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		

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E 131	Continued From page 1 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	E 131		

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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		

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E 131	Continued From page 3 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.	E 131		

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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		

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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		

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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		

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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		

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Concerns E-158

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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	We do not agree with the finding of lack of compliance under E000 and E131 .0302. Contrary to the state's assertion and the opinions rendered under E3000, it is by common medical practice among abortion providers, textbook instruction and referenced scientific journal research that supports the use of parenteral Methotrexate used as a solution dissolved in water or orange juice, administered by mouth, as efficacious as an abortifacient in early gestational pregnancies (See Exhibits I,II, and III). However, without admitting error or fault, we have voluntarily removed Methotrexate in all forms from our formulary as of 4.26.2013 and will not be using Methotrexate as an abortifacient in the future (See Exhibits IV,V,and VI). We, therefore, feel that since we do not use Methotrexate nor plan to use it again that the finding of imminent danger and the resulting closure of the Abortion Clinic at 3220 Latrobe Drive in Charlotte should be rescinded.	5/13/13
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		

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E 131	Continued From page 1 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	E 131	Regarding the comment made by an interviewed physician, we disagree with the citation in E131. The physician on duty by The NC medical Practice Act is responsible and has the obligation to supervise the dosage and route of administration of any medication that they order. If the physician did not want to give Methotrexate orally it was his decision not to do so since the licensed abortion clinic does not practice medicine, the physician does. The Abortion clinic merely made this available in their formulary (see Exhibit VII -section XII p. 1 APWHC Policy & Procedure Manual)	

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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	All medical abortion patients are scheduled for a follow-up appointment during counseling for the medical abortion procedure. Patients must agree to return to APWHC for this follow-up appointment to ensure the medical termination is complete and check for possible complications. Medical abortion patients who fail to return for their follow-up appointments receive letters via USPS mail at the contact address which they provide us in their patient chart and/or telephone calls to their listed contact number in which it is explained to the patient that it is imperative they contact our office to reschedule their missed follow-up appointment. This has been our long-standing policy and will continue to be practiced by APWHC.	

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E 131	Continued From page 3 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.	E 131		

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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	E138 It is our policy and documented in our Policy and Procedure manual that a physician must complete all aspects of the patients medical record and that they must verify the products of conception as indicated in the Rules and Regulations 1DA-14E.0311 (See Exhibit VIII-section XI p.1 APWHC Policy & Procedure Manual). In addition, we have added the APWHC Physician Pathology Review Policy (See Exhibit IX) We have a Q/A program that goes over the charts daily and at other times to correct deficiencies (See Exhibit X-section V p2 APWHC Policy & Procedure Manual). In addition, we have added the APWHC Quarterly Chart Review Policy (See Exhibit XI) Although we have made a best effort, a deficient chart slipped through the cracks. We will endeavor to not let this happen again and continue our routine policy of chart review and repair. We will continue to monitor staff and physicians to accurately complete all aspects of the medical chart in a timely manner. We will counsel and correct those found not in compliance with our policy.	5/20/13

