(X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY **IDENTIFICATION NUMBER:** COMPLETED AND PLAN OF CORRECTION A. BUILDING: B. WING 110748 10/11/2017 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 400-B CRUTCHFIELD ST NORTH DURHAM WOMEN'S HEALTH, INC DURHAM, NC 27704 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE DATE (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES (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 137 E 137 .0305(A) Medical Records MEDICAL RECORDS 10A NCAC 14E .0305 Staff meeting held the day after the (a) A complete and permanent record shall be 10/12/17 "Annual Inspection" and the 2 maintained for all patients including: patient charts in question were the date and time of admission and (1) discussed in detail. This was clearly discharge; the patient's full and true name; and simply a case of oversight by a (2)the patient's address; (3) normally meticulous and detailed the patient's date of birth; (4) "record-keeper/record-completer" the patient's emergency contact (5)Physician ("human error"). All information; required "tasks" were performed the patient's diagnoses; (6)the patient's duration of pregnancy; (7)but not properly documented. the patient's condition on admission and (8)Patient care was in no way discharge: compromised. Office Manager a voluntarily-signed consent for each discussed with all staff the state surgery or procedure and signature of the physician performing the procedure witnessed by requirements for medical records. a family member, other patient representative. or To avoid this issue in the future a facility staff member; policy was implemented that day the patient's history and physical (10/12/2017) that the RN will examination including identification of pre-existing or current illnesses, drug sensitivities or other review all charts at the end of the idiosyncrasies having a bearing on the procedure day to ensure all required or anesthetic to be administered; and documentation is complete. There documentation that indicates all items has been 100% compliance since listed in Rule .0304(d) of this Section were provided to the patient. this policy was implemented. See attached "Exhibit 1" for This Rule is not met as evidenced by: amended Policies and Procedures Based on medical record review and staff and (item #4) physician interview, the facility failed to ensure an H&P (history and physical examination) was documented prior to a surgical procedure for 2 of 20 sampled patients (patients #5 and #12). The findings include: 1. Review of a closed medical record for patient Division of Health Service Regulation

Division of Health Service Regulation

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

TITLE

(X6) DATE

STATE FORM

PRINTED: 10/13/2017 FORM APPROVED Division of Health Service Regulation (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING: B WING 10/11/2017 110748 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 400-B CRUTCHFIELD ST NORTH DURHAM WOMEN'S HEALTH, INC DURHAM, NC 27704 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID COMPLETE DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) Continued From page 1 E 137 E 137 #5 on 10/10/2017 revealed a 25 year old female who presented for a surgical abortion on 10/09/2017. Review revealed a pre-printed form with areas to document "C.V. Exam" (cardiovascular exam), "Resp. Exam" (respiratory exam), and "Pelvic Exam." Review revealed that these areas were blank. Further record review revealed no documentation of a physical examination recorded in the medical record. Interview on 10/11/2017 at 1045 with a clinical staff member revealed that the physician examines each patient prior to their procedure. Interview revealed there was no policy and procedure that required documentation of the physician's History and Physical in the medical record. During an interview on 10/11/2017 at 1130 with MD #1 (the physician who performed the procedure), the physician stated that the exam should be documented but was not documented for Patient #5. The physician stated, "I must have just missed this one. I wonder what else was going on that day." The physician was observed completing and signing the H&P documentation for Patient #5 during the interview. 2. Review of a closed medical record for patient #12 on 10/11/2017 revealed a 25 year old female who presented for a surgical abortion procedure on 5/04/2017. Review revealed that the areas for "C.V. Exam", "Resp. Exam," and "Pelvic Exam" were blank. Further record review revealed no

documentation of a physical examination

Interview on 10/11/2017 at 1045 with a clinical staff member revealed that the physician examines each patient prior to their procedure.

recorded in the medical record.

Division of Health Service Regulation (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING: _____ B. WING 10/11/2017 110748 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **400-B CRUTCHFIELD ST** NORTH DURHAM WOMEN'S HEALTH, INC DURHAM, NC 27704 SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETE DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE **PREFIX** PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) E 137 E 137 Continued From page 2 Interview revealed there was no policy and procedure that required documentation of the physician's History and Physical in the medical record. During and interview on 10/11/2017 at 1130 with MD #1 (the physician who performed the procedure), the physician stated that the exam should be documented but was not documented for Patient #12. The physician stated, "I must have just missed this one. I wonder what else was going on that day." The physician was observed completing and signing the H&P documentation for Patient #12 during the interview. E 138 E 138 .0305(B) Medical Records 10A-14E .0305 (b) All other pertinent information such as pre- and post-procedure instructions, laboratory report, drugs administered, report of abortion procedure, and follow-up instruction, including family planning advice, shall be recorded and authenticated by signature, date, and time. This Rule is not met as evidenced by: Based on medical record review and staff and physician interview, the facility failed to ensure that an operative note was documented for 2 of 17 patients who underwent a surgical abortion procedure (#5 and #12). The findings include: 1. Medical record review for Patient #5 on 10/10/2017 revealed a 25 year old female who

