pennsylvania
DEPARTMENT OF HEALTH
(717) 783-1379

November 16, 2010

[redacted]
Planned Parenthood Southeastern Pennsylvania (PPSP)
8 South Wayne Street
West Chester, Pennsylvania 19382

RE: Planned Parenthood Southeastern Pennsylvania, Facility ID# 00208701

Dear [redacted]:

On October 19, 2010, an on-site survey was conducted at Planned Parenthood of Southeastern PA located at 8 South Wayne Street, West Chester, PA 19382.

The survey revealed that the facility provided services in accordance with 28 Pa. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics.

Pursuant to section 313(a) of the MCARE Act 40 P.S §1303.313(a), a medical facility subject to MCARE Act is required to report to the Department and to the Patient Safety authority a **serious event within 24 hours** after it confirms a serious event.

Pursuant to section 315(e) of the MCARE Act 40 P.S. §1303.315(e), the Planned Parenthood of Southeastern PA (PPSP) facility's duty to report a serious event went into effect upon the (PPSP) facility submission of a Patient Safety Plan to the Department on March 9, 2007.

Review of the PA-PSRS event submitted by the agency on May 24, 2010 revealed the report submission type was categorized as an "Infrastructure Failure" and should have been categorized as a "serious event", According to the facility's submitted event report, "When switching to a new form of Rh testing, validation testing was not done. This would have involved doing the Rh tube test side by side with the slide test to validate results". According to the PA-PSRS event report, the event occurred on March 30, 2010 and the agency submitted the event report on May 24, 2010 (55 days later).

During the onsite survey on October 19, 2010, a review of the facility's recommendations for System Improvement revealed steps the facility will be taking to prevent recurrence or a similar event in the future which included the following: "Rewrite of Lab policy to include detailed description of required validation testing whenever there is a change in lab test. Information distributed to managers, who would be responsible for staff training. Staff training records are placed in the Lab binder. Validation testing was instituted as soon as the problem was identified. Patients were contacted who had testing on days prior to this. Patients have been asked to return to repeat the test to confirm accuracy."

Based on review of the facility's training manual on October 19, 2010 approximately 1:30 PM, there was no documentation to show staff members performing the validation tests were trained by qualified personnel and there was no documentation to show all 35 affected patients were followed up by the facility after receiving the facility's letter on March 30, 2010.

As a result of the survey findings, you are required develop a corrective action within 10 calendars days from the date of this letter. 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 for a mechanism for monitoring. 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] at (717) 783-1379.

Sincerely,

[redacted]
Division of Home Health

cc: File

1607

Planned Parenthood®
Southeastern Pennsylvania

Thursday, December 16, 2010

Department of Health
Division of Home Health

Harrisburg Pa. 17104

RE: Facility ID #00238701 Plan of Correction

I apologize for the delay in providing this Plan of Correction. I had a death in my family which hindered my ability to get this to you in a timely manner.

Enclosed you will find the Plan of Correction for our Locust St., Philadelphia site, facility ID #00238701. Included is the audit tool with which we will use to assess adherence to our policy for the monitoring of patients in our recovery room.

I have also enclosed a quality assurance plan for our West Chester site as an addendum to their previously submitted Plan of Correction related to Rh testing.

Please let me know if there is anything further you need.

Sincerely,

[redacted]

- Microscopy skill will be evaluated annually as part of the clinician's Peer Review.
- Proficiency testing is completed three times a year by the Clinical Services Coordinator through the proficiency test provider.
- The same proficiency test is done as a group activity twice annually at clinician meetings
- Copies of individual clinician proficiency testing results are kept in the clinician's HR file and the Lab Binder

Proficiency Testing Results

- When results are received from the test provider, they are given to or faxed to the Laboratory Director for review and signature.
- Once signed. they are returned to the office to which they belong and placed in the Lab Binder. In the case of the Microscopy results, these are placed in the Clinical Services Coordinator's HR file

