

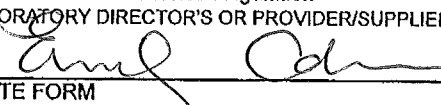
Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AB0009	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/07/2015
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF WINSTON SALEM	STREET ADDRESS, CITY, STATE, ZIP CODE 3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103
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6/19/2015-CBB
VPS/2015 TB

(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	<p>.0305(A) MEDICAL RECORDS</p> <p>10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered.</p> <p>This Rule is not met as evidenced by: Based on policy and procedure review, closed medical record reviews and staff interviews, the clinic staff failed to maintain a complete medical record; by failing to ensure the physician performing surgery signed a witnessed, voluntarily-signed consent in 8 of 8 medical records reviewed of patients having a surgical abortion procedure (SAB) completed (#'s 7, 4, 5, 1, 8, 3, 10, 9).</p> <p>The findings included:</p> <p>Review of the clinic's policy titled "Surgical Abortion Policy, V11-A-1", revised June 2012, revealed when a patient has a SAB there must be a "Witnessed voluntarily-signed consent for each surgery or procedure and signature of the</p>	E 137	<p>At Planned Parenthood South Atlantic (PPSAT), patient signatures on consents for surgical and medication abortions require a witness by trained staff members. Prior to and after each procedure, physicians review and sign off on the patient's medical record to ensure histories are reviewed, required examinations are performed, voluntary consents are obtained, and patients are witnessed as per NCDHHS regulations 10A-14E.0305(a).</p> <p>Inspectors clarified that in addition to patient and witness signatures, NCDHHS regulation 10A-14E.0305(a) also requires physician signature on consents.</p> <p>PPSAT Plan of Correction:</p> <ol style="list-style-type: none"> 1. For paper medical records (downtime forms) we have revised the signature line of the consents CIIC-022 and CIIC-027 to include physician signature directly on the consent (please see attached). This went into effect 5/11/15. 2. For electronic records, we have created a system by which the physician may directly sign the consents (CIIC-022 and CIIC-027), in addition to the medical chart as a whole. The physician's signature will be present on printed copies of these consent forms. Training in the process is planned for 06/04/15 and full implementation will take place by 06/08/15. 3. Administrative staff will review all charts at the end of each clinic day to ensure compliance with physician signatures on CIIC-022 and CIIC-027 forms. Daily monitoring will continue until consistent compliance is demonstrated. 4. Review for compliance with physician signature on CIIC-022 and CIIC-027 will be added to annual surgical and medical abortion chart audits scheduled for July 2015. 	<p>5/11/15</p> <p>06/08/15</p> <p>Daily</p> <p>July 2015</p>

Division of Health Service Regulation LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  DATE FORM	TITLE VICE PRESIDENT OF PATIENT SERVICES Ce/3/15	(X6) DATE
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Division of Health Service Regulation

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E 137	<p>Continued From page 1</p> <p>physician performing the procedure"; Further review of the policy revealed under "Medical Record Documentation XI" the medical record must contain a "Witnessed, voluntarily-signed consent for each surgery or or procedure and signature of the physician performing the procedure".</p> <p>1. Medical record review of patient #7 revealed the patient had a SAB completed on 05/15/2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>2. Medical record review of patient #4 revealed the patient had a SAB completed on 04/14/2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>3. Medical record review of patient #5 revealed the patient had a SAB completed on 03/31/2015. Medical record review revealed no documentation of the signature of physician performing the SAB</p>	E 137		

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E 137	<p>Continued From page 2</p> <p>on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>4. Medical record review of patient #1 revealed the patient had a SAB completed on 02/01/2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>5. Medical record review of patient #8 revealed the patient had a SAB completed on 01/31/2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>6. Medical record review of patient #3 revealed the patient had a SAB completed on 12/19/2014.</p>	E 137		

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E 137	<p>Continued From page 3</p> <p>Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>7. Medical record review of patient #10 revealed the patient had a SAB completed on 12/02/2014. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p> <p>8. Medical record review of patient #9 revealed the patient had a SAB completed on 11/15/2014. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent.</p> <p>Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.</p>	E 137		

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Planned Parenthood South Atlantic

 Asheville
 Charlottesville
 Raleigh

 Blacksburg
 Columbia
 Roanoke

 Chapel Hill
 Durham
 Vienna

 Charleston
 Fayetteville
 Wilmington

 Charlotte
 Greensboro
 Winston-Salem
What is an in-clinic abortion?

