pennsylvania
DEPARTMENT OF HEALTH

COPY

November 1, 2010

[redacted]
Abortions As An Alternative
5188 Neshaminy Blvd.
Bensalem, PA 19020

RE: Abortions As An Alternative, Facility ID # 00278701

Dear [redacted]:

On October 26, 2010, the Department of Health(Department), Division of Home Heath (Division), conducted an on-site survey at your abortion facility, Abortions As An Alternative, located at 5188 Neshaminy Blvd., Bensalem, PA 19020. The survey findings revealed that the facility failed to provide services in accordance with 28 Pa. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. Specifically, the facility did not meet the following requirements:

0001 – Requirements for Abortion – 29.33(1)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(1) Each medical facility shall have readily available equipment and drugs necessary for resuscitation. If local anesthesia is utilized to perform an abortion in a medical facility during the first trimester, then the following equipment shall be ready to use for resuscitative purposes:

(i) Suction source.

(ii) Oxygen source.

(iii) Assorted size oral airways and endotracheal tubes.

(iv) Laryngoscope.

(v) Bag and mask and bag and endotracheal tube attachments for assisted ventilation.

(vi) Intravenous fluids including blood volume expanders.

(vii) Intravenous catheters and cut-down instrument tray.

(viii) Emergency drugs for shock and metabolic imbalance.

(ix) An individual to monitor respiratory rate, blood pressure and heart rate.

Based on a tour of the facility and interviews with the physician and office staff, the facility failed to have readily available all the equipment and drugs necessary for resuscitation and care of patients:

Findings include:

Observational tour on October 26, 2010 at 1130 revealed the following:

The following equipment and drugs necessary for resuscitation were not present:

- Oral suction source
- Assorted size oral airways and endotracheal tubes
- Laryngoscope
- Intravenous catheters and cut down instrument tray
- Emergency drugs for shock and metabolic imbalance (including the reversal drug for Valium used as a sedative during procedures)
- Sufficient number of blood volume expanders (only two 500cc bags of Lactated Ringers solution were found).

The following equipment and drugs necessary for resuscitation that were not readily available for use:

Oxygen source was one 500 cc tank that the physician and secretary took 10 minutes to determine how to use.

Oxygen mask covered with a layer of dust, tubing lying on shelf, no cover provide for mask and tubing and both with thin layer of dust.

Only one male airway in box on back shelf with bag and mask that was covered in dust.

Two non-workable instruments (laryngoscope with no light source) with no attachable light source.

The following equipment and drugs necessary for patient care was not readily available for use for safe patient care and/or not in a usable state:

Observational tour of the examination room revealed:

Ultrasound machine, microscope, and blood pressure cuffs had not been inspected, certified for use and no calibrated.

Tubing on blood pressure cuff was discolored and corroded.

Contents of a locked safe house located in the room with the ultrasound/examination room revealed the following:

- 5 - Diazepam (Valium) liquid vials with expiration date of June 1, 2010
- 3 - Open in use liquid vials of Diazepam (Valium) with expiration date of June 1, 2010
- 4 - Demerol syringe with expiration date of October 1, 2002
- 2 – Demerol Tubex without needle with expiration date of October 1, 2002

Observational tour of the procedure room revealed:

Multiple bottles found in cabinets including:
Hydrogen peroxide with expiration date of 1985
30 cc vial of normal saline with expiration date of February 1978
2 - Hibiclens dated October 1984
1 - Hibiclens dated March 1989
1- unsterile instrument tray wrapped in brown paper
4 - sterile instrumentation trays that were not wrapped properly
10 instruments marked sterile with breaks in seals rendering unsterile
Vacuum suction with no documentation of calibration
1 open vial of 2 % Xylocaine that was not dated when opened
1 open vial of sodium bicarbonate that was not dated when opened

Rhogam was housed in refrigerator that sat on the floor with no temperature log, freezer with excess ice accumulation and no thermometer to take temperature.

