pennsylvania
DEPARTMENT OF HEALTH

November 4, 2010

[redacted]
Abortions As An Alternative
6043 Germantown Avenue
Philadelphia, PA 19144

RE: Abortions As An Alternative, Facility ID # 00288701

Dear [redacted]:

On November 1, 2010, the Department of Health (Department), Bureau of Community Programs, Division of Home Heath (Division), conducted an on-site survey at your abortion facility, Abortions As An Alternative, located at 6043 Germantown Avenue, Philadelphia, PA 19144. 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 November 1, 2010 at 1045 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)

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

Oxygen source was one 2000 cc tank that the office staff took 5 minutes to determine how to use.
Oxygen mask covered with a layer of dust, tubing lying on tank, no cover provide for mask and tubing and both with thin layer of dust.
One non-workable instrument (laryngoscope) 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 not calibrated.

Observational tour of the procedure room revealed:

- The following sterile intravenous medications for patient use were observed under the cabinet, directly on the floor:
  2 – Ampoules of Fentanyl 5 ml with expiration date of May 1, 2010
  12- Ampoules of Fentanyl 5 ml with expiration date of April 1, 2009
  15 – vials of Diazepam (Valium) 5 mg/cc with expiration date of January 1, 2010
  5- vials of Diazepam (Valium) with expiration date of May 1, 2009
  1 – Bottle of Ibuprofen with contained 2 ampoules of Fentanyl with expiration date of April 1, 2009

- Opened, uncapped needles were also observed lying directly on the floor under the cabinet with the identified medications.

Interviews with the physician and the office staff revealed that the medication for sterile intravenous patient use are placed on the floor under the cabinet so the drug dealers in the area cannot find them. The office has had several break-ins for people seeking drugs.

Observation of the contents of the cabinets in the procedure room revealed:

1 bottle of Hydrogen peroxide with expiration date of July 2006
30 cc open vial of bacteriostatic water with no expiration date or date when opened
4 instrument trays wrapped in brown paper with no dates and discolored
29 packs of instruments marked sterile with breaks in seals
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
1 box of 3 cc syringes with 21 gauge one inch needle with expiration date of December 2006
6 packs of suture with discolored covering
3 wrapped speculums in dirty and dusty paper
3 dose packs of Diflucan 150 mg with expiration date of 1999
10 Demulen dose packs with expiration date of January 1993
25 opened needle in metal container
15 tablets of Maxidone with expiration date of January 2004
1 container of formalin dated May 20, 2000

The Hemoglobin machine and vacuum extraction device were observed to have no evidence of inspection, certification or calibration to ensure proper functioning for patient use.

Observational tour of the hall way work area revealed:

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

The autoclave device bore no evidence of inspection or documentation of cleaning.

A refrigerator which contained one (1) Tubex of Gentamycin with expiration date of August 1992, and Rhogam. The refrigerator had no temperature log, the freezer portion of the refrigerator had excess ice accumulation and there was no thermometer to take temperature. Rhogam and other medications were observed in a pool of water in the refrigerator. The physician had also placed his lunch in this refrigerator.

Observation of the hallway closet revealed:

1000cc of Normal saline intravenous solution with expiration date of 1994

2 bottles of normal saline with expiration date of August 1990

2 boxes of 3cc syringes with expiration date of August 2010

3 boxes of 3 cc syringe with expiration date of September 2010

There was only one bathroom in the facility. The bathroom had no ceiling tiles, exposing pipes.

Physician and staff member were present for the tour and interviews 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 ensure 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, 3 and 4. Hemoglobin readings were taken by non-calibrated equipment.

Findings include:

Hemoglobin readings are taken from machine that bears no evidence of having been calibrated or inspected.

The physician failed to perform and document urine protein and sugar. A review of medical records revealed:

Review of medical record # 1 on November 1, 2010 at 1200 revealed no documentation of testing for urine protein and sugar prior to procedure..

Review of medical record # 2 on November 1, 2010 at 1215 revealed no documentation of testing for urine protein and sugar prior to procedure..

Review of medical record # 3 on November 1, 2010 at 1230 revealed no documentation of testing for urine protein and sugar prior to procedure.

Review of medical record # 4 on November 1, 2010 at 1245 revealed no documentation of testing for urine protein and sugar prior to procedure.

During an interview with the physician on November 1, 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 interviews with facility's 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 four (4) medical records reviewed, medical records # 1, 2 and 3.

Findings include:

Review of medical records revealed:

Review of medical record # 1 on November 1, 2010 at 1200 revealed that the form stating that the patient received counseling was dated May 20, 2010 and signed by the patient. However, the counseling form was not witnessed or signed by the physician. The patient underwent a procedure after the counseling form was signed on May 24, 2010. There was no documentation of contraceptive counseling.

Review of medical record # 2 on November 1, 2010 at 1215 revealed that the form stating that the patient received counseling was dated August 27, 2009, May 13, 2010, and October 21, 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 August 27, 2009, May 13, 2010 and October 21, 2010. The patient underwent procedures each time after counseling form was signed. There was no documentation of contraceptive counseling.