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		

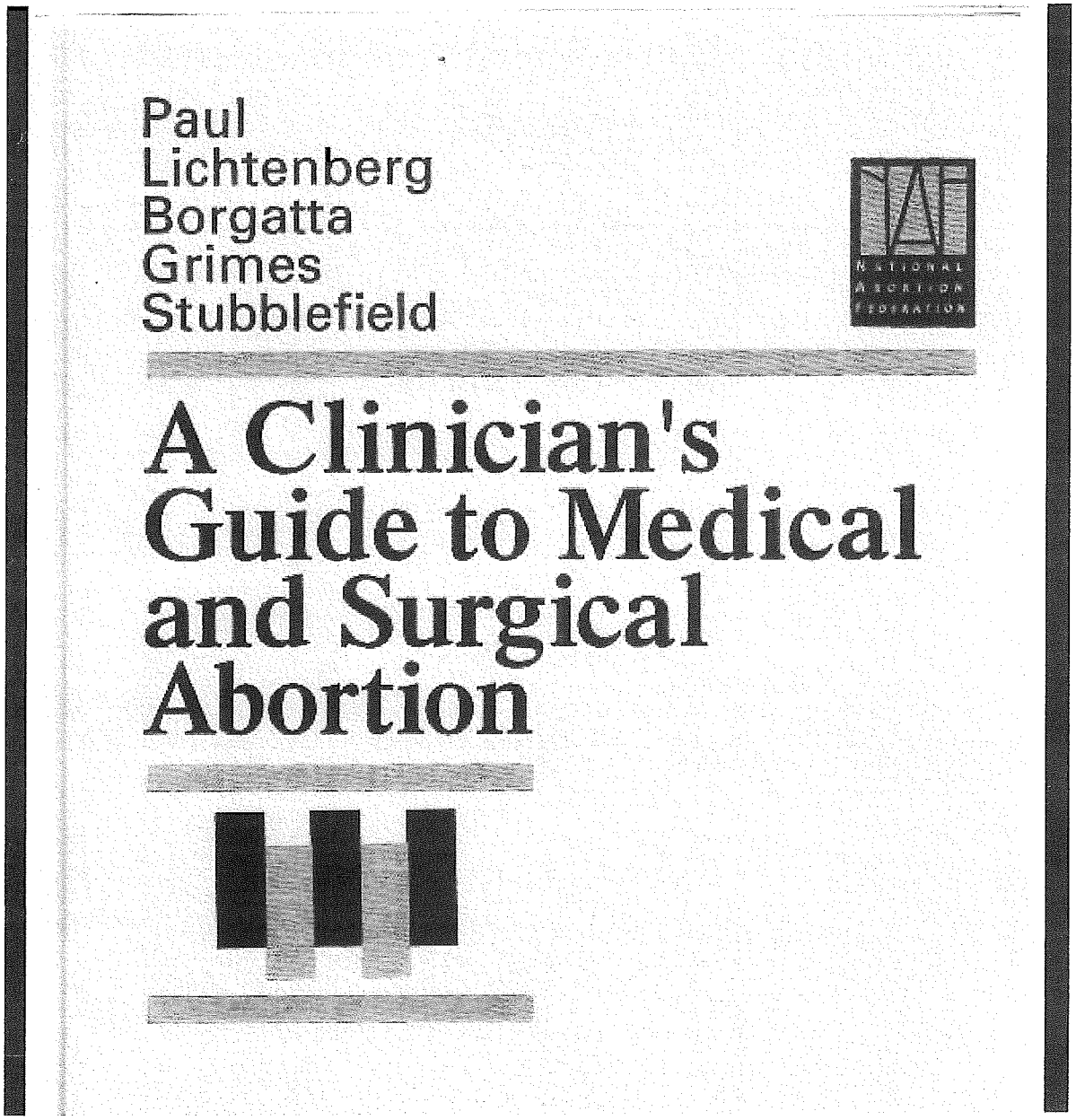
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

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		

Exhibit I

Please see highlighted areas for substantiation of parenteral Methotrexate used orally.



Churchill Livingston

A Division of Harcourt Brace & Company

NY

1999

methotrexate-related side effects. This pilot study established that methotrexate in combination with vaginal misoprostol was potentially effective for early abortion.

Two larger trials supported a longer interval between methotrexate and misoprostol administration. In the first study, 178 women at 63 days' gestation or less received methotrexate 50 mg/m² intramuscularly followed 5–7 days later by misoprostol 800 μg vaginally.[6] Patients who did not expel the gestational sac received a repeat misoprostol dose. By 14 days after methotrexate administration, 96% of subjects successfully aborted, 14% of these patients required a repeat misoprostol dose. However, 26% of patients were at less than 35 days' gestation, and 66% were at less than 45 days. Additionally, the investigator followed subjects for only 1–2 weeks after the misoprostol, which may be insufficient to identify all cases of incomplete expulsion. Also, only 2 of 178 women reported methotrexate-related side effects, a rate notably lower than that reported in other series.

The second report was a randomized controlled trial[7] comparing the efficacy of intramuscular methotrexate 50 mg/m² followed by vaginal misoprostol 800 μg administered 3 or 7 days later in pregnancies up to 56 days' gestation. As in other trials, patients received a repeat dose of misoprostol if the gestational sac was not expelled. The overall effectiveness rates were 83% and 96% in the 3- and 7-day groups, respectively. Only 65% of patients in the 3-day group and 68% in the 7-day group passed the pregnancy within 24 hours of the first or second dose of misoprostol.

A multicenter trial of 500 women at 56 days' gestation or less used methotrexate 50 mg/m² intramuscularly followed 7 days later by misoprost 800 μg vaginally.[8] Subjects received a repeat miso prostol dose 24 hours later if abortion did not occu Overall, 87.7% of subjects completely aborted with out the need for a surgical procedure. The succes rate was significantly better at 49 days' gestation o less than at more than 49 days (Table 8–1). Onl 70% of subjects aborted by 14 days after the meth otrexate (Table 8–2). Women who passed the preg nancy within 24 hours of the first or second dos of misoprostol experienced bleeding and spottin for 14 ± 7 days; those who passed the pregnanc after a delay had bleeding and spotting for 11 ± days. Side effects occurred after injection of meth otrexate, although some could have resulted fro "morning sickness" (Table 8–3). After misoprost administration, nausea occurred in 12%, vomitin in 8%, diarrhea in 7%, and subjective fever or chill in 3% of subjects.

