STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	8-3910	A. BLDG: 00 B. WING:	08/23/2017

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
PLANNED PARENTHOOD KEYSTONE - ALLENTOWN STATE LICENSE NUMBER: **00218701**	**29 NORTH 9TH STREET ALLENTOWN, PA 18101**

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M 0000	INITIAL COMMENT This report is the result of a Special Monitoring survey conducted on August 23, 2017, at Planned Parenthood Keystone - Allentown (PPKey-Allentown). It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health Regulations § 28 Pa Code, Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics.	M 0000		
M 0007		M 0007		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE:	(X6) DATE:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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M 0007	Continued from page 1 29.33(7) Requirements for Abortion Rho (D) - - immune globin (human) shall be administered to each Rh-negative patient at the time of any abortion, unless contraindicated. Evidence of compliance with this paragraph shall appear in the medical record of the patient. If for any reason the patient refuses the administration of Rh immune globulin when recommended, this refusal shall be noted in the clinical record of the patient. This REGULATION is not met as evidenced by:	M 0007	Action Plan: Center Manger and all staff, including clinician are responsible for ensuring RhoGam is given the same day as service. Policy and Procedure: 1. Rh typing must be performed, unless reliable written documentation of Rh type is available. Otherwise, Rh testing is done on-site on the day of procedure. (Patients may present a blood donor card or lab report of their Rh status in lieu of testing) If testing was done during a previous visit, this result may also be used. 2. If Rh-negative, The staff will flag the chart by using a different color folder - a red folder - and mark results on forms 3. If Rh-negative, Rh0 (D) immune	Completion Date: **09/07/2017** Status: **APPROVED** Date: **10/06/2017**

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M 0007	Continued from page 2	M 0007	globulin (RhoGam) will be prescribed according to the Medical Standards and guidelines. 4. Information regarding Rh (D) immune globulin must be given to the patient in writing and must be documented in her medical record. The staff is responsible to have the patient convey understanding and answer all questions, using the clinician as a resource as needed. 5. If the patient refuses after receiving the education by clinician, the patient is required to sign the appropriate release (Release When Test Not Obtained). The refusal is also documented. 6. When patient agrees to receive the Rh0 (D) immune globulin (RhoGam), this occurs in the Post Procedure Room and is required to be documented. 7) Because the patient will be checking out by proving the details in the red folder, The patient must be	

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M 0007	Continued from page 3	M 0007	asked by the check-out staff if she has received a Rhogam shot. 8) The check out team will ask the patient to please wait and check the status with the clinician. 9)If the Rhogam shot was given but not documented in the red folder, the Center Manager will follow up with clinician. 10) If the Rhogam shot was not given, the check out team will notify the Center Manager who will refer the patient to the clinician 11) It is important that the Rhogam shot be given the same day as to not inconvenience the patient to return to the center another day for a procedure that should have been done the same day as RH negative results were identified. 12) It is also important that the PP team apologize for the delay if the check out team identifies that the shot was not initially administered.	

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M 0007	Continued from page 4	M 0007	13) The RQM Director will monitor each facility daily and provide feedback and coaching as needed. 14) It is required that, when appropriate, the patient receives the Rhogam shot the same day. Center Managers cannot rely on running reports the next day and calling patients back to the center for a shot. This shot must be given the same day to those patients who need the shot, unless the shot is refused. All responses and end results for patient must be documented that day. 15)The RQM Director will run daily reports of all facilities and inform the staff immediately to contact a patient which somehow did not receive a shot and there was no documentation to reveal a reason for refusal. An incident report will also be filed same day of notification. The Center Manager will be coached and re-educated.	

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M 0007	Continued from page 5	M 0007	16) Policy will be reviewed with Unit Managers during the 2 separate monthly visits to their center by the RQM Director. Meetings to start 10/9/17 and will be completed by 10/31/17. Daily reports will be run in the interim by the RQM Director.	

