinking. Interview revealed the dosage was either 3 cc (cubic centimeters)/ 75 mg or 4 cc/ 100 mg for each patient and the medication is used for medical abortion procedures. Review of the Methotrexate injection package insert revealed the manufacturer of the medication was "APP." Review of the package insert revealed no evidence that the injectable medication could be administered orally. Interview on 04/20/2013 at 1155 with a physician that was working at the clinic revealed the route of administration of Methotrexate was determined by the facility's medical director. The physician stated that he had worked at the clinic 14 years and until two years ago, the clinic gave Methotrexate intramuscular. The physician stated around two years ago the administration decided to begin giving the Methotrexate injectable orally. The physician stated "I don't	E 131		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 131	Continued From page 3	E 131		

order (the medication). The clinic decides. I just sign. Oral or Injectable is not indicated on the order. The nurse and clinic are independent from me. I leave it to the clinic to decide. I have never seen the (Methotrexate) pill used here."

A telephone interview was conducted on 04/20/2013 at 1300 with the Medical Affairs Representative for Fresenius Kabi (pharmaceutical company that manufactured the Methotrexate used by the clinic). The interview revealed there is not a recommendation for the usage of injectable Methotrexate to be given orally. The interview revealed the packet insert contains the indications and dosages for administration of the Methotrexate. The interview revealed a Medical Abortion is not an indication on the manufacture's recommendation.

Telephone interview on 04/23/2013 at 1100 with the Assistant Director, Education with Carolina Poison Center (PharmD, DABAT) revealed Methotrexate injectable is not usually given orally. The interview revealed the concern whether the patient is absorbing the dosage intended because due to the fact that as the dosage increases the percent that is absorbed decreases. The interview revealed she was unsure why injectable Methotrexate would be given orally when there is oral Methotrexate available.

Telephone interview on 05/09/2013 at 0830 with the Medical Advisor of the Division of Health Service Regulation revealed he does not advise the usage of injectable Methotrexate to be given orally. The interview revealed he had a concern with the absorption of injectable Methotrexate given orally. The interview revealed the questioning of the usage of injectable Methotrexate being given orally.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 138	.0305(B) MEDICAL RECORDS 10A-14E .0305 (b) All other pertinent information such as pre- and post-operative instructions, laboratory report, drugs administered, report of operation and follow-up instruction including family planning advice shall be recorded and authenticated. This Rule is not met as evidenced by: Based on medical record review and staff interview, the facility failed to ensure the completion of an operative report following a surgical abortion procedure for 1 of 5 surgical records reviewed (#3). The findings include: Review of a closed medical record revealed a 24 year-old female that presented to the facility on 01/22/2013 for a surgical abortion procedure. Review of the record revealed the patient was 7 weeks gestation via ultrasound. Review revealed the procedure started at 1410 and ended at 1415 and the patient was discharged home at 1430 after signing out against medical advice (AMA). Review of the record revealed a pre-printed section in the medical record for "Operative Note (completed by physician) Preop Diagnosis: _____ weeks gestation intrauterine pregnancy Postop Diagnosis: _____ weeks gestation intrauterine pregnancy Operation: Dilation and evacuation ..." Further review revealed this section included medication administered during the procedure and operative procedure, findings, complications and condition of the patient at the completion of the procedure. Review revealed the "Operative Note" section of the record was blank.	E 138		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 138	Continued From page 5 Interview on 04/20/2013 at 1140 with administrative staff revealed there was no policy available that referenced the completion of an operative report. Interview revealed the physician should have completed that section and it was not completed. Interview revealed there was no evidence of an operative report for this patient following the surgical procedure.	E 138		
E 158	.0311(B) SURGICAL SERVICES 10A-14E .0311 (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 158	Continued From page 6 P.O.C. (3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record. (4) The facility shall establish procedures for obtaining, identifying, storing and transporting specimens. (5) The facility shall establish a method for follow-up of patients on whom no villi are seen. This Rule is not met as evidenced by: Based on clinic policy review, medical record review and staff interview, the physician performing the surgical abortion failed to specifically note the presence or absence of chorionic villi and fetal parts or the amniotic sac in the examination of the products of conception prior to the discharge of the patient in 1 of 5 patients that had a surgical abortion procedure done (#3). The findings include: Review of the clinic's "Surgical Services" policy (not dated) revealed "2. Tissue Examination: a. The physician performing the abortion shall examine the products of conception prior to discharging the patient from the clinic. The examination of the POC's under eight (8) weeks shall consist of identifying the presence or absence of Chorionic villi or the amniotic sac. If such tissue is not identified by gross examination or if the villi are not identified by the float test the physician shall put the specimen in a container of formalin, labeled with the patient's name and other identifying information and send to a certified laboratory for a board certified or eligible	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(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
E 158	Continued From page 7 Pathologist's review. The examination of the POC's nine (9) weeks or more shall consist of obtaining an accurate weight, gross examination of the specimen. If amniotic sac or fetal parts appropriate for gestational age are not identified, or if the weight of the POC falls substantially below the appropriate weight range for the fetal age the physician shall put the specimen in a container of formalin, labeled with the patient's name and other identifying information and send to a certified laboratory for a board certified or eligible Pathologist's review." Medical record review of Patient #3 revealed a 24 year-old female admitted on 01/22/2013 for a surgical abortion procedure. Record review revealed the patient had a Dilation and Evacuation for an intrauterine pregnancy of 7 weeks gestation. Review of the record revealed no documentation of the gross description of the products of conception (POC). Interview with clinic administrative staff on 04/20/2013 at 1140 revealed the physician failed to document the examination of the Products of Conception. The interview revealed there was no documentation of an examination of the POC available. NC00087132	E 158		