Because a preliminary evaluation of regimens u ing oral methotrexate showed encouraging results a multicenter trial evaluated a 50-mg oral dose fo lowed by misoprostol 800 μg vaginally.[9] Overal 93% of subjects completely aborted, with 78% pas ing the pregnancy within 24 hours of the first o second doses of misoprostol (Table 8–2). For thes women, bleeding and spotting lasted 15 ± 8 day Women who passed the pregnancy after a dela had bleeding and spotting for 11 ± 7 days. Subject reported side effects more often after oral meth trexate than after intramuscular administration, a though this might be due to different patient pop ulations or to the way side effects data wer collected (Table 8–3).

Methotrexate offers the advantage of being i expensive and, unlike mifepristone, is widely ava

days' gestation. Using misoprostol 800 μg vaginally appears to result in acceptable efficacy through 63 days' gestation. Finally, decreasing the dose of mifepristone to 200 mg and combining it with misoprostol 600 μg orally effects abortion through 56 days' gestation, although a 49-day gestation limit may be more appropriate.

Clinical trials suggest no difference in efficacy for regimens using 200 or 600 mg of mifepristone. Moreover, pharmacokinetic studies of serum levels show no significant difference at any dose of 100 mg or greater. Thus the lower dose is an effective, less expensive alternative. In addition, studies with 200 mg suggest that rates of bleeding and expulsion between administration of mifepristone and the prostaglandin are reduced when the lower dose is used. These factors may be of clinical benefit, as they lessen the need for additional evaluation and the likelihood that women will expel the pregnancy at an unanticipated time.

European, Chinese, and U.S. clinical trial protocols have included surgical aspiration if the abortion is not complete by a 2-week follow-up visit. Schaff et al. demonstrated that this intervention is not necessary, and that additional doses of misoprostol or simply waiting (if the pregnancy is not viable) is an acceptable alternative.

Methotrexate effectively induces abortion up to 49 days' gestation when administered as 50 mg/m² intramuscularly or 50 mg orally. Although the efficacy appears to decrease for gestations after 49 days, no sharp decline is evident at any particular gestational age. For both methotrexate and mifepristone abortion, efficacy appears to be higher at 42 days than at 49 days.

All $Rh_0(D)$-negative patients receive $Rh_0(D)$ immune globulin, although some experts have questioned the necessity of this practice in early medical abortion patients. A dose of 50 μg suffices for gestations of 12 weeks or less. If the blood type is not known at the time of mifepristone or methotrexate administration, the patient can receive the immune globulin anytime before she uses the prostaglandin.

Protocols Using

sively, gemeprost is used in fewer than 5% of medical abortions.

The medical contraindications to mifepristone abortion include contraindications to outpatient abortion, such as a hemorrhagic disorder, use of anticoagulants, and severe anemia, as well as known allergy to mifepristone or the prostaglandin analogue. Because of the antiglucocorticoid properties of mifepristone, women with chronic renal insufficiency and long-term corticosteroid use are also ineligible for mifepristone abortion. In principle, there are no contraindications to misoprostol use. However, because a small number of women smokers over age 35 experienced adverse cardiac events following sulprostone administration, the medical commission in France extended the same restriction to women using misoprostol or gemeprost. Nonsmokers over age 35 are still candidates for mifepristone and misoprostol abortion. Mifepristone does not affect asthma, but severely asthmatic patients may require chronic corticosteroid use. Gynecological contraindications include pregnancy over 49 days, suspected ectopic pregnancy, fibroids resulting in excessive bleeding, and an intrauterine device (IUD) in situ.

From a medical point of view, mifepristone/misoprostol abortion requires three visits. However, French law mandates a waiting period from the time a woman decides to have an abortion to the time that the abortion takes place; thus medical abortion in France requires four visits.

Visit 1 occurs when the woman requests an abortion and selects the method of abortion appropriate for her. The woman must decide whether she wants a mifepristone abortion. If the woman is hesitant to participate in this type of abortion, she should not proceed.

The pregnancy must be 49 days or less at the time the patient takes the mifepristone. The clinician estimates the age of the pregnancy by the woman's menstrual history, gynecological examination, and quantitative βhCG measurement. Sonography is performed if there is a discrepancy between the menstrual dates and uterine size, vaginal bleeding is present, or there are symptoms of a possible ectopic pregnancy. Suspicion of an ectopic

Exhibit II

4/20/13 Oral methotrexate compared with injected... [Am J Obstet Gynecol. 1999] - PubMed - NCBI

PubMed

Display Settings: Abstract

Am J Obstet Gynecol. 1999 Jul;181(1):149-52.