Drawer housed:

A vial of progesterone with expiration date of February 1982
Tincture of benzoin with expiration date of April 1983
Urine dipsticks with expiration date of January 1978
25- vials of oxytocin with expiration date of July 2010

Other equipment and drugs that were not readily available included:

14 - Benadryl 25 mg for oral use with expiration date of August 1970
6 - bottles of 100 tablets of 200 mg of Ibuprofen with expiration date of June 2010
1 - bottle of 100 tablets of 200 mg of Ibuprofen with expiration date of July 2010
3 bottles of 100 tablets of 200 mg of Ibuprofen with expiration date of October 2009
14 - formalin bottles with expiration date of May 1, 2003
2 - bottles of urine dipstick for protein and sugar with expiration date of August 1989
13 - sterile wrapped discolored laminaria with no expiration date - wrapper turned yellow
1- Depo-Provera expired August 1989
2 - 500 mg of Ciprofloxacin dated December 1988

No inspection, certification and calibration of Hemoglobin machine or vacuum extraction to ensure proper functioning for patient use.

Observational tour of the file room revealed:

The following equipment and drugs necessary for safe patient care were not readily available for use for safe patient care:

The autoclave was in a room with a file cabinet with 1000c bottle of distilled water, a roll of toilet paper and file box on top of the autoclave. There was no inspection of the autoclave and

no documentation of cleaning of autoclave. Rack inside autoclave was covered with brown substance. Sitting next to the autoclave were six (6) rolls of toilet paper and the biohazard container with six containers of fetal tissue.

Observational tour of the facility also revealed:

A waiting room that housed chairs for patient and table that were covered with a layer of dust.
Only one bathroom that was small and could accommodate only one person and would not allow for a person to assist the patient.

Physician and staff member were present for the tour and interview during the tour confirmed the above findings.

0006 - Requirements for Abortion – 29.33(6)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(6) Prior to the performance of an abortion, the attending physician shall insure that the patient has had tests for hemoglobin or hematocrit, blood group and RH type, and urine protein and sugar. All of the foregoing laboratory results shall be entered in the medical record of the patient.

Based on the review of medical records and interview with facility physician, the facility failed to ensure that all patients had urine tested for protein and sugar and documented in the medical record for medical records # 1, 2 and 3. Hemoglobin readings were taken by non-calibrated equipment.

Findings include

Hemoglobin reading is taken from machine that has never been calibrated.
Physician failed to perform and document urine protein and sugar.

Review of medical records revealed:

Review of medical record # 1 on October 26, 2010 at 1300 revealed no documentation of testing for urine protein and sugar prior to procedure
Review of medical record # 2 on October 26, 2010 at 1330 revealed no documentation of testing for urine protein and sugar prior to procedure
Review of medical record # 3 on October 26, 2010 at 1345 revealed no documentation of testing for urine protein and sugar prior to procedure

During an interview with the physician on October 26, 2010 at 1300, physician stated "I do not perform urine test for sugar and protein."

0009 - Requirements for Abortion – 29.33(9)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(9) Each medical facility is encouraged to offer contraceptive services to patients. Both optional contraceptive counseling and supportive counseling, as needed by patients, shall be offered and made available on the premises or through referral.

Based on the review of medical records and interview with facility physician and office staff, the facility failed to document that contraceptive services were offered to patients or made available through a referral for three (3) of three (3) medical records reviewed, medical records # 1, 2 and 3.

Findings include:

Interview on October 26, 2010 at 1130 with office staff who functions as a secretary and assists the physician with procedures revealed that she takes the call from the patients, obtains insurance information, verifies insurances and scheduled patient for counseling, and then schedules the procedures for 24 hours after the physician does a history and physical, explains the procedure, performs a ultrasound (vaginal or abdominal) and in office Hemoglobin, RH and urine pregnancy test. The secretary writes out instructions on an index card for the patient to not drink for an hour before the procedure and not to eat for four hours, to wear loose fitting clothing and to bring pads.

