STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	8-6704	A. BLDG: 00 B. WING:	06/06/2019

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
PLANNED PARENTHOOD KEYSTONE - YORK STATE LICENSE NUMBER: **00198701**	**728 SOUTH BEAVER STREET** **YORK, PA 17401**

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M 0000	INITIAL COMMENT This report is the result of an Annual Registration survey conducted on June 6, 2019, at Planned Parenthood - York. 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 0001		M 0001		

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

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M 0001	Continued from page 1 29.33(1) Requirements for Abortion Each medical facility shall have readily available equipment and drugs necessary for resuscitation. If local anesthesia is utilized to perform an abortion in a medical facility during the first trimester, then the following equipment shall be ready to use for resuscitative purposes: (i) Suction Source (ii) Oxygen Source (iii) Assorted size oral airways and endotracheal tubes (iv) Laryngoscope (v) Bag and mask and bag and endotracheal tube attachments for assisted ventilation (vi) Intravenous fluids including blood volume expanders (vii) Intravenous catheters and cut-down instrument tray (viii) Emergency drugs for shock and metabolic imbalance (ix) An individual to monitor respiratory rate, blood pressure and heart rate. This REGULATION is not met as evidenced by:	M 0001	During the interview with EMP 4 it was explained that the supplier sent the wrong AED pads and that we were waiting for the new ones to arrive which they have since been received. To prevent reoccurrence, the Center Manager will set a calendar reminder 2 months prior to their expiration date to reorder the AED pads to ensure we receive the correct item by the time the older ones expire. The Center Manager will include the RQM Manager on the reminder and the RQM Manager will follow-up to ensure that the proper ones have been received. Any issues with ordering will be reported to the Director of Purchasing	Completion Date: **07/31/2019** Status: **APPROVED** Date: **07/12/2019**

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M 0001	Continued from page 2 Based on a review of facility documents and staff interview (EMP), it was determined that the facility failed to have the necessary equipment available for resuscitation if such a need arose. Findings: Review of the AED log on June 6, 2019, at 9:30AM, indicated that the pads for the machine had expired May 27, 2019. Interview with EMP 4 at 1:30PM, revealed that there was not another set of AED pads to use.	M 0001		
M 0003		M 0003		

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M 0003	Continued from page 3 29.33(3) Requirements for Abortion Abortions shall be performed only by a physician who possesses the requisite professional skill and competence as determined and approved by the medical facility in accordance with appropriate procedures. This REGULATION is not met as evidenced by:	M 0003	While the provider in question was granted clearance by our Medical Director, the documentation was not complete until the Board of Directors signs off on the privileges. An emergency board meeting was called and the correct documentation was sent to surveyors after the date of inspection. To avoid this deficient practice in the future, The Human Resources Director will ensure the privileging documentation is completed by both the Medical Director and the Board of Directors prior to allowing the provider to work unsupervised. The Director of Risk and Quality will audit this process to ensure proper documentation is in place prior to unsupervised work date for all future hires of abortion physicians.	Completion Date: **07/11/2019** Status: **APPROVED** Date: **07/12/2019**

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M 0003	Continued from page 4 Based on a review of facility documents and interview with staff (EMP) it was determined that the facility failed to have a physician privileged prior to practicing. Findings: A review of the Clinical Privileging Policy revealed the following - "The granting of clinical privileges is an integral component of an affiliate's Quality/Risk Management Program for ensuring compliance with medical and personnel standards. It is the process by which an affiliate determines that only those health professionals who by state law, education and experience are qualified to perform a particular clinical function are allowed to do so. The granting of clinical privileges must be documented, and a copy placed in the personnel file. Determination of Privileges - At the completion of the designated orientation and/or proctoring period the medical Director or designee will: ... 4. A written record of the request for clinical privileges,	M 0003		

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M 0003	Continued from page 5 and the scope of privileges granted is documented on the Clinical Privileging Form and maintained in the licensed personnel record. Credential file CF2 revealed no documented evidence of priviliges. Interview with EMP 8 at 1:30PM verified no evidence in CF2.	M 0003		
M 0007		M 0007		