Oral methotrexate compared with injected methotrexate when used with misoprostol for abortion.

Weber EB.

Department of Family Practice, University of British Columbia, Vancouver, British Columbia, Canada.

OBJECTIVE: This study was undertaken to compare oral to injected methotrexate with respect to effectiveness, side effects, and acceptability.

STUDY DESIGN: One hundred women in an urban primary care practice were randomly assigned in phase 1 to receive 50 mg/m(2) methotrexate by either the oral or the injected route. In phase 2 another 67 women were allowed to choose between the oral and injected routes. In both phases and in all groups the methotrexate was followed 5 to 7 days later by misoprostol administered vaginally by the patient. The main outcome was the success rate (the number whose pregnancies aborted without surgery); other outcomes included side effects and acceptability.

RESULTS: There were no differences in rates of success, side effects, or acceptability between groups receiving oral and injected methotrexate. Among the women in phase 2 the oral form was chosen by 57.5%.

CONCLUSION: This study indicates that for medical abortions induced with methotrexate and misoprostol it is possible to offer both the oral and injected routes of methotrexate without sacrificing efficacy and that about half of the women offered a choice will choose the oral route.

Publication Types, MeSH Terms, Substances

LinkOut - more resources

Oral use of parenteral Methotrexate has also been used in the treatment of Rheumatoid Arthritis,

Display Settings: Abstract Send to:

J Rheumatol. 1996 Mar;23(3):455-8.

Oral administration of an easily prepared solution of injectable methotrexate diluted in water: A comparison of serum concentrations vs methotrexate tablets and clinical utility.

Marshall HS, Gengler L.

St. Paul-Ramsey Medical Center, Saint Paul, MN 55101-2595, USA.

Abstract

OBJECTIVE: To investigate whether the injectable formulation of methotrexate (MTX) given as an easily prepared oral solution of MTX diluted in water results in serum concentrations similar to those obtained with MTX tablets; to describe an easy and safe method of dispensing the drug.

METHODS: Six patients (5 women, 1 man) with rheumatoid arthritis were given 10 mg of liquid MTX orally. The liquid was prepared by diluting 0.4 ml of the injectable formulation of MTX (50 mg/2 ml) in 8 ounces of water. One to 2 weeks later these patients were given 10 mg of MTX in the tablet form. MTX serum concentrations were determined using a fluorescence polarization immunoassay. The area under the concentration vs time curve (AUC), maximum concentration (Cmax) and the time to reach maximum concentration (tmax) were determined from the resulting concentration vs time curves.

RESULTS: There was no statistical difference in the variables measured (AUC, Cmax, tmax), demonstrating comparable concentrations with these 2 methods of MTX administration. Patients found the medication easy to administer, potential hazards with the use of needles were avoided, and the cost of the drug was greatly decreased.

CONCLUSION: The administration of this easily prepared MTX solution is an alternative to the conventional administration of MTX tablets, and may be of particular benefit in patients with financial limitations.

PMID: 8882982 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms, Substances

LinkOut - more resources

d. Other regimens using parenteral methotrexate
   1) Creinin (68) reported a case series of 100 women ≤49 days' gestation who received methotrexate 75 mg IM regardless of body surface area followed 5-7 days later by misoprostol 800 µg vaginally. The misoprostol dose was repeated if abortion had not occurred.
      a) Complete abortion occurred in 95% (95% CI 91, 99%) of patients. The complete abortion rate did not vary by gestational age.
      b) Abortion occurred in the 24 hours following the initial or repeat misoprostol dose in 71%; the remaining 24% of women who aborted did so after a delay of 22 ± 10 days.
   2) Wiebe et al (67) randomized 100 women ≤49 days' gestation to receive 50 mg m^2 of the parenteral form of methotrexate IM or orally (in 10 ml of orange juice) followed by moistened misoprostol 600 µg vaginally. The misoprostol was repeated if the woman experienced only light vaginal bleeding.
      a) The success rates for the oral and injected forms were 95% and 89%, respectively (p=0.30). A sample size of 830 would have been required to establish a significant difference.
      b) When patients were given a choice between oral and intramuscular administration, only 57% chose the oral route.