XI. Quality Maintenance

- Prior to the introduction of a new test, testing personnel must be trained by qualified personnel. Qualified personnel can include lab supervisors, the Clinical Services Coordinator, or a trainer from the supplier of the test.
- When a new test is used, it must be used at the same time as the old test to provide validation of test results for a minimum of 25 tests. Controls and testing must be documented and kept in the lab binder.
- Following the introduction of a new test, an audit will be performed within a month to assess documentation of appropriate training by all testing personnel, and documentation of validation testing. A summary of the results is compiled, and evaluated by the VP of Patient Services for further action.
- In the event that procedures are not completed as set out in policy, the staff member will receive remedial training and observation, a reassessment of skills in 3 months, and yearly reassessment thereafter if found to be proficient.
- Whenever discrepancies occur with patient testing or controls, patient records must be scrutinized to determine whether there were any adverse effects.

Risk & Quality Management

New Lab Test Audit Tool

Standard:

1. Testing personnel must be trained by qualified personnel. Qualified personnel can include lab supervisors, the Clinical Services Coordinator, or a trainer from the supplier of the test.
2. Validation testing is done for a minimum of 25 tests.

Date: _____

Test Name: _____

New Test Training done by: _____

Testing Personnel doing New Test that do NOT have documented training: _____

_____

Validation Testing Complete: YES NO

Planned Parenthood®
Southeastern Pennsylvania

Serving Chester, Delaware, Montgomery and Philadelphia Counties

C[illegible]
Department of Health
Division of Home Health
[illegible]
Harrisburg, Pa. 17104

RE: Corrective Action Plan, Facility ID# 00208701

D[illegible]

In response to your letter of November 16, 2010, the following is Planned Parenthood's Plan of Correction for the 2 items you sited.

- You wrote, *"a medical facility subject to MCARE Act is required to report to the Department and to the Patient Safety authority a serious event within 24 hours after it confirms a serious event."* Our PA-PSRS report was made on May 24, 2010 because this was the date that we received the medical records from the hospital which confirmed what the patient reported. In addition, the report was completed as an Infrastructure Failure because I was thinking in terms of root cause. With further review, I can see where it could also have been considered a serious event. I have included a copy of the definitions as outlined in PA-PSRS. I think you will agree there is a significant degree of ambiguity.
  Plan of Correction:
  - Correspondence with the PA-PSRS no later than December 15 to seek guidance on the following:
    1. Clarification of when confirmation of an event occurs given the all too frequent misrepresentation/misunderstanding by patients about what has transpired.
    2. Determining report type when ambiguity exists
- Documentation to show that those performing validation testing were trained by qualified personnel.
  - Immucor, the supplier of the Rh test product has done training with all of the staff on November 1, 2010, with a follow-up on November 24, 2010. This documentation is in the Lab Binder, along with the documentation of patient contact. A copy is included with this plan.

Please let me know if you require anything further.

RECEIVED
NOV 29 2010
PA DEPT OF HEALTH
DIVISION OF HOME HEALTH

Sincerely

[redacted]

1144 Locust Street • Philadelphia, PA • 19107-6797 • Phone (215) 351-5500 • Fax (215) 351-5595
ppsp@ppsp.org • www.ppsp.org

Serious Event

An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.

Remember: To be considered a **"serious event,"** the event, occurrence, or situation must meet all of the criteria under Column A or all of the criteria under Column B:

Column A	**or**	*Column B*
• Involved the clinical care of a patient in a medical facility • Resulted in the death of the patient		• Involved the clinical care of a patient in a medical facility • Compromised patient safety • Resulted in an unanticipated injury requiring additional healthcare services

Infrastructure Failure

An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.
Remember: To be considered an "infrastructure failure", a report must meet all of the criteria under Column A or all of the criteria under Column B:

Column A	**or**	*Column B*
• An undesirable or unanticipated event, occurrence, or situation • Involves the infrastructure of a medical facility • Could seriously compromise patient safety		• An undesirable or unanticipated event, occurrence, or situation • Involves discontinuation or significant disruption of a service • Could seriously compromise patient safety

