FORM APPROVED Division of Health Service Regulation

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	conducted on 04/19 investigative finding identified. The invedata to validate the administration of ar administered to path Abortion Procedure findings revealed and safety of patier revealed the admin form of Methotrexa Procedures. Manu Medical Affairs for I of Methotrexate), A Carolina Poison Cethe Division of Heal recommend the admethotrexate to be facility 's failure to according to the macould affect the absolute Therefore, the patie intended dosage of	omplaint investigation 2-20/2013. Based or gs, violations of the restigation continued to findings related to the injectable medication ients orally for Medicas (MABP). The investigative findings related to the injectable medication or maniferation or maniferation or maniferaturer's packet inserted and Medical Adotted the Service Regulation or ministration of injectary injectary in medical to patier and medical adoministration of injectary in medical medicaturer's recommon of the medical medication or dereducation or der	n the ules were of collect the collect second stigative the health sings injectable on ert, nufacturer ucation visor for n do not able station nendation ation.				
E 131	.0302 PERSON IN	AUTHORITY		E 131			
	The governing auth to have authority ar	602 Person in Author nority shall designate nd responsibility for the professional function	a person ne				
	reviews, observation interviews, review of information and interviews.	et as evidenced by: review, medical reco n, staff and physician of medication packag erviews with medicat	ı e insert				
Division of H	ealth Service Regulation						· · · · · · · · · · · · · · · · · · ·

TITLE

(X6) DATE

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

PRINTED: 05/10/2013 FORM APPROVED

(X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: _ C B. WING AB0032 04/20/2013 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLETE **PREFIX** PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) 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

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Division of Health Service Regulation (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING: _ C B. WING _ AB0032 04/20/2013 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PRÉFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 131 Continued From page 2 E 131 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

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Division of Health Service Regulation (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** COMPLETED A. BUILDING: _ C B. WING 04/20/2013 AB0032 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) 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.

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(X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** COMPLETED A. BUILDING: _ C B. WING AB0032 04/20/2013 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (X5) COMPLETE (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PRÉFIX **PREFIX** DATE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) E 138 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.

Division of Health Service Regulation

Division of Health Service Regulation STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** COMPLETED A. BUILDING: _ C AB0032 B. WING 04/20/2013 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID ID PROVIDER'S PLAN OF CORRECTION (X5) PRÉFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLETE **PREFIX** TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 138 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 158 .0311(B) SURGICAL SERVICES E 158 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

Division of Health Service Regulation

certified or board eligible pathologist shall be done on the

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: C B. WING AB0032 04/20/2013 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLETE PREFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 158 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

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STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** COMPLETED A. BUILDING: __ C B. WING AB0032 04/20/2013 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID (X5) (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLETE **PREFIX** PRÉFIX DATE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) E 158 Continued From page 7 E 158 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

Division of Health Service Regulation

Division of Health Service Regulation STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA COMPLETED **IDENTIFICATION NUMBER:** A. BUILDING: 04/20/2013 AB0032 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG **DEFICIENCY**) E 000 INITIAL COMMENTS E 000 We do not agree with the finding of lack of compliance under E000 and E131 An unannounced complaint investigation was .0302. Contrary to the state's assertion conducted on 04/19-20/2013. Based on the investigative findings, violations of the rules were and the opinions rendered under identified. The investigation continued to collect E3000, it is by common medical practice data to validate the findings related to the administration of an injectable medication among abortion providers, textbook administered to patients orally for Medical instruction and referenced scientific Abortion Procedures (MABP). The investigative findings revealed an imminent threat to the health journal research that supports the use and safety of patients. Investigative findings of parenteral Methotrexate used as a revealed the administration orally of an injectable form of Methotrexate for Medical Abortion solution dissolved in water or orange Procedures. Manufacturer's packet insert, juice, administered by mouth, as Medical Affairs for Fresenius KABI (manufacturer efficacious as an abortifacient in early of Methotrexate), Assistant Director Education Carolina Poison Center and Medical Advisor for gestational pregnancies (See Exhibits the Division of Health Service Regulation do not recommend the administration of injectable I,II, and III). Methotrexate to be given orally to patients. The 5/13/13 However, without admitting error or facility 's failure to administer the medication according to the manufacturer's recommendation fault, we have voluntarily removed could affect the absorption of the medication. Methotrexate in all forms from our Therefore, the patient would not receive the intended dosage of medication ordered by the formulary as of 4.26.2013 and will not physician for the medical abortion procedure. be using Methotrexate as an abortifacient in the future (See Exhibits E 131 E 131 .0302 PERSON IN AUTHORITY IV, V, and VI). We, therefore, feel that 10A NCAC 14E .0302 Person in Authority since we do not use Methotrexate nor The governing authority shall designate a person to have authority and responsibility for the plan to use it again that the finding of administrative and professional functions of the imminent danger and the resulting clinic. closure of the Abortion Clinic at 3220 This Rule is not met as evidenced by: Latrobe Drive in Charlotte should be Based on protocol review, medical record reviews, observation, staff and physician rescinded. interviews, review of medication package insert information and interviews with medication