There are two kinds of in-clinic abortions

- **In-clinic suction abortion:** suction is used to take the pregnancy out of your uterus (womb).
- **In-clinic D&E abortion:** both suction and surgical tools are used to take the pregnancy out of your uterus (womb).

Which procedure you have and the way the abortion is done depends on how long you've been pregnant. This is figured out by counting from the first day of your last period or by an ultrasound.

At Planned Parenthood South Atlantic, we offer both kinds of in-clinic abortion.

Before having an abortion, you need to know the most common benefits, risks, side effects, emotional reactions, and other choices you have. We are happy to answer any questions you have.

What are the benefits of abortion?

- It is a safe and effective way to end a pregnancy.

What are the side effects of abortion?

Side effects don't usually last long and don't need to be treated. Call us if the problem doesn't go away or you are worried. Common side effects are

- light or medium bleeding. If your bleeding is very heavy — soaking more than 2 maxi pads for 2 hours in a row, call us.
- cramping
- feeling tired (usually from anesthesia and/or pain medications)

Besides an in-clinic abortion, what other choices do I have?

If you are pregnant, you have three options to think about — abortion, adoption, and parenting.

If you choose abortion and are less than 9 weeks pregnant, you may be able to use the abortion pill. You can also have an abortion in a hospital or by another doctor or nurse, now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks of abortion?

Abortion is very safe. But, there are risks with any medical procedure. Your risk may be higher if you

- are not healthy
- have had a c-section or certain other surgeries

Risk also goes up the longer you are pregnant and if sedation is used.

Risks linked with in-clinic abortion are

- **Incomplete abortion** — This means some of the pregnancy tissue may be left inside the uterus (womb). This may

What are the risks of abortion? (con't)

lead to heavy bleeding, infection, or both. If this happens, a procedure may need to be done again. Other tests or treatments may be needed.

- **Blood clots in the uterus** — Clots may cause cramping and belly pain. A procedure may need to be done again.
- **Infection of the uterus** — Most infections can be found and treated with medicines. But, there is a small chance that a suction procedure may need to be done again. You may have to go to the hospital, or even have surgery to treat the infection.
- **The pregnancy doesn't end** — Sometimes the abortion does not end the pregnancy. It may be because the pregnancy was not in the uterus or for some other reason. If the pregnancy is ectopic (not in the uterus), you will need to see a doctor or nurse who can treat it or go to the emergency room right away. Some women may need medicine and others may need surgery. If the pregnancy is still in the uterus, a procedure may need to be done.
- **Heavy bleeding (hemorrhage)** — This may require treatment with medicine, a repeat procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Injury to the cervix (opening to the uterus)** — This may be treated with medicine or rarely with stitches
- **Injury to the uterus or other organs** — A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus) may be needed. Scars may develop inside the uterus, which may need to be treated.
- **Allergic and/or drug reaction** — Some women may be allergic to the local anesthetic (numbing medicine) or to other medicines used. It is important that you tell us about all medicines you are allergic to. Also, tell us about any medicines you are taking. We need to be sure they are safe to mix with medicines we give you.
- **Death** — Death from an abortion procedure is very rare. The risk of death from an abortion goes up the longer you are pregnant.
 - When an abortion is done when a woman is less than 20 weeks pregnant (about 4 ½ months), the risk of death from a full-term pregnancy or childbirth is higher than the risk of abortion. After 20 weeks of pregnancy, the risks are about the same.