e. Methotrexate alone
   1) Creinin (68) treated 10 women ≤42 days' gestation with a single dose of methotrexate 50 mg/m^2 IM.
      a) Abortion occurred in 100% (95% CI 73, 100%). Vaginal bleeding started 24 ± 10 days after the injection and lasted 10 ± 3 days.
      b) Four women reported side effects that could have been attributed to the methotrexate (nausea, dizziness and headache); all of these effects were limited to the first 4 days after the injection.
   2) Schaff et al (69) treated 40 women ≤35 days' gestation with methotrexate 50 mg/m^2 IM; further intervention (vaginal misoprostol or surgical abortion) was offered on day 21 if abortion had not occurred.
      a) Ten of the women had not aborted by day 21. Two other women had requested misoprostol prior to day 21 and successfully aborted. One subject still had gestational cardiac activity by 21 days after the methotrexate but did successfully abort after misoprostol treatment.
      b) Vaginal bleeding started 16 ± 8 days after the injection and lasted 10 ± 5 days.
      c) Side effects were reported at a rate similar to a comparison group who used methotrexate and misoprostol.
   3) Özeren et al (70) treated 36 women ≤63 days' gestation with methotrexate 50 mg/m^2 IM; the dose was repeated 3 days later if quantitative serum ß-hCG levels increased by 50%. A surgical abortion was performed if the medical abortion was not successful by day 21.
      a) Treated subjects averaged 45 ± 8 days' gestation (range 31-60 days). Twenty-two (61%) required a repeat dose.
      b) Medical abortion was successful in 69% of women; abortion was 100% successful in the 15 women ≤42 days' gestation and in 10 of 12 (83%, 95% CI 62, 100%) women from 43 to 49 days' gestation.

Exhibit IV

STATE OF NORTH CAROLINA

AFFIDAVIT

IN RE: ADMINISTRATIVE ACTION REGARDING A PREFERRED WOMEN'S HEALTH CENTER LLC

I, Stuart L. Schnider MD, PhD, first being duly sworn, deposes and says:

(1) I am an adult citizen and resident of North Carolina.

(2) I am a license physician and the Medical Director for A Preferred Women's Health Center, LLC ("The Facility").

(3) Since April 26, 2013, I have directed that the Facility ceased the use of Methotrexate in an oral manner.

(4) From this day forward, the Facility will not use Methotrexate in any off label modality.

(5) I have informed the following employees and independent contractors who provide service at the Facility of this policy;

Rachel Hales

Lois Turner

Dr. Jim Newton

Jeanne Thomas, RN

Cawana Talbert

(6) Attached hereto is the acknowledgement from the above reference individuals that they have been informed of the Facility's Medical Director's instructions with respect to Methotrexate and that they will abide by those directives.

Further affiant sayeth not.

Stuart L. Schnider, M.D. PhD

Sworn and subscribed before me
This 13 day of May, 2013

Name: Danielle Moore

DANIELLE MOORE
NOTARY
My Comm. Expires
March 26, 2018
PUBLIC
GASTON COUNTY, NC

My Commission Expires: March 26, 2018

Notary Public

By my signature attached hereto, I acknowledge that on May 13, 2013, I was informed that Dr. Stuart L. Schnider in his capacity as Medical Director of A Preferred Women's Health Center, LLC, has directed that Methotrextate not be used in an oral manner or any manner that would be considered off label.

Danielle Moore

DANIELLE MOORE NOTARY PUBLIC GASTON COUNTY, NC My Comm. Expires March 26, 2018

Exhibit V

APWHC offers the Mifepristone misoprostol (Cytotec) medical abortion following the guidelines recommended by the National Abortion Federation.

MEDICAL HISTORY and PHYSICAL EXAMINATION should include:

1. pertinent medical and obstetrical history, including history of allergies and all current medications;
2. vital signs and pertinent physical examination as indicated; and
3. determination of gestational age by clinical assessment (ultrasound may be used in place of, or in addition to bimanual pelvic examination).

LABORATORY EVALUATION should include:

1. test to confirm pregnancy; a qualitative (urine) hCG* is routine;
2. documentation of Rh status;
3. hemoglobin or hematocrit (recommended); and
4. other tests as medically indicated.

Low –Dose Mifepristone and Buccal Protocol

Maximum date range 63 days gestation by ultrasound estimation
200 mg Mifepristone (1 tab) by mouth at the clinic
800 ug (4 tabs) placed between the patient's cheek and gum (Buccal area) at home between 24 and 36 hours after the Mifepristone is administered
Follow up recommended in two weeks

A Preferred Women's Health Center
3228 Latrobe Drive
Charlotte, NC 28211
(888) 562-7415

Exhibit VI

Medical Abortion Policy Change 5.13.13

Effective April 26th, 2013 A Preferred Women's Health Center will no longer be using IM Methotrexate, specifically using the IM solution orally to terminate early gestations, which is not recommended on its package insert. This policy change has been reviewed with the Medical Director, Administrators, Physicians, Lead RN, and Clinic Manager, and will be reviewed with additional personnel at the earliest possible time.