Division of Health Service Regulation

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

Administrator

9/20/13

Division of Health Service Regulation (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES IDENTIFICATION NUMBER: COMPLETED AND PLAN OF CORRECTION A. BUILDING: _ B. WING 04/20/2013 AB0032 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID **IEACH CORRECTIVE ACTION SHOULD BE** PRĚFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL **PREFIX** CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 131 Continued From page 1 E 131 Regarding the comment made by an manufacturers and poison control, the facility's interviewed physician, we disagree with governing authority failed to ensure medication the citation in E131. The physician on administered for medical abortion procedures was administered according to the manufacturers duty by The NC medical Practice Act is recommendations. responsible and has the obligation to supervise the dosage and route of Findings include: administration of any medication that Review of a clinic "MAB (medical abortion they order. If the physician did not procedure) Protocol" (not dated) revealed "For want to give Methotrexate orally it was Medical Abortion patients who had an ultrasound confirming an intrauterine pregnancy of less than his decision not to do so since the seven weeks: Patient is to be given 3 cc or 4 cc licensed abortion clinic does not (depending on BSA body surface area) of Methotrexate orally in the office on day one. Use practice medicine, the physician does. the BSA formula to determine the appropriate The Abortion clinic merely made this dosage. ..." available in their formulary (see Exhibit 1. Closed medical record review of Patient #9 VII -section XII p. 1 APWHC Policy & revealed a 21 year-old female that presented to the clinic on 02/16/2013 for a medical abortion Procedure Manual) 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

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	that was working of administration of by the facility's me stated that he had and until two year Methotrexate intrastated around two decided to begin	D/2013 at 1155 with a at the clinic revealed of Methotrexate was edical director. The part worked at the clinic as ago, the clinic gave amuscular. The physologiving the Methotrexattle	the route determined on ysician 14 years estician nistration ate	ţ			

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	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 Direct Poison Center (Ph Methotrexate inject The interview reve patient is absorbindue to the fact that percent that is absorbingercent that is absorbingercent.	etor, Education with CarmD, DABAT) revertable is not usually galed the concern who gathe dosage intendent as the dosage incresorbed decreases. The she was unsure why do be given orally who	Carolina aled iven orally. ether the ed because eases the he r injectable				
	the Medical Advisor Service Regulation the usage of inject orally. The intervie with the absorption given orally. The i	ew on 05/09/2013 at 0 or of the Division of had revealed he does not be made able Methotrexate to ew revealed he had an of injectable Methodosage of injectable a given orally.	lealth ot advise be given concern trexate				