Review of medical record # 3 on November 1, 2010 at 1230 revealed that the form stating that the patient received counseling was dated September 9, 2010 and signed by the patient. However, the counseling form was not witnessed or signed by the physician. There was no documentation of contraceptive counseling.

Interviews with the physician and office staff on November 1, 2010 at 1300 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 was 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 four (4) of four (4) medical records reviewed, medical records # 1, 2, 3 and 4.

Findings include:

Interview on November 1, 2010 at 1130 revealed a staff of two, the physician and his office staff person. The office staff person functions as a secretary and assists the physician during procedures. There were no policies or procedures for the training of staff that perform vital signs during the procedure.

There was no recovery room and no recovery room staff. When questioned about procedures performed, the physician stated that he only does first trimester abortions up to 12 weeks, does very few pharmacological abortions (mostly surgical abortions), and does not use general anesthesia. The physician further stated that he monitors the patient during the procedure in the procedure room.

The physician stated that he 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, no intravenous catheters are used. The physician administers the para-cervical 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 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 to the patients by the secretary after she dresses the patients, The secretary stated that "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. The 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 November 1, 2010 at 1200 and revealed that:

A procedure was performed on May 24, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1117, 1130 and 1146, which was during the procedure. No blood pressure,

pulse or oxygen saturation percent documented after the procedure or before leaving the facility. No respirations documented in the medical record. No discharge evaluation was documented by the physician.

Review of medical record # 2 was conducted on November 1, 2010 at 1215 and revealed that:

A procedure was performed on August 29, 2009. There was no documentation of blood pressure, pulse, respirations and oxygen saturation percent during or after the procedure or before leaving the facility. No discharge evaluation was documented by the physician.

A procedure was performed on May 14, 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 was documented by the physician.

A procedure was performed on October 25, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1111, 1143 and 1200, which was during the procedure. There was no documentation of respirations and blood pressure, pulse and oxygen saturation percent after the procedure or before leaving the facility. No discharge evaluation was documented by the physician.

Review of medical record # 3 was conducted on November 1, 2010 at 1230 and revealed that:

A procedure was performed on September 13, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1018, 1032 and 1048, which was during the procedure. There was no documentation of blood pressure, pulse, respirations and oxygen saturation percent during or after the procedure was performed. No discharge evaluation was documented by the physician.

Review of medical record # 4 was conducted on November 1, 2010 at 1245 and revealed:

A procedure was performed on July 27, 2010. The only documented blood pressure, pulse and oxygen saturation percent were at 1845, 1901 and 1927, which was during the procedure. There was no documentation of blood pressure, pulse, respirations and oxygen saturation percent during or after the procedure was performed. No discharge evaluation was documented by the physician.

During the interview with the physician on November 1, 2010 at 1300, he stated that prior to February 2010 no blood pressure, pulse or oxygen saturation percent were taken and documented.

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 and 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 three (3) of three (3) patients (Patient's # 5, 6 and 7).

Office staff stated that after the procedure is completed, all fetal tissue is places in formalin containers and placed in plastic bags and taken back to the physician's other facility located at 5188 Neshaminy Blvd., Bensalem, PA and place in a large biohazard container.

Observations on November 1, 2010 at 1115 revealed that three (3) fetal tissue samples obtained from procedures performed on patients # 5, 6 and 7 were placed in formalin container and placed in a cabinet in procedure room. Only two of the containers were dated and none of the containers were labeled with a name or other identification of the patient.

During an interview with the physician on November 1, 2010 at 1115, the physician stated: "I did not know that they were there."

During the survey, the physician placed the containers in a red trash bag for transfer to his facility to be placed in a biohazard container.

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 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 interviews with physician and office staff, the facility failed to document private medical consultation by a physician to determine that, based on the physician's best clinical judgment, the abortion was necessary for the procedures documented in four (4) of four (4) medical records, medical records 1, 2, 3 and 4.

Findings include:

A consent form for the procedure was signed and dated by the patient in each of medical records 1, 2, 3 and 4. However, the consent forms were not signed by the physician. There was no policy or procedure for obtaining consents. The same consent form is used for all procedures performed on the patient.

Review of medical records revealed:

Review of medical record # 1 on November 1, 2010 at 1200 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated May 20, 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician.

Review of medical record # 2 on November 1, 2010 at 1215 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated August 27, 2009, May 13, 2010 and October 21, 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician. The same consent form was used for August 27, 2009, May 13, 2010 and October 21, 2010.

Review of medical record # 3 on November 1, 2010 at 1230 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated September 9, 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician.

Review of medical record # 4 on November 1, 2010 at 1245 revealed that the consent for the procedure form titled "Consent for operation and other medical services" was dated July 27, 2010 and signed by the patient. However, the consent was not witnessed or signed by the physician.

Interviews with the physician and office staff member on November 1, 2010 at 1300 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]

[redacted]

cc: [redacted]