(X3) DATE SURVEY



Division of Health Service Regulation
STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA

NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 400-B CRUTCHFIELD ST DURHAM MY C27704 DURHAM NO 27704 SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) E 138 Continued From page 3 presented on 10/09/2017 for a surgical abortion procedure at 7 weeks and 5 days gestation. Review revealed that the procedure started at 0956 and ended at 1001. Review revealed that conscious seddation was used during the procedure. Review revealed that the procedure started at 0956 and ended at 1001. Review revealed that conscious seddation was used during the procedure. Review revealed that the procedure started at 0956 and ended at 1001. Review revealed that conscious seddation was used during the procedure Review revealed that the patient was discharged at 1046. Review revealed a pre-printed form labeled "Surgical Procedure Form" with a section labeled "Operative Note" which included a pre-printed narrative note with space for documenting the following: "paracervial block performed with co of 19% lidocaine" "Evacuation of the uterine contents was performed using a mm suction curette"The uterus was / was not explored with a sharp curette." Further review revealed an area to document complications. Review revealed the Operative Note section of the form was blank. Interview on 10/11/2017 at 1130 with MD #1 (the physician who performed the procedure) revealed an Operative Note section of the form was blank. Interview Note documentation many have been overlooked for Patient #5. The physician was observed completing the Operative Note for Patient #50 during the interview.	STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED					
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amended Policies and Procedures 2. Medical record review for Patient #12 on 10/11/2017 revealed a 25 year old female who presented for a surgical abortion procedure on 05/04/2017 at 14 weeks and 2 days gestation. Review revealed the the procedure started at 1149 and ended at 1156. Review revealed that conscious sedation was used during the procedure. Review revealed the patient was amended Policies and Procedures (item #4)	E 138	presented on 10/0 procedure at 7 we Review revealed the 10956 and ended a conscious sedation procedure. Review discharged at 104 pre-printed form later Form" with a section which included a procedure for docume block performed with e cervix was different was / was a curette." Further and the performed using a uterus was / was a curette." Further and the performed using a uterus was / was a curette. Further and the performed using	9/2017 for a surgical abortion eks and 5 days gestation. hat the procedure started at t 1001. Review revealed that in was used during the virevealed that the patient was 6. Review revealed a abeled "Surgical Procedure on labeled "Operative Note" ore-printed narrative note with enting the following: "paracervial with cc of 1% lidocaine" ated to a size Pratt dilator" ated to a size Pratt dilator" at uterine contents was a mm suction curette" "The not explored with a sharp eview revealed an area to ient's level of verbal uring the procedure and an area plications. Review revealed the ection of the form was blank. 1/2017 at 1130 with MD #1 (the formed the procedure) revealed es should be completed for each e. Interview revealed that the ocumentation may have been attent #5. The physician was ting the Operative Note for the interview. review for Patient #12 on led a 25 year old female who urgical abortion procedure on weeks and 2 days gestation. the the procedure started at at 1156. Review revealed that on was used during the		"Annual Inspection" and the 2 patient charts in question were discussed in detail. This was clearly and simply a case of oversight by a normally meticulous and detailed "record-keeper/record-completer" Physician ("human error"). All required "tasks" were performed but not properly documented. Patient care was in no way compromised. Office Manager discussed with all staff the state requirements for medical records. To avoid this issue in the future a policy was implemented that day (10/12/2017) that the RN will review all charts at the end of the day to ensure all required documentation is complete. Then has been 100% compliance since this policy was implemented. See attached "Exhibit 1" for amended Policies and Procedures		10/12/17				

Division of Health Service Regulation (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: B WING 10/11/2017 110748 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **400-B CRUTCHFIELD ST** NORTH DURHAM WOMEN'S HEALTH, INC DURHAM, NC 27704 (X5) COMPLETE DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) E 138 E 138 | Continued From page 4 revealed a Surgical Procedure form with the Operative Note section left blank. Interview on 10/11/2017 at 1130 with MD #1 (the physician who performed the procedure) revealed an Operative Note should be completed for each surgical procedure. Interview revealed that the Operative Note documentation may have been overlooked for Patient #12. The physician was observed completing the Operative Note for Patient #12 during the interview. E 158 E 158 .0311(B) Surgical Services 10A-14E .0311(b) Tissue Examination: 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. If adequate tissue is not obtained based (2) on the gestational age, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure. The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens This Rule is not met as evidenced by: Based on review of facility policy, review of medical records, and physician interview, the facility failed to document a pathological