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E 138	.0305(B) MEDICAL	RECORDS		E 138	E138 It is our policy and documented	în our	5/20/12
		All other pertinent			It is our policy and documented	-1-	5/20/13
	information such as				Policy and Procedure manual th	iat a	
	post-operative instr				physician must complete all asp	ects of	
	laboratory report, d report of operation				the patients medical record and	l that	
	instruction including				they must verify the products of	f	
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	This Bula is not m	et as evidenced by:			and Regulations 1DA-14E.0311	(366	
		et as evidenced by. record review and st	aff		Exhibit VIII-section XI p.1 APWI	IC Policy	į.
	interview, the facility failed to ensure the completion of an operative report following a			& Procedure Manual). In additi	on, we		
				have added the APWHC Physic	ian		
	surgical abortion pr records reviewed (a	abortion procedure for 1 of 5 surgical		-	Pathology Review Policy (See E	xhibit IX)	
	•	•		-	We have a Q/A program that g	oes over	
	The findings includ	e:		L	the charts daily and at other tin		
		medical record reve		4	correct deficiencies (See Exhibi		
		at presented to the faurgical abortion proce			section V p2 APWHC Policy & Procedure		
		rd revealed the patie			Manual). In addition, we have		
	weeks gestation via	a ultrasound. Reviev	w revealed		the APWHC Quarterly Chart Re	view	1
	the procedure start	ted at 1410 and ende	ed at 1415		Policy (See Exhibit XI)		
	and the patient was	s discharged home a gainst medical advice	at 1430 e (AMA).		Policy (See Exhibit VI)		
	Review of the reco	rd revealed a pre-pri	nted		Although we have made a best	effort, a	
	section in the medi	ical record for "Opera	ative Note	1			
	(completed by phys	sician) Preop Diagno	osis:		deficient chart slipped through	 	
	weeks gesta	ation intrauterine pre	gnancy		cracks. We will endeavor to no	t let tills	
	intrauterine pregna	weeks gesta ancy Operation: Dil	ation and		happen again and continue ou	r routine	
	evacuation "Fur	ther review revealed	l this		policy of chart review and repa	ir. We	
	section included m	edication administer	ed during		will continue to monitor staff a	and	, i
	the procedure and	operative procedure	, tindings,		physicians to accurately comp		
	complications and	condition of the patie procedure. Review re	evealed		aspects of the medical chart in	a timely	. [
	the "Operative Not	e" section of the reco	ord was		aspects of the medical chart if	a thirty	
	blank.				manner. We will counsel and		
Division of H	ealth Service Regulation	<u></u>			those found not in compliance	with ou	r lon sheet 5 of 8
STATE FOR				6890	v1 policy.		- IOII SHEEL O'OI O

Division of Health Service Regulation (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING: 04/20/2013 B. WING AB0032 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) PREFIX PRÉFIX DATE TAG TAG DEFICIENCY) F 138 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 158 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

Division of Health Service Regulation STATE FORM

Division of Health Service Regulation (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: _ 04/20/2013 B. WING AB0032 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3320 LATROBE DRIVE A PREFERRED WOMENS' HEALTH CEN CHARLOTTE, NC 28211 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE SUMMARY STATEMENT OF DEFICIENCIES In (X4) ID (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PRÈFIX DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG **DEFICIENCY**) E 158 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 falled 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

Division of Health Service Regulation							
	NT OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIE		1	LE CONSTRUCTION	(X3) DATE	SURVEY
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	POC's nine (9) wee obtaining an accura of the specimen. If appropriate for gest or if the weight of the below the appropriate age the physician scontainer of formaliname and other ide to a certified laborar eligible Pathologist' Medical record revivear-old female adraurgical abortion prevealed the patient Evacuation for an in weeks gestation. Reproducts of conception of the patient of the patient of the patient evacuation for an in the sex of conception. The interview with clinic od/20/2013 at 1140 to document the extended the patient of t	ew of Patient #3 reve mitted on 01/22/2013 rocedure. Record re t had a Dilation and htrauterine pregnanc Review of the record of the gross descripti	sist of amination I parts dentified, tially the fetal in a satient's and send fied or sealed a 24 for a view by of 7 revealed on of the on failed ducts of re was no				

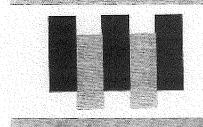
T tidin; D

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

Paul Lichtenberg Borgatta Grimes Stubblefield



A Clinician's Guide to Medical and Surgical Abortion



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 methotsexate and misoprostol administra-tion. In the first study, 178 women at 63 days' gastation or less received methotrexate 50 mg/m infrancialarly followed 5–7 days later by miso-prestol 800 up voginally." Patients who did not ex-cel the gestational sac received a repeat misoprostol dose. By 14 days after methodrexate 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' gre-tation, and 66% were at less than 45 days. Additionally, the investigator followed subjects for only 1-2 weeks after the misoprestol, which may be insufficient to identify all cases of incomplete expulsion. Also, only 2 of 178 women reported methotrexate-related side effects, a rate sorably lower than that reported in other series.

The second report was a randomized controlled high comparing the efficacy of intramuscular methotrexate 50 mg/m² followed by vaginal misoprostol 800 mg administered 3 or 7 days later in the controlled management of the first second misoprosphane. 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 63% and 98% 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 misesymetril.