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M 0007	Continued from page 6 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	An analysis was completed at the time of the missed Rhogam and it was learned there was an issue with the RH negative alert in our electronic health records system which was corrected the same day. As a preventative measure, the Center Manager audits RH negative patients by running a report at the end of day to ensure that RH negative patients receive the medication prior to leaving the facility. Any deviations get reported to the Director of RQM and then reported to the state via the PSRs system according to our Patient Safety Plan. A PSRs report was filed for the patient noted in the deficiency and required written notification was sent to the patient. This was reviewed on 6.6.2019 survey date.	Completion Date: **07/11/2019** Status: **APPROVED** Date: **07/12/2019**

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M 0007	Continued from page 7 Based on a review of facility documents, medical records (MR) and staff interview (EMP), it was determined the facility failed to follow their policy to ensure Immune Globulin was administered to one of four Rh-negative patients (MR2). Findings: Review on June 6, 2019, of facility "Rh Policy," last reviewed July 2018, revealed, "POLICY: MiCROGam or RhoGam shall be administered to each Rh-negative patient at the time of any abortion, unless contraindicated or patient refuses. RESPONSIBILITY: Providers, APCs, Center Managers and MCAs providing patient care are collectively responsible for following the procedures listed below to ensure all Rh-negative patients receive MiCROGam or RhoGam. PROCEDURES: 1. Rh typing must be performed on all patients who have an ultrasound, 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	M 0007		

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M 0007	Continued from page 8 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, MiCROGam or RhoGam will be prescribed as indicated and according to the Medical Standards and Guidelines. 4. Information regarding Rh0 (D) immune globulin medication must be given to the patient in writing and must be documented in the medical record. a Medication Abortion Patients-Physician administers and documents MiCROGam or RhoGam at time of Mifeprex. 5. If the patient refuses, she must sign the appropriate release (Release When Test Not Obtained). ... ." Review of MR2 on June 6, 2019, revealed the patient was admitted on September 18, 2018, 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 MR2 indicating the patient had previous Rh typing	M 0007		

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M 0007	Continued from page 9 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. Interview with EMP7 on June 6, 2019, at 1:30PM confirmed that the patient was Rh-negative and that RhoGam injection was missed.	M 0007		

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S 0000	INITIAL COMMENT This report is the result of an Annual Registration survey conducted on June 6, 2019, at Planned Parenthood Keystone-York. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999	S 0000		
S 0119		S 0119		

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S 0119	Continued from page 1 551.31 (a) (1) Application/Authorization to Operate an ASF APPLICATION AND AUTHORIZATION TO OPERATE AN AMBULATORY SURGICAL FACILITY 551.31 Licensure (a) A Class A ASF shall meet the following criteria: (1) No license shall be required for the operation of a Class A ASF, however, such a facility shall be accredited by the Accreditation Association for Ambulatory Health Care, the Joint Commission on the Accreditation of Health Care Organizations, the American Association for the Accreditation of Ambulatory Surgical Facilities or another nationally recognized accrediting agency acknowledged by the Medicare program in order to be identified as providing ambulatory surgery. This REGULATION is not met as evidenced by:	S 0119	Part 1 - Sterilized packs (wrapped in blue sterilization paper) are the items in our facility that are required to be kept in a temperature and humidity controlled environment. They will be stored in a chamber that will be monitored weekly. The policy and log will be revised to reflect this new practice. The staff will be trained and procedure implemented by 8/10/2019. Monitoring of temperature and humidity will be performed by staff on each day surgical services are provided (weekly) and report any deviations to the Center Manager. The Center Manager will report any deviations to the Risk and Quality Manager for remediation. Part II - The Human Resources Department will update current policies to include TB surveillance. This will be completed by 7/16/2019 at which time the Director of Risk and Quality will review to ensure completion of updates are in compliance with the regulations noted in these findings.	Completion Date: **08/11/2019** Status: **APPROVED** Date: **07/15/2019**