What will be done to get me ready for the abortion?**Education and Consent** — A staff person will

- talk to you about your medical history
- tell you about the abortion
- answer any questions you have
- get your written consent (permission) to have the abortion

Laboratory Tests — You will have

- a pregnancy test (if an ultrasound doesn't show a pregnancy in the uterus)
- a blood test to check your Rh factor - a protein on the outside of red blood cells
- a blood test to see if you have anemia (low iron)
- other tests your doctor or nurse thinks you need

Ultrasound — You may need an ultrasound. It can help tell how long you've been pregnant. A probe (like a wand) will be placed on your abdomen (belly) or into your vagina to get a picture of the pregnancy.

Physical Exam — You will have your blood pressure taken and have a pelvic exam. You may get other exams if the doctor or nurse thinks you need them.

Review — A doctor or nurse will talk to you about your medical history, exams, and any tests you had to decide if the abortion can be done at Planned Parenthood.

Pain Medicine — A staff person will tell you about pain medicines that can be used. You will be given written instructions to read and sign if you are going to get medicine to make you relaxed or drowsy during the abortion.

Opening (dilating) your cervix — Your cervix may need to be opened (dilated) before your abortion. If so, you will be given separate information about the medicine and/or steps that will be taken to open (dilate) your cervix.

What will happen to me during my abortion?

You will be given pain medicine. You may get medicine to numb your cervix. You and your doctor will talk about what other medicines you may need to help with pain and discomfort during your abortion.

After your pain medicine begins to work, your doctor will decide if your cervix is ready (open enough). If your cervix needs to be dilated (opened) more, your doctor will stretch it with dilators.

When your cervix is stretched open enough, the contents of your uterus (womb) are taken out with suction. Suction is used by putting a small plastic tube into your uterus and connecting it to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the opening in the cervix. The way it is done will depend on how long you've been pregnant.

You may feel cramping during and after the abortion as your uterus gets smaller. Your doctor may also use a curette (a thin surgical tool) to remove the pregnancy. What has been removed will be looked at to help make sure the abortion is finished.

What will happen to me after my abortion?

You will be taken to a recovery area for rest. We will also watch to see if you are OK. You will be given instructions on what to expect and how to care for yourself. We will talk about birth control plans with you, unless this was already done.

When you feel comfortable, in about 30 minutes or so, you may leave. You may need someone to drive you home. This depends on if you had medicine to make you relaxed or drowsy during the abortion.

What else do I need to know?

You will be given instructions on caring for yourself after your abortion and information on when to come back to us if you are having a problem.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at the health center. We are happy to help you.

- I am having an in-clinic suction abortion
- I am having an in-clinic D&E abortion

Client Signature _____

Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____

Date _____

CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

Signature of any other person consenting _____ Date _____

Relationship to client _____

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness Signature _____

Date: _____

Physician signature _____

Date _____

Health Center Contact Info		
ASHEVILLE 828-252-7928	BLACKSBURG 540-951-7009	CHAPEL HILL 866-942-7762
CHARLESTON 843-628-4380	CHARLOTTE 704-536-7233	CHARLOTTESVILLE 434-296-1000
COLUMBIA 803-256-4908	DURHAM 866-942-7762	FAYETTEVILLE 866-942-7762
GREENSBORO 336-373-0678	RALEIGH 919-833-7534	ROANOKE 540-562-3457
VIENNA 304-295-3331	WILMINGTON 910-762-5566	WINSTON-SALEM 336-768-2980



Planned Parenthood South Atlantic

 Asheville
 Charlottesville
 Raleigh

 Blacksburg
 Columbia
 Roanoke

 Chapel Hill
 Durham
 Vienna

 Charleston
 Fayetteville
 Wilmington

 Charlotte
 Greensboro
 Winston-Salem

What is the abortion pill and how do I take it?

“Abortion pill” is a popular name for a medicine called mifepristone. It is the first pill you will take to end your pregnancy and starts the abortion process. Pregnancy needs a hormone called progesterone to grow normally. Mifepristone blocks the body’s own progesterone, causing the pregnancy to end.

After you take the abortion pill, you need to take a second medicine called misoprostol. It opens the cervix and makes the uterus contract. This empties the uterus and completes the process. The whole process is called medication abortion.

