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Allentown Medical Services

2200 Hamilton Street; Suite 200
Allentown, PA 18104

January 6, 2011

RECEIVED

JAN 1 3 2011

PA DEPT OF HEALTH
DIVISION OF HOME HEALTH

Department of Health

Harrisburg, PA 17104

Re: Is Plan of Correction Acceptable?

On December 16, 2010 we faxed to you a proposed Plan of Correction which was in response to your letter of December 9, 2010 citing us with a number of deficiencies. A copy of our proposed Plan of Correction which was sent on December 9, 2010 is enclosed with this letter.

On December 17
, 2010 I personally called your office and confirmed receipt of the faxed Plan of Correction. Since that time, we have not received a response from the Department, one way or the other, as to whether or not the proposed Plan of Correction was acceptable to the Department.

If our Plan of Correction is acceptable to the Department, then there is no need to reply to this letter. If we don't hear from you we will assume that the enclosed Plan of Correction is acceptable. If, on the other hand, there is some aspect of our Plan of Correction that is unacceptable to the Department, please kindly immediately inform me.

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.

Thank you very much for your time and attention to this letter.

Sincerely,

[redacted]

Notified
1/18/11
[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.

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:

7. Cited Issue: "The facility failed 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.

8. Cited Issue: "No documentation of patient assessment in recovery room and no evaluation of patient status was documented".

   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.

9. Cited Issue: Internal Policies of AMS "did not include assessment and documentation of respiration."

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

10. Cited Issue: For a number of patient records reviewed, the Department found "no assessment and documentation of bleeding and cramping per facility policy"

    POC: For these records reviewed, it appears that our nurses may have failed to provide adequate documentation of bleeding and cramping, as per our own internal policies. While we point out that this is not a legal violation of the ACA, and there is no evidence that assessment of bleeding and cramping was not actually performed by the staff or that the patients

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.