3909

(717) 783-1379

December 9, 2010

Allentown Medical Services
2200 Hamilton Street Suite 200
Allentown, PA 18104

RE: Allentown Medical Services, Facility ID # 00028701

Dear [redacted]

On November 18, 2010, the Department of Health (Department), Bureau of Community Programs, Division of Home Heath (Division), conducted an on-site survey at your abortion facility, Allentown Medical Services. 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, review of policy and procedure and medical records and interviews with the physician and administrator, the facility failed to have readily available an individual to monitor respiratory rate, blood pressure and heart rate and to document patient assessment per facility policy for eleven (11) of eleven (11) medical records, nine (9) of nine (9) patients who receive conscious sedation or twilight sedation and two (2) of two (2) who received local anesthesia. (Medical records # 1,2,3,4, 5,6,7,8,9,10 and 11)

Findings include:

Review of policies and procedures on November 18, 2010 at 1300:

Policy # 9.7 titled "Documentation Policy and Procedure" states for the procedure rooms the health care team will document pulse oximeter, vital signs when needed and the time the procedure started and ended. For the recovery room policy states vital signs, medication administration (on recovery room record), physical findings and medical complaints must be documented

Policy # 9.1B Bradypnea/apnea states one of the side effects of medications used in twilight sleep is impairment of the normal breathing reflex. It is important to monitor all patients who receive twilight sleep with pulse oximeter.

Policy # 9.1C Hypoxemia states patients who receive twilight sleep must be monitored by pulse oximeter with alarms set to go off at 85%.

Policies failed to include the assessment and documentation of respiratory rate.

Review of form on November 18, 2010 at 1030 titled "Abortion Procedure Record" revealed that pre-operative blood pressure, pulse, oxygen saturation and temperature are to be documented with staff initials. There is a statement "The patient was continuously monitored using pulse oximeter and visual observation. Her medical condition and vital signs did or did not remain within normal limits at all times during the procedure." There was no documentation of blood pressure, pulse, respirations and oxygen saturation during procedure.

Interview with the physician was conducted on November 18, 2010 at 1100. Physician referenced the medical record that states: "The patient was continuously monitored using pulse oximeter and visual observation." He also referenced the fact that the majority of these women are healthy and do not require frequent vital signs.

Review of medical records revealed:

Review of medical record # 1 on November 18, 2010 at 1100 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 2 on November 18, 2010 at 1100 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 3 on November 18, 2010 at 1115 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 4 on November 18, 2010 at 1115 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 5 on November 18, 2010 at 1130 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 6 on November 18, 2010 at 1130 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 7 on November 18, 2010 at 1200 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 8 on November 18, 2010 at 1200 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had twilight sedation and signed a permit for conscious sedation.

Review of medical record # 9 on November 18, 2010 at 1245 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure.

Review of medical record # 10 on November 18, 2010 at 1215 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had local anesthesia.

Review of medical record # 11 on November 18, 2010 at 1215 revealed that there was no preoperative documentation of blood pressure, pulse, respirations and oxygen saturation and no documentation of blood pressure, pulse, respirations and oxygen saturation during or at the end of the procedure. Patient had local anesthesia.

The following equipment 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 facility room revealed:

> Ultrasound machine, vacuum suction, pulse oximeter and blood pressure cuffs had not been inspected, certified for use and not calibrated.
>
> Medication refrigerator had a thick accumulation of ice on freezer.

Interview with the administrator on November 18, 2010 at 1315 confirmed the above findings.

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 administrator, the facility failed to ensure that each patient was supervised constantly while recovering from surgery or anesthesia/sedation , no documentation of patient assessment in recovery room and no evaluation of patient status was documented in the medical records on discharge or prior to the released from recovery by the physician for eleven (11) of eleven (11) medical record s, nine (9) of nine (9) patients who receive conscious sedation or twilight sedation and two (2) of two (2) who received local anesthesia . (Medical records # 1,2,3,4,5,6,7,8,9,10 and 11)

Findings include:

Review of policies and procedures on November 18, 2010 at 1300:

Policy # 9.7 titled "Documentation Policy and Procedure" states for the procedure rooms the health care team will document pulse oximeter, vital signs when needed and the time the procedure started and ended. For the recovery room policy states vital signs, medication

administration (on recovery room record), physical findings and medical complaints must be documented

Policy 8.11H titled "Protocol for Recovery "states patients who receive conscious sedation should be monitored by pulse oximeter and where appropriate ECG monitor. On arrivals take blood pressure and pulse and record on the recovery room record, then take and record vital signs again in 10 to 15 minute intervals. In addition, record the degree of the patient's bleeding, cramping and any other complaints in the recovery room. All patients should stay in recovery room for at least one hour.

Policy did not include assessment and documentation of respiration.

Review of formon November 18, 2010 at 1030 titled "Recovery Room Record" revealed that there is designed area to document blood pressure, pulse, bleeding minimal, moderate or heavy and cramping and comments area. No designated area to document oxygen saturation, respiration or temperature.

Review of medical records revealed:

Review of medical record # 1 on November 18, 2010 at 1100 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 2 on November 18, 2010 at 1100 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 3 on November 18, 2010 at 1115 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 4 on November 18, 2010 at 1115 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 5 on November 18, 2010 at 1130 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen

saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 6 on November 18, 2010 at 1130 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 7 on November 18, 2010 at 1200 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 8 on November 18, 2010 at 1200 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 9 on November 18, 2010 at 1245 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had twilight sedation and signed a permit for conscious sedation. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record #10 on November 18, 2010 at 1215 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had local anesthesia. No assessment and documentation of the condition of the patient prior to discharge.

Review of medical record # 11 on November 18, 2010 at 1215 revealed no assessment and documentation of bleeding and cramping per facility policy. No documentation of oxygen saturation per policy. No documentation of respirations rate or quality. Patient had local anesthesia. No assessment and documentation of the condition of the patient prior to discharge.

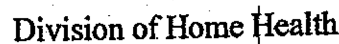
Interview with the administrator on November 18, 2010 at 1315 confirmed the above findings.

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.

Thank you for the cooperation you and your staff extended to me during the survey.

Sincerely,



Division of Home Health