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M 0007	Continued from page 6	M 0007	1.Center Manager or designee will be responsible for running an Rh Report from the Electronic Health Record at the end of day of services to ensure all Rh Negative patients received MiCROGam or RhoGam as indicated. Any patients who did not receive Rhogam as indicated, will be contacted and offered correct dose to be administered within 72 hours. 2.For Medication Abortion Patients - Physician administers and documents Rhogam at time of Mifeprex. The Chief Medical Officer (CMO) will communicate this requirement to all physicians. 3.For Surgical Patients - Licensed RN or APC or MD staffing Post Procedure room administers and	

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M 0007	Continued from page 7	M 0007	documents Rhogam. Lead Clinician will confirm this is included as part of Post Procedure responsibilities. CMO will communicate this instruction at APC meeting on 9/11/2017. 4.All Rh Negative Charts will be audited. 5.Rh Policy and Procedures will be updated. 6. Dir. of RQM is responsible for the effectiveness check of this plan and the final POC summary will be reported to the CEO of PP Keystone. The updated policy will be communicated to the Center Managers on 9/11/2017. Implementation is set for 09/12/2017.	

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M 0007	Continued from page 8 Based on review of facility documents, medical records (MR) and staff interview (EMP), it was determined the facility failed to follow the facility's policy to ensure Immune Globulin was administered to one of two Rh-negative patients (MR6). Findings include: Review on August 23, 2017, of the facility's "Rh Policy," effective January 23, 2015, revealed "Policy: All patients seeking an abortion, whether it is surgical or medication, must have documentation of Rh status on their chart. Responsibility: Center Manger and all staff working on abortion procedure days Procedures: 1. Rh typing must be performed, unless reliable written documentation of Rh type is available. a. Rh testing is done on-site on the day of procedure. b. Patients may present a blood donor card or lab report of their Rh status in lieu of testing. c. If testing was done during a previous visit, this result may also be used. 2. If Rh-negative, flag the chart with a red folder and mark results on forms. 3. If Rh-negative, Rh0 (D) immune globulin (RhoGam)	M 0007		

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M 0007	Continued from page 9 will be prescribed according to the Medical Standards and guidelines. 4. Information regarding Rh0 (D) immune globulin must be given to the patient in writing and must be documented in her medical record. 5. If the patient refuses, she must sign the appropriate release (Release When Test Not Obtained). Rh0 (D) immune globulin (RhoGam) is always given in the Post Procedure Room and documented on the Post Procedure Room Record. ..." Review of MR6 on August 23, 2017, revealed the patient was admitted on August 11, 2017, for a medication abortion. The facility tested the patient's blood and determined the patient was Rh-negative (a blood group that lacks the Rh antigen in the red blood cell). There was no documentation in MR6 indicating the patient had previous Rh typing performed, that RhoGam (a medication used to prevent antibodies from forming and to avoid complications with future pregnancies) was prescribed for the patient, or the patient refused the administration of RhoGam.	M 0007		

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M 0007	Continued from page 10 Interview with EMP1 and EMP2 on August 23, 2017, at approximately 2:00 PM confirmed MR6 was admitted to the facility for a medication abortion; the facility tested the patient's blood and determined the patient was Rh-negative. EMP1 and EMP2 confirmed there was no documentation in MR6 indicating previous Rh typing was performed. EMP1 and EMP2 confirmed RhoGam was not prescribed for the patient, and there was no documentation the patient refused the administration of RhoGam. EMP1 and EMP2 confirmed the facility did not administer RhoGam to the patient for their Rh-negative status.	M 0007		
M 0032		M 0032		

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M 0032	Continued from page 11 29.43(b) Facility Approval All medical facilities except hospitals may become approved facilities upon submission of an application to the Department from a person authorized to represent such facility and, at the discretion of the Department, satisfactory completion of an on-site survey. This REGULATION is not met as evidenced by:	M 0032	The policy and procedures on "Emergency Supplies" was provided to surveyors during the visit on 08/23/2017. One of the purposes of the Emergency Supplies policy is to check for expired and used supplies monthly. It specifically states the following: "The clinician is responsible for checking the emergency supplies for expiration dates and used supplies on a monthly basis. The center manager is responsible for ordering new supplies as needed and ensuring that monthly checks are completed." Esmolol Hydrochloride 100 mg (milligrams/10ml (milliters)) a medication used to treat increased heart rate and increased blood pressure was ordered prior to the visit on 08/23/2017. The new ordered medication was on site during the visit, but not in the emergency kit. During this visit, the new ordered medication was placed in the emergency kit. In addition, the three 32-ounce bottles of emergency eye wash located in the laboratory area	Completion Date: **09/07/2017** Status: **APPROVED** Date: **10/06/2017**