The policy will be monitored by Administrator Rachel Hales in conjunction with Clinic Managers with quarterly reviews of the APWHC Medical Abortion Policy to ensure complete compliance.

By signing below, I confirm that I have been informed and understand the APWHC Medical Abortion policy change.

Name (Printed)	Signature	Date
Stuart L. Schneider, MD, MD		5/13/13
Lois E. Turner Schneider		5/13/2013
Rachel Hales		5/13/13
Jeanne D. Thomas RN		5/13/13
Cawana T Talbert		5/13/13
		5.28.13

A Preferred Women's Health Center
3220 Latrobe Drive
Charlotte, NC 28211
(888) 562-7415

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The policy will be monitored by Administrator Rachel Hales in conjunction with Clinic Managers with quarterly reviews of the APWHC Medical Abortion Policy to ensure complete compliance.

By signing below, I confirm that I have been informed and understand the APWHC Medical Abortion policy change.

Name (Printed)	Signature	Date
J.I. Newton	J.I. Newton, M.D.	5/13/13

A Preferred Women's Health Center
3220 Latrobe Drive
Charlotte, NC 28211
(888) 562-7415

Exhibit VII

XII
Medications and Anesthesia

1. Medications

a. Only medications or treatments that have been written as an order for that patient shall be given by the nursing staff.

b. Medications may only be given in accordance with the nurse practice act. Each medication or treatment must be noted on the patient's medical record.

c. Each patient (in absence of an allergy to medication or class of medications) (unless otherwise indicated by written protocol of the physician) shall receive:

1. 800mg Ibuprofen PO, preoperatively
2. 25/50 mg of Visteril PO, preoperatively (Hydroxyzine)
3. 10cc's of intracervical 1% lidocaine, immediately pre-procedure
4. Other medications, antibiotics as may be ordered by the physician
5. Patient's may receive at their request or the physician's discretion intra-Operative, self-inhalation with Nitrous Oxide-Oxygen mixture for additional analgesia

a. The patient will have the nasal inhalation apparatus fitted to their nose. Initially 100% oxygen will be given. Slowly the amount of oxygen will be titrated to give the patient maximum relaxation. The concentration of Nitrous will not exceed 70%. The patient will be under constant observation by the physician under the Nitrous Oxide analgesia. During the procedure, control of the nose piece is by the patient. The patient can remove themselves from the gas at any time. Upon completion of the procedure, the gas mixture shall be titrated back to 100% Oxygen.

b. The Nitrous Oxide, Oxygen inhalation apparatus shall be secured in a locked room when not in use.

2. No flammable anesthetics shall be used in this clinic.

Exhibit VIII

XI
Surgical Services

1. Facilities: The operating room shall be used exclusively for surgical procedures.

a. Infection Control

1. Cleaning: After each procedure, the operating room shall be completely cleaned using antiseptic cleanser. Particular attention shall be made to any blood or tissue products. The operating table will be cleaned. The suction machine and apparatus will be cleaned.

2. Instruments: After each procedure, the surgical instruments shall be cleaned, wrapped, and sterilized. Only sterile instruments, gloves, and materials will be used for a pregnancy termination procedure.

b. Universal Precautions: The policy of this clinic shall be that of following universal precautions with respect to the handling of all blood, blood containing, and human tissue products. Needles and all sharps shall be disposed of in approved sharps containers. Any employee exposed to blood, blood products, blood contaminated material, or human tissue will immediately notify the Registered Nurse or Clinic Manager. They will be referred to the physician on duty for appropriate counseling, evaluation, and referral for treatment as is necessary.

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 the container of formalin, labeled with the patient's name and other identifying information, and sent to a certified laboratory for a board certified or eligible Pathologist's review. The examination of POC's nine (9) weeks or more shall consist of obtaining accurate weight, and gross examination of the specimen. If amniotic sac or fetal parts appropriate for the 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 sent to a certified laboratory for a board certified or eligible Pathologist's review.

b. The results of the pathology examination done in-house or referred out shall be recorded in the patient's medical record.

c. Any further patient evaluation or subsequent treatment will be recorded in the patient's medical record.

d. All specimens sent for additional pathology examination will be placed in a container of formalin, labeled with the patient's name and other identifying information. The specimen will be stored in the dirty utility room in a labeled container for pickup either that day or the next day by courier for transportation to the Pathology laboratory.

3. All patients on whom no villi are seen at the time of the procedure will have the POC sent for review by a board certified or eligible Pathologist. All patients on whom no villi are seen by the consulting pathologist will have a letter written to them and will be contacted by phone to return for a follow-up evaluation as soon as possible.