There are a few different ways to take these medicines. There is the way approved by the FDA. Other ways to take the medicines have been studied. You might take a different amount of medicine. When you take the medicine might be different. These other ways are also safe and are usually more effective than the FDA way. We will give you instructions how to take your pills. It is important to follow these instructions.

After you take the abortion pill and misoprostol, you must make sure the medicines worked and that you’re no longer pregnant. This will be done by having an ultrasound at the clinic in 10-14 days.

Before you have an abortion, you need to know the most common benefits, risks, side effects, emotional reactions, and other choices you have. We are happy to answer any questions you have.

What are the benefits of the abortion pill?

Using the abortion pill together with misoprostol is safe and effective. At Planned Parenthood, it works about 98 out of 100 times. Women can use it in the first 9 weeks (63 days) of pregnancy.

What are the side effects of the abortion pill?

Side effects usually do not last long. They usually need little or no treatment.

- **Cramping is expected** — It will be the worst after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected** — It will be heaviest soon after taking the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- **Fever** — Having a temperature of 99-100°F is okay. It should only last a short time.
- **Other** — It is common to have diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. They usually lighten up 3 days later. They usually stop within 2 weeks.

Can I breastfeed if I take the abortion pill?

Both misoprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn’t cause any problems for you or your baby. Tell your doctor or nurse if you’re breastfeeding so you can work out the best plan together.

What feelings do women have after abortion?

Having a wide range of feelings is normal. Most women feel relieved and do not regret their decision. Others may feel sad, guilty, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

Besides taking the abortion pill, what other choices do I have?

If you are pregnant, you have three options to think about — abortion, adoption, and parenting.

If you choose abortion, you can have it done in the clinic, in a hospital or by another doctor or nurse, now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks of the abortion pill?

Using the abortion pill is very safe. But, there are risks with any medical procedure. Your risk may be higher if you are not healthy.

Risks linked with the abortion pill are

- **The pregnancy doesn't end** — Sometimes the medicines do not end the pregnancy. Since they may cause serious birth defects, you will need to take additional medicines or have an abortion in a clinic or a hospital if the pregnancy continues.
- **Incomplete abortion** — This means some of the pregnancy tissue may be left inside the uterus (womb). This may lead to heavy bleeding, infection, or both. If this happens, you may need an abortion in a clinic or a hospital. Other tests or treatments may be needed.
- **Blood clots in the uterus** — Clots may cause cramping and belly pain. You may need a procedure if that happens.
- **Bleeding too much or too long** — This may require treatment with medicine, a suction procedure, or a blood transfusion.
- **Infection of the uterus** — Most infections can be found and treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have surgery to treat the infection.
- **Allergic reaction** — Some women are allergic to the medicines that are used.
- **Death** — Death from medication abortion is very rare. The risk of death from a full-term pregnancy and childbirth is much greater.

What are the warning signs of a problem?

Call us right away if you have

- **Belly pain** — This includes feeling sick, being weak, having nausea or diarrhea, or throwing up. It should not last longer than 24 hours after you take the second medicine. Call us right away if they do. Any one of them may be a sign of a serious infection. Or it could be another problem, like ectopic pregnancy. (That is a pregnancy that grows outside the womb.)
- **Heavy Bleeding** — Call us right away if you soak through two thick, full-size sanitary pads every hour for two hours in a row. Or call us if you think your bleeding is too heavy. One out of every 100 women will bleed so much that they need a surgical procedure to stop it.
- **Fever** — Call us right away if you have a fever of 100.4°F or more if it lasts for 4 hours and it happens during the few days after you take the second pills. Fever that high can be a sign of serious infection. Or it could be another problem, like ectopic pregnancy.

What else do I need to know?

We will give you instructions on how to take care of yourself during the abortion. We will give you a time to return to Planned Parenthood for a follow-up visit.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns please call us at the health center. We are happy to help you.

Client Signature

Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature

Date

CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

Signature of any other person consenting

Date

Relationship to client

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness signature

Date

Physician signature

Date

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