A multicenter trial of 300 women at 56 days' ges-

tation or less used methodrexate 50 mg/m2 intra-

muscularly followed 7 days later by misoprost 800 kg vaginally." Subjects received a repeat misoprostol dose 24 hours later if abortion did not occil Overall, 87.7% of subjects completely aborted with out the need for a surgical procedure. The surce rate was significantly better in 49 days gestations less than at more than 49 days (Table 8–1). Oil 70% of subjects aborted by 14 days after the net ofrexate (Table 8–2). Women who passed the page nancy within 24 hours of the first or second do of misoprostal experienced bleeding and spotting for 14 \pm 7 chays, those who passed the pregnant after a delay had bleeding and spotting for H \pm days. Side effects occurred after injection of mest of results, although some could have resulted for "morning sickness" (Table 8-3). After misoprode administration, nausea occurred in 12%, voming in 8%, diamhra in 7%, and subjective fever or chill in 3% of subjects.

Because a prehentiary evaluation of regimers is ing oral methotrexate showed encouraging result ing oral metacutexate showed encouraging results a multicenter trial evaluated a 50-mg oral dose is lowed by misoprestol 800 µg vagination. Overal 91% of subjects completely aborted, with 78% pusing the pregnancy within 24 hours of the first is second doses of misoprostol (Table 8–2). For the second doses of insopressor (race 5-2), to this women, like ding and spotting losted 15 ± 8 day. Women who passed the pregnancy after a debt had bleeding and spotting for 11 ± 7 days. Subjet reported side effects more often after oral meth, trexate than after intramuscular administration. though this might be due to different patient par idations or to the way side effects data wi collected (Table 8-3).

Methotrexate offers the advantage of being # expensive and, unlike milepristone, is widely ava-

்ஸ்: gestation. Using misoprostol 8(X) நர vaginally appears to result in acceptable efficacy through 63 days gestation. Finally, decreasing the dose of mi-Spitting to 200 mg and combusing it with miso-pustol 660 µg orally effects abortion through 56 days gestation, although a 49-day gestation limit may be more appropriate.

Cinical trials suggest no difference in efficacy for rgatens using 200 or 600 mg of mifepristons. Morower, pharmacokinetic studies of serum levels show no significant difference at any dose of 100 ing or greater. Thus the lower done is an effective, Esexpensive alternative. In addition, studies with Ming suggest that rates of bleeding and expulsion letween administration of milepristone and the pustaglandin are reclused when the lower dose is not. These factors may be of clinical benefit, as they lessen the need for additional evaluation and the likelihund that women will expel the pregnancy it ar unanticipated time.

European, Chinese, and U.S. clinical trial protous have included surgical aspiration if the abor-lin is not complete by a 2-week fullow-up visit. Soul et al. demonstrated that this intervention is nd necessary, and that additional duses of misopostol or simply waiting (if the prognancy is not yither is an acceptable alternative.

Mathetrexote effectively includes abortion up to # lays' gestation when administered as 50 mg/m2 stanauscularly or 50 mg orally. Although the etheavy appears to decrease for gestations after 49 days no sharp decline is evident at any particular presional age. For both methotrexate and mile E days than at 49 clays.

All Rha(D)-regative patients receive Rha(D) imname globulin, although some experts have ques-tioned the necessity of this practice in early medical abstium patients. A dose of 50 µg suffices for ges-tations of 12 weeks or less, If the blood type is not frown at the time of milepristone or methorrexate idualistration, the patient can receive the immune golulin anytime before she uses the prostaglandin.

sively, gemeprost is used in leaver than 5% of med-

The medical contraindications to indepristone abortion include contraindications to outpatient abortion, such as a hermorphism disorder, use of anticoagulants, and severe anomia, as well as known allergy to undeprisions or the prostagiondin ana-Because of the antiglucocorticoid properties of milepristone, women with chronic renal assufficiency and long-term corticosteroid use are also ineligible for antepristone abortion. In principle, there are no contraindications to misoprostol as-However, because a small number of women suckars over age 35 experienced adverso confiac events tollowing sulprostone administration," the medical commission in France extended the same restriction to women using misuprostol or geneprost. Nonsmokers over age 35 are still cambidates for mifepristone and misoprostel abertion. Mitepristone dees not affect asthma, but severely asthmatic patients may require thennic corticosteroid use. Gynecological contraindications include pregnancy over 40 days, suspected ectopic pregnancy, filmoids resulting in excessive bleeding, and an intrauterine device (EUD) an situ

From a medical point of view, mitepristone/ misoprustul abortium requires three visits. However, French law mandates a wasting period from the films a woman decides to have an abaction to the time that the abortion takes place; thus medical

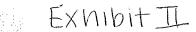
abortion in Propos requires four visits.