Exhibit IX

APWHC Physician Pathology Review Policy 05.13

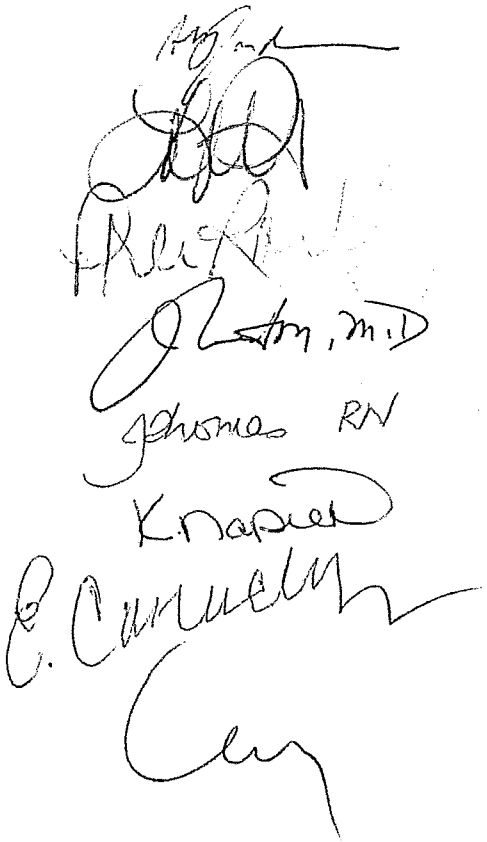
The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.

The facility has 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 fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C. Please consult APWHC P.O.C. Pathology Handling Procedure for further assistance.

This policy will be monitored by both the APWHC AB Chart Review Policy, in addition to the updated APWHC Quarterly Chart Review v. 05.13.

Failure to comply with this policy will result in counseling of the appropriate physician and/or staff member, and possible administrative action.

Cawana Talbert



A Preferred Women's Health Center
3228 Latrobe Drive
Charlotte, NC 28211
(888) 562-7415

Exhibit X

APWHC AB Chart Review Policy

Policy Purpose: To insure that documentation of information in client medical records is clear, complete, and capable of withstanding legal scrutiny.

Timeframe for Reviewing Charts: Chart review needs to be done within 72 hours from the beginning of a given clinic. This timeframe is to insure that all women who are RH-negative have received Rhogam, if consent is given, which must be administered within 72 hours of a pregnancy termination. If it is not possible to review the entire chart within this timeframe, the minimum that is absolutely required is to check RH factors for all clients, and determine that all RH-negative clients received Rhogam, or signed the appropriate waiver.

Order of Completed Charts:
1) Any referral forms/medical forms from other MDs should remain loose in the chart
2) The identification of the client should be affixed to the back page of the chart
3) signed Agreement to Alternative Dispute Resolution Sheet signed
4) signed HIPAA Consent Form
5) Completed and signed NC WRTK Counseling Certificate
6) Completed surgical or MAB paperwork
7) Any referral sheets (Ectopic Pregnancy Warning, pathology reports, referral to alternative care)

Chart Review
1) Outside referral information (no need to review)
2) Signed Agreement to Alternative Dispute Resolution Sheet
3) Signed HIPAA Consent Form
4) Signed NC WRTK Counseling Certificate
5) Medical History Form:

Page 1: There should be responses indicated to all questions on the first page. This is particularly important regarding medication allergies. Drug allergies are commonly left blank by patients. Advocates are responsible for making sure this information is complete, and should ask patients if necessary. Any "yes" response on the medical history requires a brief explanatory comment (ie date of diagnosis, treatment, whether the condition is current or not, etc.) The mailing address should also be complete for any lab results (if necessary) as well as authorization to release records if applicable.

6) Signed and dated Informed Consent with the patient's name and age at the top.
7) If the patient is Rh Negative, the Rhogam Informed consent at the bottom of the page must be signed.
7) Completed procedure information, with all blanks filled in correctly and the physician's signatures in all necessary places.

8) Recovery Room Record must be completed with patient's name, time entered into RR, post-op vitals and assessment, discharge instructions and medications given, and BC type given. Any unusual occurrences, like seizures, vasovagal reactions, fainting, etc. should be noted. Any significant deviation of pre- and/or post-op vitals should be rechecked until the difference is minimal. As a guideline, a change of 20 points or more in either diastolic or systolic BP should be rechecked.

Use the chart audit form to document any feedback or request corrections from the staff. Charts need to be corrected if signatures and initials are omitted, times are omitted, or if a referral note or documentation is needed.

Exhibit XI

APWHC Quarterly Chart Audit Policy v. 05.13.

