8-5409

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

Via Facsimile

December 17, 2010

[redacted]
Department of Health
[redacted]
Harrisburg, PA 17104
(717) 772-0232 (fax)

Re: Reply to letter of December 9, 2010 and submission of POC

Dear

This letter is in response to your letter of December 9, 2010 in which the Department of Health (Department) cited Allentown Medical Services (Allentown) with what amounts to a set of deficiencies and asked for a Plan of Correction.

Thank you for bringing to our attention areas of concern to the Department where we can improve our documentation and/or quality of care.

While we respectfully disagree with the Department's interpretation that our office "failed to provide services accordance with 28 Pa. Code ..." i.e. the Abortion Control Act (ACA), nevertheless, we intend to fully cooperate with the Department and we have included with this letter our Plan of Correction as you requested.

I would like to point out that almost all of the items issues referenced in the Department's letter involve only record-keeping issues, not direct patient care issues. There is no evidence that any of the issues referred to by the Department resulted in any patient harm or that these documentation issues pose any risk of harm to patients. They are primarily record-keeping issues and do not involve any violation of Pennsylvania law. For example, the ACA requires only that we provide "an individual" to monitor respiratory rate, blood pressure and heart rate. There is no question that we definitely had such an individual available; however, the Department's letter raises concerns that this individual did not adequately document this monitoring. While the issue of documentation is not addressed in the ACA, and we maintain that we are in compliance of the law as written, nevertheless we support the idea of improved documentation and our Plan of Correction addresses this issue. Another example is that the Department cites

us as failing to comply with the ACA because we did not always live up to our own internal policies. Nevertheless, our internal policies are more stringent than those delineated under Pennsylvania law, and a failure to always adhere to our own self-imposed internal policies is not necessarily a failure to adhere to the law.

We also note that we have been providing abortion services in Pennsylvania for more than a decade, and we have never before received a letter similar to that of December 9th and we have never before been asked for a Plan of Correction. Is this a new practice of the Department?

We hope that the Department intends to utilize this new process as a means of working together with providers and collaborating with them in effort to achieve our mutual common goal of improving health care for the public.

Finally, we hope that the Plan of Correction enclosed with this letter is satisfactory to the Department. If you have any questions or concerns about our Plan of Correction or our delivery of care, or if I can be of any further service to the Department, then please do not hesitate to contact me at [redacted].

Thank you very much for your time and attention to this letter and to our Plan of Correction.

Sincerely yours,

[redacted]

Allentown Medical Services

cc [redacted]

Plan of Correction – December 16, 2010

Allentown Medical Services

The December 9, 2010 letter of the Department describes in narrative form a number of issues of concern to the Department. We will go through the letter and identify all of the issues that we find the Department has raised and attempt to address them in this Plan of Correction. The issues are addressed in this Plan of Correction in the same order as presented in the Department's letter.

0001 – Requirements for Abortion – 29.33(1)

We maintain that we are already in legal compliance with 29.33(1), nevertheless, the Plan of Correction below will address the documentation and equipment issues cited by the Department in their letter:

1. Cited Issue: Legal Requirement to have "an individual to monitor respiratory rate, blood pressure and heart rate".

   POC: This requirement is already adhered to as we maintain that we already have an individual who is available in the procedure room to monitor the patient's vital signs. There is no shortage of staff who are available to carry out this function and we maintain that we are already in compliance with this legal requirement concerning staffing.

2. Cited Issue: Internal Policies "failed to include the assessment and documentation of respiratory rate"

   POC: Our internal policies will be revised to include the assessment and documentation of respiratory rate.

3. Cited Issue: There was "no preoperative documentation of blood pressure, pulse, respirations, and oxygen saturation" for a number of patient records reviewed.

   POC: We maintain that we did monitor patient vital signs (which includes all of the above items) and we did provide some documentation in that we documented that the patients "vital signs were within normal limits at all times during the procedure". We also point out that this is not a specified requirement of the ACA. Nevertheless, in order to provide even better documentation than we already do, our plan of correction is to modify our Abortion Procedure Record and to record on the Abortion Procedure Record the numbers for BP, P, RR into the medical record pre-operatively. O2 saturation will also be recorded for conscious sedation patients.

4. Cited Issue: There was "no documentation of blood pressure, pulse, respirations, and oxygen saturation during or at the end of the procedure" for a number of patient records reviewed.