Review of medical records revealed:

Review of medical record # 1 on October 26, 2010 at 1300 revealed that the form stating that the patient received counseling was dated September 5, 2007, July 15, 2008, May 11, 2010 and August 24, 2010 and signed by the patient. However, the counseling form was not witnessed or signed by the physician. The same counseling form was used for September 5, 2007, July 15, 2008 and May 11, 2010. Patient had procedures following theses counseling forms.

Review of medical record # 2 on October 26, 2010 at 1330 revealed that the form stating that the patient received counseling was dated July 14, 2009 and signed by the patient. However, the counseling form was not witnessed or signed by the physician.

Review of medical record # 3 on October 26, 2010 at 1345 revealed that the form stating that the patient received counseling was dated August 26, 2010 and signed by the patient. However, the counseling form was not witnessed or signed by the physician.

Interview with the physician and staff member on October 26, 2010 at 1330 confirmed the above findings.

0010 - Requirements for Abortion – 29.33(10)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(10) Each freestanding clinic shall have a written transfer agreement. The agreement shall be entered into with a hospital which is capable of providing routine emergency services as defined in this subchapter. For the purpose of this subchapter, routine emergency services will include but not be limited to the following:

(i) A physician at all times in the hospital available to provide emergency services.

(ii) Either full surgical or full obstetrical and gynecological surgical capability, including anesthesia, available for use within 30 minutes notice.

(iii) Blood bank, clinical laboratory and diagnostic radiological services for use within 30 minutes notice.

(A) This paragraph also applies to any hospital or part thereof which does not provide routine emergency services.

(B) In the case of a hospital satellite clinic, where the hospital does maintain an adequate emergency service on its main grounds, this paragraph will be deemed met if the hospital has and operates under policies and procedures which ensure transfer of patients with complications from the satellite clinic to such emergency services.

(C) The location of the hospital holding the agreement to supply emergency services shall not be farther than 30 minutes by ambulance from the clinic.

Based on review of facility documentation and interview with facility physician, the facility failed to have a written transfer agreement.

Findings include:

The facility did not have a written transfer agreement with a hospital. The physician stated that "I do not have a transfer agreement with any hospital but I have privileges at two hospitals."

0013- Requirements for Abortion – 29.33 (13)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(13) Each patient shall be supervised constantly while recovering from surgery or anesthesia, until she is released from recovery by a registered nurse or a licensed practical nurse under the direction of a registered nurse or a physician. The nurse shall evaluate the condition of the patient and enter a report of the evaluation and orders in the medical record of the patient.

Based on observation of the facility, review of medical records and interviews with physician and office staff, the facility failed to ensure that each patient were supervised constantly while recovering from

surgery or anesthesia/sedation and no evaluation of patient status was documented in the medical records upon on discharge or prior to the released from recovery by the physician for three (3) of three (3) medical records reviewed, medical records # 1, 2 and 3

Findings include:

Interview on October 26, 2010 at 1130 revealed a staff of two: the physician and his office staff who functions as a secretary and who assist the physician or who functions as a "quasi" medical assistant. There were no policies or procedures for the training of staff that perform vital signs during the procedure. The interview was performed in the waiting room where a list of patient names from that day was visible on the wall by the registration counter.

There was no recovery room and no recovery room staff. When questioned about procedures performed, the physician stated "He only does first trimester abortions up to 12 weeks, does very few pharmacological abortions (mostly surgical abortions), and does not use general anesthesia.

Physician stated that he monitors the patient during the procedure in the procedure room. There is no recovery room.

Office staff stated that on the day of the procedure she has the patient empty her bladder, takes the patient to the procedure room has the patient undress from the waist down and she stays in the room for the entire procedure. The physician takes the blood pressure, pulse and pulse oximeter reading and gives the local anesthesia via a single stick to an antecubital vessel and administers Valium 20 or 25 mg and removes the needle and attached syringe. No intravenous solutions are administered. The physician administers the paracervical block. The office staff is in attendance and take vital signs when physician tells her to which is usually at the beginning, the middle and at the end of the procedure. No vital signs are taken after the procedure and no respirations are documented in the medical record. Vital signs during the procedure are documented on an index card that is stapled to a manila folder which is the medical record. The local is 1 % lidocaine with sodium bicarbonate.

