pennsylvania
DEPARTMENT OF HEALTH
(717) 783-1379

December 1, 2010

[redacted]
1335 West Tabor Road
Suite 202
Philadelphia, Pennsylvania 19141

Dear [redacted]

On November 15, 2010, an onsite survey was conducted at Berger and Benjamin. The survey findings revealed that the clinic failed to provide services in accordance with 28 PA. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. Specifically, the clinic did not meet the following requirements:

29.33 (6) Requirements for Abortion. Prior to the performance of an abortion, the attending physician shall insure that 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.

Onsite review of medical records and interview with a physician that performs the procedures revealed the facility does not perform the tests of urine protein and sugar prior to the procedures.

Twenty (20) of twenty (20) medical records reviewed on November 15, 2010 from approximately 11:30 AM – 12:30 PM revealed there was no documentation showing the tests of urine protein and sugar had been performed prior to procedures. Interview with a physician that performs the procedures at the completion of the medical record reviews confirmed these tests were not performed.

29.33 (8) When there is an abortion performed during the first trimester of pregnancy, the tissue that is removed shall be subjected to a gross or microscopic examination, by the physician or a qualified person designated by the physician to determine if a pregnancy existed and was terminated. If the examination indicates no fetal remains, that information, that information shall immediately be made known to the physician and sent to the Department within 15 days of the analysis. Indicated no fetal remains, that information shall immediately be made known to t he physician and sent to the Department within 15 days of the analysis. If the examination indicates no fetal remains or villi, the physician shall immediately inform the patient of the possibility of an ectopic pregnancy and shall recommend appropriate follow-up. When there is an abortion performed after the first trimester of pregnancy which the physician has determined is not viable, all such tissue removes at the time of the abortion shall be submitted for tissue analysis to a board eligible or certified pathologist. If the report reveals evidence of viability or live birth, the pathologist shall report such findings to the Department within 15 days and a copy of the report shall also be sent to the physician performing the aborting. The findings of the gross or microscopic examination shall be entered in the medical record of the patient. Each facility, including the hospital, shall provide treatment or referral for treatment of any diagnosed pathological condition.

Onsite review of medical records and interview with a physician that performs procedures revealed the facility was not in compliance with this requirement.

Review of medical records on November 15, 2010 from approximately 11:30 AM – 12:30 PM revealed:

Four (4) of seven (7) clinical records in which there was documentation that a first trimester procedure had been performed did not have documentation showing the tissue had been submitted to a gross or microscopic examination. (clinical records #3, #14, #17 and #18)

Interview with a physician that performs procedures at the time of the completion of the medical record reviews confirmed this finding.

The facility needs to develop and implement a corrective action plan. Please submit your written corrective action plan to the Department of Health, Division of Home Health [redacted], along with evidence for a mechanism for monitoring. You have 10 calendar days from the date of this letter to submit a corrective action plan. Thank you and your staff for the consideration shown at the time of the survey. If you have questions, please feel free to

Sincerely,

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[redacted]

OBSTETRICS AND GYNECOLOGY

1335 W TABOR RD – SUITE 201
PHILADELPHIA, PENNSYLVANIA 19141

TELEPHONE (215) 424 - 0222

12/14/2010

[redacted]
Department of Health
Division of Home Health
[redacted]
Harrisburg,Pa. 17104

Re: Site visit November 10, 2010
Corrective action plan.

29.33(6) We are now aware of this requirement and urine protein and sugar are performed on all patients along with Hemoglobin and Rh. These results are recorded on the patient's chart and in a log. Chart reviews are now performed regularly as are review of laboratory logs. These changes were initiated on November 22, 2010.

29.33 (8) All Tissue that is removed undergoes gross examination and tissue from gestations greater than 12 weeks are sent to pathology (Cytocheck Lab ) for examination. All patients also undergo ultrasound examination prior to the procedure to ensure proper gestational sizing. Hard copy ultrasound results are on each chart. Procedures are performed under U/S guidance to ensure completion. The site visit revealed that some physicians are not properly documenting their findings.
A conference with all physician performing abortions the week of November 15, 2010 following the survey reviewed what is expected of them in regards to documentation of findings. All laboratory reports from procedures over 12 weeks gestation are to be attached to chart upon receipt. Routine chart reviews are performed to insure compliance.

These changes have been in effect for one month and recent review of charts shows them to be effective in resolving noted deficiencies.

Thank You

[redacted]