Plan of Correction – February 25, 2011

Allentown Medical Services

This Plan of Correction is in response to the February 16, 2011 letter of the Pennsylvania Department of Health ("Department") which describes in narrative form a number of issues of concern to the Department. In this proposed Plan of Correction (POC) we will respond to that 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.

At the outset, we wish to point out that aside from one citation (lack of measurement of urine glucose or protein in only 1/18 patients), we maintain that none of the deficiencies cited by the Department are violations of the Abortion Control Act or the Department's regulations, and therefore it seems that the Department may have exceeded its legal authority to issue such citations. The large majority of the deficiencies cited are simply documentation issues, not patient care issues. None of the deficiencies endangered patients. However, without conceding that the Department is legally permitted to issue such citations, nevertheless, in the interest and spirit of cooperation with the Department, as well as our desire to improve our care, we intend to correct all of the deficiencies cited by the Department, in the manner detailed in this Plan of Correction.

Timeline Background:

November 18, 2010 the Department of Health (Department) conducted a survey of our facility.

December 9, 2010 Department mailed us with a deficiency letter and requested a Plan of Correction within ten (10) days.

December 16, 2010 we submitted a Plan of Correction (POC) with a set of proposed corrections and a proposed timeline of implementation of ninety (90) days.

On January 25, 2011, we received an e-mail formally notifying us that "The Department of Health has reviewed your Plan of Correction and it has been approved." The January 25, 2011 approval of our POC without change, which gave us ninety (90) days (i.e. until April 24, 2011) to implement the POC.

On January 27, 2011, less than 48 hours after written approval of our POC, the Department showed up in our office to conduct a survey of a complaint and to monitor our implementation of the POC that was just approved. The Department's officials at this inspection seemed to be asking us to implement changes that were different than what the Department had approved in the POC.

January 28, 2011 – We sent the Department an e-mail asking for clarification as to what the Department wanted us to do, because what the Department had approved in writing and what the Department officials were demanding in person seemed to be contradictory. In particular, we asked the following three questions:

1. Is our POC still approved?
2. Do you want us to make any changes to the POC?
3. Has the Department changed its mind about giving us ninety (90) days to implement the POC?

February 17, 2011 we received a second deficiency letter citing us with certain deficiencies and asking that a POC be submitted within ten days and giving us thirty days (until March 17, 2011) to implement the POC.

February 25, 2011 the date of this Plan of Correction.

This Plan of Correction will address the issues raised in the deficiency letter in the same order as they were presented in the deficiency letter:

0001 – Requirements for Abortion – 29.33(1)

We maintain that we are already in legal compliance with 29.33(1), and we dispute any claim that we are not in compliance. 29.33(1) requires that "each medical facility shall have available equipment and drugs necessary for resuscitation" including "an individual to monitor respiratory rate, blood pressure and heart rate". The Department does not allege that such equipment/drugs/people were not present in the office or that they were not available for resuscitation. Instead, the Department cites us for failure to have our readily available, properly working, equipment be recently inspected. The Department also does not claim that we did not have an individual available to "monitor" the patient's vital signs, or that these vital signs were not, in fact, carefully monitored. Rather, they cite us for failing to record these vital signs in the medical record, in sufficient frequency and in sufficient detail. While we will readily implement the changes the Department asks for, because they are simply good medical practice, nevertheless we wish to point out that these requirements regarding the frequency of documentation of vital signs are nowhere contained in 29.33. We believe that the Department is making demands of us that may be beyond our legal requirement. Additionally, the Department cites us for failing to properly follow our own internal Policies and Procedures. Again, while we always strive to adhere to our own internal Policies and Procedures in which we hold ourselves to a higher standard than that in the statute, our internal Policies and Procedures are not the law of Pennsylvania. Furthermore, our less-than-perfect adherence to our own internal Policies and Procedures, while certainly of internal concern to us, should not be a reason to be cited with a deficiency by a state agency.

Nevertheless, we are not opposed to any of the changes asked of us by the Department and in the interest of improving quality of care this Plan of Correction 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 preoperatively document the patient's blood pressure and pulse. In addition 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 respiratory rate into the medical record pre-operatively, alongside the Blood Pressure and Pulse that are already recorded. 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 <u>continuously</u> 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 there is no question that we did, in fact, have all of this equipment "readily available for use" (as required under the ACA) . There is no issue that the required equipment is there, that it works properly, and that it is readily available for use. The Department's citation is only that it had not been recently inspected. 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.

0006 – Requirements for Abortion 29.33(6)

Cited Issue: The Department found that for 18/18 patient records reviewed we properly documented in the patient's medical record the patient's hemoglobin or hematocrit, and the patient's blood group. In addition, for 17/18 patients we properly recorded the dipstick measurement of the patient's urine protein and glucose level. However, the Department found one medical record where we failed to document in the medical record the patient's urine protein and urine glucose level, as measured by dipstick.

POC: We will stress with our Office Manager the importance of adhering to the Department's regulation requiring urine dipstick measurement of urine protein and glucose for ALL patients, and that if a patient cannot provide a urine sample then she cannot go forward with her procedure until she does provide us with a urine sample. We

will further ask our Office Manager to stress this to her staff and to enforce it for all patients undergoing abortion procedures.

0013 – Requirements for Abortion – 29.33 (13)

We maintain that we are already in legal compliance with 29.33(13), nevertheless, the Plan of Correction below will address the documentation issues cited by the Department in their letter:

6. Cited Issue: "AMS fails to ensure that each patient was supervised constantly while recovering from surgery or anesthesia/sedation"

   POC: We dispute this finding. All of our patients were, indeed, supervised constantly while recovering from surgery or anesthesia by a registered nurse or a licensed practical nurse under the direction of a registered nurse or a physician. The recovery room records of all patients are all signed and there is no evidence that the patients were not supervised constantly.

7. Cited Issue: Internal Policies of AMS "did not include documentation of respirations rate and quality."

   POC: We will modify our internal policies to include pre-operative procedure room, and recovery room, assessment and documentation of respiration rate and quality, as well as monitoring of respiration via visual observation.

8. 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.

9. Cited Issue: The facility shall develop and implement a corrective action plan, along with evidence for monitoring the implementation of the POC. We have until March 17, 2011 to implement the POC.

POC: The enclosed Plan of Correction is our proposed Plan of Correction. Since the Department has given us only twenty-nine (29) days from receipt of the Deficiency Letter to implement this POC, we do not have time to wait for a response of approval from the Department in order to reach the deadline imposed by the Department. Therefore, our implementation plan is to move forward with implementing this POC even absent a response from the Department. We will assume that if the Department finds our POC unacceptable or wants us to make changes to this POC, that the Department will not hesitate to so inform us. Nevertheless, if this POC is acceptable to the Department then we would respectfully ask for written acknowledgment that our POC is approved. We will monitor our implementation of this POC by conducting our own internal Compliance Audit by our Compliance Officer, no later than March 16, 2011 to monitor our success at implementation of the POC. If our Compliance Officer cites us internally with any deficiencies in the implementation of this POC, then we will attempt to move quickly to correct any such deficiencies. If our Compliance Officer finds that we have successfully implemented our POC, then on March 17, 2011 we will submit to the Department our modified forms and our changed Policies and Procedures for the Department's approval.

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