POC: To adhere to a high standard of safe care, our patients are being continuously monitored, on a second by second basis, during the procedure via monitoring equipment which has alarms built in to alert the physician and the team if the patient's oxygen saturation or pulse rate drop below acceptable standards. Additionally, it is our policy to document into the patient's medical record, patient vital signs at least every 10 to 15 minutes. The large majority of our procedures are first trimester procedures which last, on average, 3 to 4 minutes. These patients are not undergoing general anesthesia, nor are they undergoing deep sedation. For such patients, it is not considered the generally accepted standard of care to require documentation of vital signs every 3 or 4 minutes. Neither the American Association of Anesthesiologists nor any other generally recognized accrediting organization requires such frequent documentation of vital signs. Nor is this legally required under the Pennsylvania ACA.

Accordingly, our POC is to record intra-operative vital signs for any procedures which last longer than 15 minutes, and to record the patient's vital signs upon arrival into the recovery room, which is essentially at the end of the procedure. In addition, we have always recorded any abnormal vital signs which are detected during our continuous monitoring.

5. Cited issue: The following equipment necessary for patient care was not readily available for use 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/or not calibrated.

POC: We wish to point out that we had "readily available for use" (as required under the ACA) all of this equipment. There is no issue that the required equipment is there and readily available for use. Our POC is to have all of this equipment either inspected or certified or calibrated on an annual basis, and to document such inspection or certification or calibration.

6. Cited Issue: Medication refrigerator had a thick accumulation of ice on freezer.

POC: We will defrost the freezer.

were in any way jeopardized, nevertheless, we are not happy that our documentation is not up to our own policies. Our Plan of Correction is to privately discuss this shortcoming with our nurses and to point out to them that they are not providing adequate documentation and that the PA Department of Health has identified this as a problem. Hopefully, a gentle word of reproach will be adequate to persuade our nurses to improve their documentation. However, we will also follow this up with an internal review in 3 months to ensure that their documentation has improved.

11. Cited Issue: For a number of patient records reviewed, the Department found "no documentation of oxygen saturation per policy. No documentation of respirations rate or quality."

    POC: It is unclear from the Department's letter whether they are referring to documentation in the Procedure Room record or in the Recovery Room Record. Our internal policy provides for recording of "vital signs when needed" during the procedure. We have already agreed to modify our policy to include pre-operative documentation of respiration. As discussed above, these procedures generally last only 3 to 4 minutes, and it is not the generally accepted standard of care to record respiratory rate that frequently. Our Plan of Correction is to record the oxygen saturation and respiratory rate in the procedure room record immediately pre-operative to beginning the procedure and to visually observe and monitor respiration quality after that and to monitor oxygen saturation continuously on a second by second basis via pulse oximetry intra-operatively during the procedure.

12. Cited Issue: For a number of patient records reviewed, the Department found "no assessment and documentation of the condition of the patient prior to discharge".

    POC: While we maintain that we did provide patient assessment in the recovery room and some evaluation of patient status, we agree that this may not have been explicitly documented. Our Plan of Correction is to modify our Recovery Room record to provide a space for the specific documentation of the evaluation of the condition of the patient prior to discharge, as well as providing instruction to the staff on how to fill out the form. This will improve our documentation and provide a mechanism for explicit reporting the condition of the patient upon discharge.

Last Issue Cited: Evidence of a mechanism for monitoring implementation of the POC. The Department has asked for "evidence of a mechanism for monitoring implementation of the POC". It is unclear whether the Department wants us to provide them with a mechanism for the Department to monitor the implementation of the POC, or whether the Department merely wants a mechanism for us to self-monitor the POC. However, we can provide the Department with both options. If the Department wants to directly monitor

the implementation of this POC, then since it is essentially all documentation, we can simply provide the Department with the documentary evidence of the implementation of the POC. This will permit the Department to first-hand review, and comment upon, the implementation of the POC. Alternatively, if the Department would prefer that we self-monitor the implementation of the POC, we can do that as well through our own internal compliance program. Our compliance officer can make a site visit and inspect the office to ensure adequate implementation of the POC. We plan to have the POC fully implemented and completed within ninety (90) days, and shortly after that the Compliance Officer can complete a site visit and review and monitor the implementation of the POC.

Finally, we hope that this Plan of Correction is acceptable to the Department of Health.