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M 0032	Continued from page 12	M 0032	were expired. New bottles were ordered on the same day of visit 08/23/2017. The bottles arrived and can be located in the laboratory. Action Plan: 1."Daily, Weekly, Monthly Form": This form is a tool for Center Managers,Clinicians and Medical Care Assistants must complete accordingly. The form lists all tasks related to maintaining compliance. Center Managers and the RQM Manager are responsible for ensuring the form is complete and the tasks are done. One of the tasks listed on this form is checking the Emergency Supplies on a monthly basis to ensure that medications are discarded and ordered prior to their expiration dates. 2. The Daily, Weekly, Monthly Form will be audited by the Dir. of Risk and Quality Management in person as well as remotely.	

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M 0032	Continued from page 13	M 0032	3. Director of RQM is responsible for the effectiveness check of this plan and the final POC summary will be reported to the CEO of PP Keystone. A policy on "Daily, Weekly, Monthly Form" has been communicated to the Center Managers and Clinicians on 09/11/2017 and at every scheduled monthly meeting with Center Managers and Administration, which includes Director of RQM The RQM Dir (who is an RN) will visit each facility every two weeks to ensure that these policies are being followed and help with any needed education or demonstration. The Emergency Supplies process was again discussed at the recent 10.2.17 meeting. The staff was advised about the importance of emergency supplies checks being monitored and expired supplies discarded appropriately. This includes eye wash supplies as well.	

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M 0032	Continued from page 14	M 0032	Emergency drugs will be kept in kit with a red plastic lock and then the kit placed in a locked room when not in use. The clinician will check the emergency supplies for expiration dates as well as used supplies on a monthly basis. The Center Manager is responsible for ordering new supplies which is also monitored by the RQM Director. RQM will review this process in detail with the Allentown staff on October 12, 2017 and schedule visits with other Centers to occur by the end of October.	

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M 0032	Continued from page 15 Based on review of facility documents, observation, and staff interview (EMP), it was determined the facility failed to ensure expired medications were removed from the emergency kit and failed to ensure expired emergency eyewash was removed from the laboratory areas. Findings include: Review on August 23, 2017, of the facility policy, "Emergency Supplies," dated effective January 1, 2015, revealed "Policy: An adequate amount of current emergency medical supplies will be kept in each Medical Center and will be easily accessible to medical center staff. Emergency drugs will be kept in a locked Kit when not in use. Responsibilities: The Clinician is responsible for checking the emergency supplies for expiration dates and used supplies on a monthly basis. The Center Manager is responsible for ordering new supplies as needed and ensuring that monthly checks are completed. Procedures: ...4. ... b. Expired supplies must be	M 0032		

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M 0032	Continued from page 16 discarded or destroyed ..." 1) Observation tour on August 23, 2017, at approximately 11:15 AM revealed an emergency kit with two vials of esmolol hydrochloride (a medication used to treat increased heart rate and increased blood pressure) 100 mg (milligrams)/10ml (milliliters), which expired in July 2017. Interview with EMP2 on August 23, 2017 confirmed the emergency kit with two vials of esmolol hydrochloride, which expired in July 2017. 2) Observation tour on August 23, 2017, at approximately 11:15 AM revealed one 32-ounce bottle of emergency eye wash located in the laboratory area and two 32-ounce bottles of emergency eyewash located in the lab, which expired in July 2017. Interview with EMP2 on August 23, 2017, confirmed the one 32-ounce bottle of emergency	M 0032		

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M 0032	Continued from page 17 eye wash located in the laboratory area and the two 32-ounce bottles of emergency eyewash located in the lab, which expired in July 2017.	M 0032		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - ALLENTOWN

STATE LICENSE NUMBER: 00218701

SURVEY EXIT DATE: 08/23/2017

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Nancy J. Lescavage
Deputy Secretary for Quality Assurance

Rachel L. Levine, MD
Secretary of Health

pennsylvania
DEPARTMENT OF HEALTH

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