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PRINTED: 10/13/2017 FORM APPROVED 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: 110748 B. WING 10/11/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 400-B CRUTCHFIELD ST NORTH DURHAM WOMEN'S HEALTH, INC DURHAM, NC 27704 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 158 Continued From page 5 E 158 examination after a surgical abortion procedure Staff meeting held the day after the for 2 of 17 sampled patients (#5 and #12). "Annual Inspection" and the 2 10/12/17 The findings include: patient charts in question were discussed in detail. This was clearly Review of the facility's "Abortion Procedure" and simply a case of oversight by a policy (not dated) revealed, "The physician examines the tissue specimen grossly to identify normally meticulous and detailed "POC's (e.g., gestational sac, placental "record-keeper/record-completer" fragments, fetal parts). For smaller specimen's Physician ("human error"). All [sic] with minimal tissue (earlier pregnancies), required "tasks" were performed hydroflotation with backlighting will help identify but not properly documented. chorionic villi." Patient care was in no way 1. Review of medical record for Patient #5 compromised. Office Manager revealed a 25 year old female who presented for discussed with all staff the state a surgical abortion procedure on 10/09/2017 at 7 requirements for medical records. weeks and 5 days gestation. Review revealed a preprinted Surgical Procedure Form with a To avoid this issue in the future a section labeled "Pathological Examination." policy was implemented that day Review revealed spaces labeled "GROSS FETAL (10/12/2017) that the RN will PARTS," "PLACENTAL TISSUE," review all charts at the end of the "GESTATIONAL SAC," and "VILLI" with lines to document findings. Review revealed that this day to ensure all required section was blank. documentation is complete. There has been 100% compliance since Interview with MD #1 on 10/11/2017 at 1130 this policy was implemented. revealed that the physician examines the POCs after each surgical procedure. Physician stated See attached "Exhibit 1" for that he "missed" documentation of POCs for Patient #5. Physician was observed completing amended Policies and Procedures the missing documentation for Patient #5 during (item #4) the interview.

2. Review of medical record for Patient #12 revealed a 25 year old female who presented for a surgical abortion procedure on 5/04/2017 at 14 weeks and 2 days gestation. Review revealed the Pathological Examination section of the Surgical

Procedure Form was blank.

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING:		(X3) DATE COMF	(X3) DATE SURVEY COMPLETED							
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	revealed that the pl after each surgical that he "missed" do Patient #12. Physic	#1 on 10/11/2017 at 1130 hysician examines the POCs procedure. Physician stated ocumentation of POCs for sian was observed completing entation for Patient #12 during										
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Exhabit

North Durham Women's Health, Inc

Policies and Procedures (14E.0303) (1)-(7)

1. Patient Selection

a) Patient secure in her decision to terminate pregnancy and understands the alternatives.

b) Patient has positive pregnancy test and a measurable intra-uterine pregnancy up to 19 weeks 6 days on ultrasound.

c) Patient presents adequate funds (cash or credit card) to cover the fee for service at time of

d) Patient must complete history and consent forms, agree to the terms of the consent form and sign all forms.

2. Patient Exclusion

a) Patient undecided or unsure about her decision to terminate pregnancy or any evidence of coercion.

b) Patient has negative pregnancy test and empty uterus on ultrasound (not pregnant)

c) Patient has positive pregnancy test and empty uterus on ultrasound (further evaluation and

follow-up required)

- d) Patient has inadequate funds for procedure fee. Patient advise to call and reschedule when adequate funds are available and she is informed of her EGA and how much time she has before she exceeds 19 weeks 6 days. EGA.
- e) Patient cannot understand consent forms and needs to reschedule and return with an interpreter.

f) Patient refuses to complete and sign forms.

- g) Patient request IV sedation, but has no one to drive her home. Switch to "local" only or reschedule.
- h) Medical Director and Clinical Staff deem that patient will be unable to tolerate exams and procedure and will not be able to cooperate for procedure to be done safely. Reschedule for IV sedation or sleep sedation.
- i) Patient arrives late for appointment (usually there is a 10-15 minute grace period)

j) Patient is verbally and/or physically abusive to staff or physician.

3. Discharge Criteria (see Discharge Instruction Sheet)

a) Patient has stable normal vital signs

b) Patient has no excessive bleeding and is experiencing no unusual pain or cramps

c) Patient is ambulatory and has some oral intake

- d) Discharge Instruction Sheet discussed with patient by R.N., patient expresses understanding, and her questions have been answered
- e) Post-op medications discussed and prescriptions provided

f) Follow-up visit and contraception plan stressed

g) If patient had IV sedation, she must have someone to drive her home

h) Patient informed that if she has questions, concerns or complaints about her care at the Clinic, and the staff does not address these issues to her satisfaction before she leaves, she may call the Complaint Intake Unit of the N.C. division of Health Service Regulation at 919-855-4500.

4. Abortion Procedure

a) Physician to review medical history with patient prior to abortion procedure and document same on back of intake form

b) Surgical procedure form to be completed/signed by physician performing the abortion as soon as procedure is complete

c) RN to review all charts at end of day to ensure completion al all paperwork

d) Surgical abortions (up to 19.6 weeks) are performed at the Clinic