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S 0119	Continued from page 2	S 0119	Once the TB Surveillance program is implemented, The Director of Human Resources or designee will audit employee files after the first 90 days after implementation and files will be audited annually thereafter. Any deviations from the program will be reported to the Director of RQM for corrective action plan development. All appropriate staff will be trained on the TB program. Part III - The policy, MED-1600, referenced in this deficiency should be corrected to read RQM-600C Cleaning Disinfection and Sterilization where the quote, " Spore testing must be conducted every week in a health center providing family planning services and daily in a health center providing abortion/surgical services" is located. Planned Parenthood Keystone does not have a policy numbered MED-1600 as the policy for Sterilization – Spore Test Log is numbered MED-1006.	

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S 0119	Continued from page 3	S 0119	RQM 600C Cleaning Disinfection and Sterilization has been updated to reflect current business practices that spore testing should be completed weekly as surgical services are only conducted once a week in the center. The corrective action for the missing sterilization log entries is as follows: 1. The Center Manager will conduct a retraining on the use of the log and conduct a weekly audit of the logs to ensure this activity is being completed according to policy. 2. The RQM Manager will audit the log monthly to ensure the task is being completed. 3. Any deviations will be brought to the attention of the Director of Risk and Quality Management for further action. Part IV - The corrective action for the missing Lidocaine log entries is as follows: 1. The Center Manager will conduct a retraining on the use of the log and	

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S 0119	Continued from page 4	S 0119	then conduct weekly audit of the logs to ensure this activity is being completed according to policy. 2. The RQM Manager will audit the log monthly to ensure the task is being completed. 3. Any deviations will be brought to the attention of the Director of Risk and Quality Management for further action. Part V - The corrective action for the missing Daily Weekly Monthly log entries is as follows: 1. The Center Manager will conduct a retraining on the log's use and will conduct a weekly audit of the logs to ensure this activity is being completed according to policy. 2. The RQM Manager will audit the log monthly to ensure the task is being completed. 3. Any deviations will be brought to	

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S 0119	Continued from page 5	S 0119	the attention of the Director of Risk and Quality Management for further action. Additionally, MED-1004 Refrigerator and Temperature Monitoring was revised to meet current practice. The facility freezer is used to store tissue scheduled for disposal only. Since the facility does not keep temperature regulated items in the freezer, and the materials are not required to be frozen by our contract with our disposal company, it did not incorporate a freezer monitoring program.	

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S 0119	Continued from page 6 Based on a review of facility policy, observation and interview with staff (EMP), it was determined that the facility failed to meet the minimum Medicare standard 416.44 (a)(1) . In order for the facility to be recognized by the accrediting organization, the facility must comply with the minimum Medicare standards. Standard: Physical environment for compliance, that is established by the facility's accrediting organization by failing to notify the Center Manager or Designee the levels within Procedure Room, Post Procedure Room, and Clean Lab to ensure the levels were within acceptable range. 416.44 (a)(1) Standard: Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. A review of facility policy "Temperature and Humidity Monitoring last reviewed January 2018 revealed "... 1. The temperature and humidity will be checked in the	S 0119		

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S 0119	Continued from page 7 Procedure Rooms, Post-Procedure Room and Clean Lab once in the morning before procedures begin and once at the end of the day... 2. The temperature and humidity will be logged on MED-1005F ... 3. If the temperature and humidity are out of range, it must be documented on the log what action was taken by the center staff to rectify the issue ...4. If temperature and humidity are consistently out of the acceptable range (two or more readings in a row), the Center Manager must contact Facilities Manager or designee in order to be advised of next steps. Document the action on the Temperature and Humidity Log. On June 6, 2019, an observation of the facility "Temperature & Humidity Log" revealed that monitoring for Procedure Room 1, Post-Procedure room and Clean lab were not in the acceptable ranges. Temperature 68-73 degrees Fahrenheit and Humidity 34-60% ... From November 2018 - December 2018. Temperature was not within range seven times and	S 0119		

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	8-6704	A. BLDG: 00 B. WING:	06/06/2019