In addition to the APWHC AB Chart Review Policy, effective May 2013 a Quarterly Chart Review will be performed as well. The purpose of this audit is to ensure not only completion of patient charts, but also to check Quality Assurance Indicators regarding treatment.

Quarterly Chart Audit for Medical Abortions

1) Select 50 medical abortion charts from the completed quarter (January-March, April-June, July-September, October-December)
2) For each chart, document the following information: chart number, patient name, date seen, medication received, number of weeks gestation, whether or not patient returned for follow up, any extraneous marks in chart, visible intrauterine pregnancy pictured in ultrasound, were early warnings given if necessary, and whether or not the patient needed surgical reaspiration following the medical abortion procedure.
3) Scan in documentation and email to RHales@apwhc.com to be saved in the appropriate clinic's Quality Assurance Google Folder. Keep original copy for APWHC Quality Assurance notebook.

Quarterly Chart Audit for Surgical Abortions

1) Select 50 medical abortion charts from the completed quarter (January-March, April-June, July-September, October-December)
2) For each chart, document the following information: chart number, patient name, date seen, number of weeks gestation, whether or not the chart was complete, whether or not patient returned for follow up, were there any problems, and if so identify them.
3) Scan in documentation and email to RHales@apwhc.com to be saved in the appropriate clinic's Quality Assurance Google Folder. Keep original copy for APWHC Quality Assurance notebook.

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Quarter QA Medical Abortions			Year:__________	Quarter:____	Clinic Location: ____________________				
Chart #	Patient Name	Chart Complete?	Patient Name	# of Weeks	Returned for F/U	Returned for Follow up Y or N	Visible IUP?	Early warnings given if necessary?	Reasp?

Quarter QA SurgicalAbortions

Year:_____ Quarter:____ Clinic Location: _____

Chart #	Patient Name	Date Seen	# of weeks	Chart Complete?	Returned for F/U?	Any Problems?	If yes, describe.

F A X

APWHC LLC
P.O. Box 38470
Charlotte, NC 28278
(888) 562-7415
http://www.apwhc.com

To: Cecilia Fax number: (919) 715-3073	
From: Rachel Fax number: (704) 364-0396	
Date: 5/23/2013	
Regarding: **APWHC Plan Of Corrections**	
Phone number for follow-up: 888-562-7415	

Comments:

Cecilia-

Attached you will find the specified corrections for E 138 and E 158 per our discussion yesterday. I'll go ahead and FedEx a hard copy directly to your office at 1205 Umstead Dr. Let me know if you have any additional questions.

Thanks!

Rachel Hales
APWHC Administrator
Office: (888) 562-7415
Cell: (919) 414-9724
RHales@apwhc.com

PRINTED: 05/10/2013
FORM APPROVED

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 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	E138 It is our policy and documented in our Policy and Procedure manual that a physician must complete all aspects of the patients medical record and that they must verify the products of conception as indicated in the Rules and Regulations 1DA-14E.0311 (See Exhibit VIII-section XI p.1 APWHC Policy & Procedure Manual). We have a Q/A program that monitors charts daily to check for completed pre- and post-operative instructions, lab reports, drugs administered, operative report, pathology, and follow up instructions including family planning advice, and correct any deficiencies noted(See Exhibit X-section V p2 APWHC Policy & Procedure Manual). In addition, we have added the APWHC Quarterly Chart Review Policy (See Exhibit XI) to monitor chart completion.	5/20/13

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	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	E158 It is our policy and documented in our Policy and Procedure manual that a physician must complete all aspects of the patients medical record and that they must verify the products of conception as indicated in the Rules and Regulations 1DA-14E.0311 (See Exhibit VIII-section XI p.1 APWHC Policy & Procedure Manual). In addition, we have added the APWHC Physician Pathology Review Policy (See Exhibit IX)	5/20/13
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		

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	AB0032	A. BUILDING: _____ B. WING _____	C 04/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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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
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	E158 continued We have a Q/A program that monitors charts daily to check for completed pre- and post-operative instructions, lab reports, drugs administered, operative report, pathology, and follow up instructions including family planning advice, and correct any deficiencies noted(See Exhibit X-section V p2 APWHC Policy & Procedure Manual). In addition, we have added the APWHC Quarterly Chart Review Policy (See Exhibit XI) to monitor chart completion. Although we have made a best effort, a deficient chart slipped through the cracks. We will endeavor to not let this happen again and continue our routine policy of chart review and repair. We will continue to monitor staff and physicians to accurately complete all aspects of the medical chart in a timely manner. We will counsel and correct those found not in compliance with our policy.	5/20/13

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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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		