Planned Parenthood®
Southeastern Pennsylvania

STAFF TRAINING SIGN-IN SHEET

Name of Training: Rh Testing

Name of Trainer: [redacted]

Center: SUWC

Date: 11/1/10

Staff Name & Title - Please *PRINT*	Staff Signature
[illegible]	[illegible]

IMMUCOR GAMMA

Technical Services Report Form

4.0 Actions:

Various items were discussed with [redacted], [redacted] and will be summarized below:

- Purchasing of Anti-IgG (or any anti-human globulin) is not necessary for this site as this reagent is used for weak D testing. If this product is used, then an IgG-coated red blood cell reagent such as Check Cells should be used to confirm reactivity.
- Current reagents & purpose was discussed.

1. Anti-D reagent - for testing patient's diluted red blood cells to determine Rh type.
2. Rh-Hr Control reagent - Negative control for the Anti-D test and used in parallel with Anti-D reagent when testing patients.
3. CorEQC reagent cells - used as a positive control (Rh positive) once every 24 hours or on days when Anti-D reagent is used.
4. A_2 Reference cells - used as a negative control (Rh negative) once every 24 hrs or on days when Anti-D reagent is used.

[redacted] 24NOV2010

		(√) / NA	Initials
5.0	Relevant reports and attachments are attached to TS.046F1	NA	
6.0	Technical Support has been notified of any incidental findings/errors while on site.	NA	[redacted]

Performed by:	[redacted]	Date: 24NOV2010
Facility Representative:	[redacted]	Date: 11/24/2010

IMMUCOR GAMMA

Technical Services Report Form

Facility name: Planned Parenthood

Date of visit: 24Nov2010

Address: 8. South Wayne St.
West Chester, PA 19382.

			(√) / NA	Initials
1.1	Trackwise history has been reviewed prior to the site visit.		NA	
1.2	The site visit dates have been communicated to the complaint initiator (if applicable).		NA	
2.3	Equipment		Serial number/NA	
	Galileo		NA	
	Echo		NA	
	CSW		NA	
	Immuspin		NA	
	Incubator ☐ P2 Incubator ☐ Incubator block		NA	
2.4	Purpose	Complaint (PR) # / NA	On-site Complaint (PR) # / NA	
	Training	NA	NA	
	Troubleshooting	NA	NA	
	Observation	NA	NA	

3.0	Objectives: Site visit to clarify use of Anti-D, Rh-Hr control, and reagents used for daily manual Quality Control. [redacted] 24NOV2010

IMMUCOR GAMMA

Technical Services Report Form

Facility name: Planned Parenthood

Date of visit: 01Nov2010

Address: 8 South Wayne St.
West Chester, PA 19382

			(√) / NA	Initials
1.1	Trackwise history has been reviewed prior to the site visit.		NA	
1.2	The site visit dates have been communicated to the complaint initiator (if applicable).		NA	
2.3	Equipment		Serial number/NA	
	Galileo		NA	
	Echo		NA	
	CSW		NA	
	Immuspin		NA	
	Incubator ☐ P2 Incubator ☐ Incubator block		NA	
2.4	Purpose	Complaint (PR) # / NA	On-site Complaint (PR) # / NA	
	Training	NA	NA	
	Troubleshooting	NA	NA	
	Observation	NA	NA	

3.0	Objectives: Train facility staff proper technique using Anti-D and Rh-Hr control reagent.

IMMUCOR GAMMA

Technical Services Report Form

4.0 Actions:

Provided training on proper tube testing techniques using Anti-D and Rh-Hr Control reagents for the following staff members: see attachment

		(V) / NA	Initials
5.0	Relevant reports and attachments are attached to TS.046F1	✓	[redacted]
6.0	Technical Support has been notified of any incidental findings/errors while on site.	NA	

Performed by :	[redacted]	Date: 01Nov2010
Facility Representative:		Date: 11/1/10