The physician documents everything on white paper sometimes in English and sometime in Arabic. The physician handwriting is not legible and it takes him several minutes to decipher his own writing.

Written instructions are given in writing by the secretary after she dresses the patients, "Patient's walk out like or in a drunken state." Patients are not allowed to drive home and must have a driver or a cab is called. Patient is given 2 - 500mg Doxycycline pills to take the day of the procedure and a prescription for ibuprofen or for what medication the patient are usually uses for pain such as Vicodin or percodan.

Review of medical record revealed:

Review of medical record # 1 occurred on October 26, 2010 at 1300 and revealed:

A procedure was performed on May 19, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1830 and 1840. No blood pressure, pulse or oxygen

saturation percent documented after the procedure or before leaving the facility. No respirations documented in the medical record.

A procedure was performed on August 31, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1010, 1020 and 1130. There was no documentation of respirations and blood pressure, pulse and oxygen saturation percent were not documented after the procedure or before leaving the facility. No discharge evaluation is documented by the physician.

Review of medical record # 2 was conducted on October 26, 2010 at 1330 and revealed:

A procedure was performed on August 26, 2009. There was no documentation of blood pressure, pulse, respirations and oxygen saturation percent during or after the procedure or before leaving the facility.

A procedure was performed on August 31, 2010. There was no documentation of blood pressure, pulse and oxygen saturation percent during or after the procedure or before leaving the facility. No discharge evaluation is documented by the physician.

Review of medical record # 3 was conducted on October 26, 2010 at 1345 and revealed:

A procedure was performed on July 15, 2009. There was no documentation of blood pressure, pulse, respirations and oxygen saturation percent during or after the procedure was performed. No discharge evaluation is documented by the physician.

During the interview with the physician on October 26, 2010 at 1345, he stated that prior to February 2010 no blood pressure, pulse or oxygen saturation percent were taken and documented.

0014 - Requirements for Abortion – 29.29.33(14)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(14) Corridor doors, elevators, and other passages shall be adequate in size and arrangement to allow a stretcher-borne patient to be moved from each procedure room and recovery room to a street-level exit.

Based on observational tour of the facility, it determined that corridor and entrance door to procedure and procedure room was not adequate in size and arrangement to accommodate stretchers.

Findings include:

One corridor to procedure room is very narrow and would not accommodate a stretcher. The procedure room itself would not accommodate a stretcher due to the size of the room and narrow hall

way to enter.

0015 - Requirements for Abortion – 29.33(15)

Every medical facility shall meet the following requirements with respect to the provision of abortions:

(15) All tissues obtained from abortions not subject to paragraph (8) shall be refrigerated, frozen, submersed in a proper preservative solution, and transported to a hospital, laboratory or incinerator on a regular basis for disposition.

Based on observations, interview with physician and staff, the physician failed to ensure all tissue obtained from abortions not subject to paragraph eight (8) were frozen, refrigerated, or submersed in a proper preservative solution, and transported to a hospital, laboratory, or incinerator on a regular basis for disposition for the procedures performed on six (6) of six (6) patients (Patient's # 4, 5, 6, 7, 8 and 9) and all other procedures fetal tissues in formalin containers.

Improper handling of tissue was observed. When questioned about gross microscopic examination, physician stated that he performs a gross examination, places the tissue for examination in formalin and discards remaining tissue in a biohazard waste container. A large biohazard container with bags of formalin containers was found outside of the office by the door to the right of the office sitting on the driveway, accessible to the public and free to be moved or taken by anyone. There was no secured lid or locking device and it was observed to be able to be opened by anyone and not in appropriate biohazard red bags.

Office staff stated that after the procedure all fetal tissue is places in formalin containers and placed in plastic bags and taken outside to the large biohazard container.

Observations on October 26, 2010 at 1200 revealed that six (6) fetal tissue samples obtained from procedures performed on patients # 4, 5, 6, 7, 8 and 9 were placed in formalin container and place in cabinet in procedure room. Each container was located in the cabinet in the procedure room in formalin containers that were dated but not labeled with a name.

