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
	110748	A. BUILDING: _____ B. WING _____	10/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH DURHAM WOMEN'S HEALTH, INC	400-B CRUTCHFIELD ST DURHAM, NC 27704

(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 137	.0305(A) Medical Records 10A NCAC 14E .0305 MEDICAL RECORDS (a) A complete and permanent record shall be maintained for all patients including: (1) the date and time of admission and discharge; (2) the patient's full and true name; (3) the patient's address; (4) the patient's date of birth; (5) the patient's emergency contact information; (6) the patient's diagnoses; (7) the patient's duration of pregnancy; (8) the patient's condition on admission and discharge; (9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member; (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered; and (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the patient. This Rule is not met as evidenced by: Based on medical record review and staff and 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	E 137	Staff meeting held the day after 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. There has been 100% compliance since this policy was implemented. See attached "Exhibit 1" for amended Policies and Procedures (item #4)	10/12/17

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E 137	Continued From page 1 #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 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.	E 137		

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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 137		
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	E 138		

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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 sedation 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 __ cc of 1% lidocaine"... "the cervix was dilated to a size __Pratt dilator"... "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 the patient's level of verbal responsiveness during the procedure and 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 should be completed for each surgical procedure. Interview revealed that the Operative Note documentation may have been overlooked for Patient #5. The physician was observed completing the Operative Note for Patient #5 during the interview. 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 discharged from the clinic at 1256. Further review	E 138	Staff meeting held the day after 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. There has been 100% compliance since this policy was implemented. See attached "Exhibit 1" for amended Policies and Procedures (item #4)	10/12/17

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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 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) If adequate tissue is not obtained based on the gestational age, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure. (3) 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	E 158		

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E 158	Continued From page 5 examination after a surgical abortion procedure for 2 of 17 sampled patients (#5 and #12). The findings include: Review of the facility's "Abortion Procedure" policy (not dated) revealed, "The physician examines the tissue specimen grossly to identify "POC's (e.g., gestational sac, placental fragments, fetal parts). For smaller specimen's [sic] with minimal tissue (earlier pregnancies), hydroflotation with backlighting will help identify chorionic villi." 1. Review of medical record for Patient #5 revealed a 25 year old female who presented for a surgical abortion procedure on 10/09/2017 at 7 weeks and 5 days gestation. Review revealed a preprinted Surgical Procedure Form with a section labeled "Pathological Examination." Review revealed spaces labeled "GROSS FETAL PARTS," "PLACENTAL TISSUE," "GESTATIONAL SAC," and "VILLI" with lines to document findings. Review revealed that this section was blank. Interview with MD #1 on 10/11/2017 at 1130 revealed that the physician examines the POCs after each surgical procedure. Physician stated that he "missed" documentation of POCs for Patient #5. Physician was observed completing the missing documentation for Patient #5 during 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.	E 158	Staff meeting held the day after 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. There has been 100% compliance since this policy was implemented. See attached "Exhibit 1" for amended Policies and Procedures (item #4)	10/12/17

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E 158	Continued From page 6 Interview with MD #1 on 10/11/2017 at 1130 revealed that the physician examines the POCs after each surgical procedure. Physician stated that he "missed" documentation of POCs for Patient #12. Physician was observed completing the missing documentation for Patient #12 during the interview.	E 158		

Exhibit 1

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 check-in.
   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

(KS) 9/12