pennsylvania
DEPARTMENT OF HEALTH

(717) 783-1379

February 16, 2011

CERTIFIED MAIL

[redacted]
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 Program Licensure and Certification, Division of Home Health (Division), conducted an on-site survey at your abortion facility, Allentown Medical Services (AMS). The survey findings reveal that AMS failed to provide services in accordance with 28 Pa. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. The Division provided you with a Deficiency Letter dated December 9, 2010, in which it details the deficiencies and requests that you submit a Plan of Correction (POC) within ten (10) calendar days. You faxed a POC to the Division on December 16, 2010. By letter dated January 6, 2011, you confirmed faxing the POC and stated, in pertinent part, that "[i]f our Plan of Correction is acceptable to the Department, then there is no need to reply to this letter ... Absent any reply to the contrary, we will assume our Plan of Correction is acceptable and we will move forward continuing to implement this Plan of Correction."

On January 20, 2011, the Department received a complaint concerning a patient of AMS.

On January 27, 2011, the Division conducted a joint follow-up survey (to the November 18, 2010 survey) and complaint investigation. The joint survey findings reveal that AMS failed to provide services in accordance with 28 Pa. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics and failed to implement the December 16, 2010, POC.

Specifically, AMS 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, laboratory log records, and medical records and interviews with the administrator, AMS failed to have readily available an individual to monitor the patient and to document who the individual was monitoring the patient during the procedure. There was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure rooms, no documentation preoperative, inter-operative or during procedure and at the end of the procedure per facility policy for eighteen (18) of eighteen (18) medical records of patients who had procedures performed. (Medical records # 3,4,8,9,11,12,13, 14,17,18, 19,20,21,22,23,24,25 and 26.)

Findings include:

Review of policies and procedures on January 27, 2011, at 1200 reveal that policies and procedures had not been changed per POC:

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. The recovery room policy states vital signs, medication

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

Policy # 9.1B titled "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 titled "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 in the procedure and recovery room.

Review on a January 27, 2011, at 1330 of a form titled "Abortion Procedure Record" reveals that pre-operative in the procedure room the blood pressure, pulse, oxygen saturation and temperature are to be documented with staff initials in the procedure room prior to operation. There is a pre-printed statement on the form which states that: "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 preoperative, intro-operative or during procedure and at the end of the procedure.

Interview with the administrator on January 27, 2011, at 1300 confirms that no changes have been made to the forms and the policies and procedures.

Review of Medical Records revealed:

Review of Medical Record # 3 on January 27, 2011, at 1245 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 4 on January 27, 2011, at 1230 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 8 on January 27, 2011, at 1340 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the

procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 9 on January 27, 2011, at 1345 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 11 on January 27, 2011, at 1430 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure

Review of Medical Record # 12 on January 27, 2011, at 1415 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 13 on January 27, 2011, at 1315 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 14 on January 27, 2011, at 1400 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 17 on January 27, 2011, at 1130 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 18 on January 27, 2011, at 1130 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure

room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 19 on January 27, 2011, at 1200 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 20 on January 27, 2011, at 1145 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 21 on January 27, 2011, at 1130 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 22 on January 27, 2011, at 1215 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 23 on January 27, 2011, at 1330 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 24 on January 27, 2011, at 1230 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There was no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 25 on January 27, 2011, at 1330 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There is no documentation of the individual who was monitoring the patient during the procedure.

Review of Medical Record # 26 on January 27, 2011, at 1100 revealed that there was no documentation of blood pressure, pulse, respirations and oxygen saturation in the procedure room, no documentation preoperative, intro-operative or during procedure and at the end of the procedure. There is no documentation of the individual who was monitoring the patient during the procedure.

An observational tour of the facility on January 27, 2011, at 1045 revealed that the following equipment necessary for patient care was not readily available for use for safe patient care and/or not in a usable state:

Ultrasound machine, vacuum suction, pulse oximeter and blood pressure cuffs had not been inspected, certified for use and not calibrated.

Interview with the administrator on January 27, 2011, at 1300 revealed the above equipment was not inspected, certified for use or calibrated; administrator claims she contacted two electric companies "just yesterday. There was no indication the administrator as to if or when the electric companies would be able to inspect, certify for use or calibrate the equipment.

Interview with the administrator on January 27, 2011, at 1445 confirms the above findings.

0006 – Requirements for Abortion – 29.33(6)

Prior to the 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 foregoing laboratory results shall be entered in the medical record of the patient.

Based on the review of the medical records and interview with the administrator, AMS failed to document test results for urine protein and sugar for one of eighteen medical records who had procedures performed.

Findings:

Review of Medical Record # 11 on January 27, 2011, at 1430 revealed that there was no documentation of the test results for urine protein and sugar in the medical record.

Review of the facility's laboratory log book on January 27, 2011, at 1445 revealed that on July 8, 2010, the patient for Medical Record # 11 was entered in the log book, but there was no documentation to show the patient's urine was tested for protein and sugar.

Interview with the administrator on January 27, 2011, at 1300 revealed that the log for urine test listed the patient but no results were listed. The administrator stated that the "patient must not have been able to urinate at the time." There is no documentation to support the administrator's statement.

Interview with the facility's administrator on January 21, 2011, at 1445 confirms 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 an interview with administrator, AMS fails to ensure that each patient was supervised constantly while recovering from surgery, no documentation of respirations rate and quality and oxygen saturation in the recovery room for eighteen (18) of eighteen (18) medical record of patients who had procedures performed. (Medical records # 3,4,8,9,11,12,13,14,17,18,19,20,21,22,23,24,25 and 26.)

Findings include:

Review of policies and procedures on January 27, 2011, at 1200 reveal that policies and procedures had not been changed per plan of correction:

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 documentation of respirations rate and quality.

Review on January 27, 2011, at 1300 of a form titled "Recovery Room Record" revealed that there is designated area to document blood pressure, pulse, bleeding minimal, moderate or heavy and cramping and comments area. No designated area to document oxygen saturation, respiration rate or quality and temperature.

Interview with the administrator on January 27, 2011, at 1300 revealed that no changes have been made to the forms and the policies and procedures.

Review of Medical Records reveals:

Review of Medical Record # 3 on January 27, 2011, at 1245 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 4 on January 27, 2011, at 1230 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 8 on January 27, 2011, at 1340 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 9 on January 27, 2011, at1345 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 11 on January 27, 2011, at 1430 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room. There was no documentation of vaginal bleeding and cramping.

Review of Medical Record # 12 on January 27, 2011, at 1415 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 13 on January 27, 2011, at 1315 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 14 on January 27, 2011, at 1400 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 17 on January 27, 2011, at 1130 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 18 on January 27, 2011, at 1130 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 19 on January 27, 2011, at1200 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 20 on January 27, 2011, at 1145 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 21 on January 27, 2011, at 1130 reveal that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 22 on January 27, 2011, at 1215 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 23 on January 27, 2011, at 1330 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 24 on January 27, 2011, at 1230 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 25 on January 27, 2011, at 1330 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Review of Medical Record # 26 on January 27, 2011, at 1100 reveals that there was no documentation of respirations rate or quality and oxygen saturation in the recovery room.

Interview with the administrator on January 27, 2011, at 1430 confirm 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 ten (10) calendar days from the date of this letter to submit a corrective action plan and thirty (30) days (March 17, 2011) to implement the POC.

Thank you and your staff for the consideration shown at the time of the survey. If you have questions, please feel free to contact [redacted]

Sincerely,

[redacted]

Bureau Director of Community Program
Licensure and Certification

bc: [redacted]