Interview with the physician on October 26, 2010 at 1230 revealed that "I do not know why they are there."

Physician took the tissue samples from the procedure room and placed them in a white trash bag and placed them in the biohazard container outside the door of the office.

According to the physician, fetal tissue samples are disposed of with contracted waste management company when he calls for a pick up due to the fact the facility does not have enough biohazard waste for regular pick up. Biohazard containers with fetal tissue in formalin container have been left outside building for an undetermined length of time with potential exposure to the public.

Bio- hazard container was then moved to file room with medical records with autoclave to sterile

instruments for procedure with no separation.

The physician acts as the laboratory personnel, the patient safety officer and the pathologist.

0019 Medical Consultation and Judgment – 29.36(b)

(b) *Requirements.* Except in a medical emergency where there is insufficient time before the abortion is performed, the woman upon whom the abortion is to be performed shall have a private medical consultation either with the physician who is to perform the abortion or with the referring physician. The consultation will be in a place, at a time, and of a duration reasonably sufficient to enable the physician to determine whether, based on his best clinical judgment, the abortion is necessary.

Based on review of medical records and interview with physician and office staff, the facility failed to document private medical consultation by a physician to determine that, based on th physician's best clinical judgment, the abortion was necessary for the procedures documented in three (3) of three (3) medical records, medical records 1, 2 and 3.

Findings include:

Consent for the procedure was signed and dated by the patient, however consents were not signed by the physician. There was no policy or procedure for obtaining consents. The same consent is used for repeat procedure.

Review of medical records revealed:

Review of medical record # 1 on October 26, 2010 at 1300 revealed that the consent for the procedure form titled " Consent for operation and other medical services" was dated September 5, 2007, July 15, 2008, May 11, 2010 and August 24, 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician. The same consent form was used for the procedures performed on September 5, 2007, July 15, 2008 and May 11, 2010.

Review of medical record # 2 on October 26, 2010 at 1330 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated July 14, 2009 and signed by the patient. However, the consent was not witnessed or signed by the physician.

Review of medical record # 3 on October 26, 2010 at 1345 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated August 26. 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician.

Interview with the physician and staff member on October 26, 2010 at 1330 confirmed the above findings.

Development, Implementation and Submission of Plan of Correction

The facility shall develop and implement a corrective action plan. Please submit your written corrective action plan to the Department of Health, Division of Home Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, along with evidence of a mechanism for monitoring implementation of the corrective action plan. You have 10 calendar days from the date of this letter to submit a corrective action plan.

PROVIDING ABORTION SERVICES AT YOUR FACILITY PRIOR TO CORRECTING THE CITED VIOLATIONS MAY SUBJECT YOU TO ADMINISTRATIVE, CIVIL AND CRIMINAL PENALTIES. YOU SHALL IMMEDIATELY CEASE PROVIDING SERVICES AT YOUR FACILITY UNTIL ALL THE VIOLATIONS HAVE BEEN CORRECTED TO THE SATISFACTION OF THE DIVISION.

Thank you and your staff for the consideration shown at the time of the survey. If you have questions, please feel free to contact Darlene Augustine, HQA at (717) 783-1379.

Sincerely,

[redacted]

Bureau Director of Community Program
Licensure Certification

cc: File

FILE
9-5139

[redacted]
5188 Neshaminy Boulevard
Bensalem, Pennsylvania 19020 USA

November 10, 2010

VIA FACSIMILE– (717) 772-0232
& FIRST CLASS MAIL

[redacted]
Pennsylvania Department of Health
Division of Home Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104

Re: Plan of Correction
Facility ID No: 00278701

Dear [redacted]

I am writing to advise the Pennsylvania Department of Health that I have decided to retire from the practice of medicine, effective immediately. As of today, my offices in Neshaminy and Germantown are closed. While I am not accepting patients or providing health services, I am arranging for the orderly transfer of my patients.

If you have any questions, please do not hesitate to contact me.

Very truly yours,

[redacted]

cc: [redacted]