Visit I occurs when the woman requests an abortum and selects the method of abortion appropriate for her. The woman must decide whether she wasts a infepriatione abortion, if the woman is highlant to participate in this type of abundon, she should not

The pregnancy must be 49 days or less at the time the patient takes the mitepristone. The clinician estimates the age of the pregnancy by the wornan's menstrual history, gynecological exami-nation, and quantitative BhCG measurement. Souography is performed if there is a discrepancy between the menstrual dates and sterior size, vaginal bleeding is present, or there are symptoms of a possible ectopic pregnancy. Suspicion of an estopic

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PubMed

Display Settings: Abstract

Am J. Obstat Gyngrol, 1999 Jul; 181(1):149-52.

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

Wishe ER.

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: 15: Abstract

Send to: 12

3 Recumato: 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 93 (Serger E.

St. Paul-Remsey Medical Center, Saint Paul, Mili 55101-2595, USA

Abstract

OBJECTIVE: To investigate whether the injectable formulation of methotrexate (MEX) given as an easily prepared oral solution of MEX diluted in wate 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 rhoumatoid arithritis were given 10 mg of liquid MTX grally. The liquid was prepared by dilluling 0.4 ml of the injectable formulation of MTX (50 mg/2 mi) 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 conceptration (Cmax) and the time to reach maximum concentration (Imax) were determined from the resulting concentration vs time curves

RESULTS: There was no statestical difference in the variables measured (AUC, Cmax, Imax), 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 administrator of this easily prepared MTX solution is an alternative to the conventional administrator of this easily prepared MTX solution is an alternative to the conventional administration of MTX tables, and may be of particular benefit in patients with financial limitations.

PNED 1832902 [FoldMad - midward for MEDLINE]

- 🖆 Publication Types, MeSH Terms, Substances
- LinkOut more resources



Other regimens using parenteral methotrexate

- 1. Cremin 50% reported a case series of 100 women ≤49 days' gestation who received methotrexate 75 mg IM regardless of body surface area followed 5-5 days later by misoprostol 800 μg vaginally. The misoprostol dose was repeated if abortion had not occurred.
 - as Complete abortion occurred in 95% (95% CI 91, 99%) of patients. The complete abortion rate did not vary by gestational age.
 - 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 m² 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

- Creinin (68) treated 10 women ≤42 days' gestation with a single dose of methotrexate 50 mg/m² 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/m² 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.
 - 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/m² IM; the dose was repeated 3 days later if quantitative serum β-hCG levels increased by 50%. A surgical abortion was performed if the medical abortion was not successful by day 21.
 - 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.

EXV., bit II

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. FAR

Sworn and subscribed before me This (2, day of May, 2013

Name: Drivelle Moore

My Comm. Expires March 26, 2018

N COUNT

My Commission Expires:

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 that Dr. Stuart L. Schnider in his capacity as Medical Director of A Preferred vyomen's Health Center, LLC, has directed that Methotrextate not be used in an oral manner or any manner that would be considered off label. My Comm. Expires March 26, 2018

Donn Mare	My Comm. Expires March 26, 2018 White the second s
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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

Page 1

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	100	Date	
STuart L. Sohn-la, M.)	ho Shu?	/ the crapus	5/13/13	1
LOIS E-TURNER S	/ /	his Dura	erfander	5/13/2013
Rowel Hales	ROKU	les	5/13/13	/ /
Jeanne D. Thomas	RN ADJ	homa RN	5/13/13	
Cawana T Talb	ert CJa	Chert	5/13/13	
Vimanin			5281	· >

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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

f. J. NEwton, M.J.

5/13/13

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.





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.

John mil

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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.





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.

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

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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



APWHC LLC

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



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

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Division of Health Service Regulation

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