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S 0119	Continued from page 8 Humidity was not in range 17 times. Action documented was 1- none, or 2 - adjusted temp up. Review of Temperature and Humidity Log from January 2019 - June 2019 revealed temperatures not within range 15 times and humidity not within range 24 times. Action indicated 1-none, or 2-Adjusted temp up, or 3- Adjusted temp down. No documentation noted on the log sheet to indicate that the Center Manager was notified. An interview with EMP1 on June 6, 2019, at 1:35 PM, confirmed that facility staff was aware that the temperatures and humidity were not in range. Based on observation and staff interview (EMP), it was determined the facility failed to meet the minimum Medicare standard 416.51 (b). In order for the Center to be recognized by the accrediting organization, the facility must comply with the minimum Medicare Standards. Standard: Infection control program for compliance, that is established by the facility's accrediting	S 0119		

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S 0119	Continued from page 9 organization by failing to establish a surveillance component for Mycobacterium tuberculosis (M. tuberculosis) that covers personnel working in the facility, as required under local, state, or federal public health authority. Tuberculosis is a state reportable disease. 416.51 (b) Standard: The facility must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the facility has considered, selected, and implemented nationally recognized infection control guidelines. The CDC publication of Morbidity/Mortality Weekly Report dated December 30, 2005 outlines on pg. 10 "All HCWs (Health Care Workers) should receive baseline TB screening upon hire, using two-step TST (tuberculin skin test) or a single BAMT (blood assay for M. tuberculosis) to test for infection with M. tuberculosis." Review of personnel Files for EMP1, EMP 2, EMP 3, EMP 4 and EMP 5, files revealed no baseline or	S 0119		

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S 0119	Continued from page 10 risk assement. An interview with EMP6 on June 6, 2019 at 11:00 AM, confirmed the facility does not have a policy which includes the surveillance of tuberculosis. Based on a review of facility policy, observation and interview with staff (EMP), it was determined that the facility failed to meet the minimum Medicare standard 416.51(b). In order for the Center to be recognized by the accrediting organization, the facility must comply with the minimum Medicare . 416.51(b) HAI risk mitigation measures include: Surgery - related infection risk mitigation measures: addressing aseptic practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate. Monitoring the sterilization equipment for spores and compliance, that is established by the facility's accrediting organization by failing to monitor the Sterilization/Spore test log. Based on review of the Sterilization / Spore test log	S 0119		

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S 0119	Continued from page 11 for three months. Review of the Cleaning Disinfection & Sterilization policy reviewed 1/12/2018. Policy " Invasive procedures - including surgery, biopsies, injections or venipuncture-all involve the contact of sterile tissue or mucous membranes with a piece of medical equipment or a medical device. Every time this kind of procedure is performed, there is the possibility of infection from microbes on the instrument or device. Cleaning, disinfection and sterilization are the only means of reducing this risk. Sterilization - Sterilization completely kills or eliminates all microorganisms. All critical items need sterilization". "MED-1600 - Sterilization -Spore Test Log should be used to document each autoclave run". "Spore Autoclave Testing (see MED-1006 for additional information) Spore testing must be conducted every week in a health center providing family planning services and daily in a health center providing abortion/surgical services."	S 0119		

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S 0119	Continued from page 12 Review of the Sterilization/Spore Test Log indicated no testing was completed from Jan 22, 2019 - April 1, 2019. From April 1, 2019 - June 4, 2019 testing was completed weekly and not daily as per the facility's policy for those providing abortion services. Interview with EMP 4 at 1:30PM could not explain why testing was not completed from January 22, 2019 - April 1, 2019. Based on a review of facility policy, observation and interview with staff (EMP), it was determined that the facility failed to meet the minimum Medicare standard 416.48(a) Standard: Administration of Drugs. In order for the Center to be recognized by the accrediting organization, the facility must comply with the minimum Medicare Standards. 416.48 (a) Standard: Administration of Drugs - "Accepted professional practice and acceptable standards of practice" mean that the drugs and biologicals are	S 0119		

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S 0119	Continued from page 13 handled and provided in the ASC in accordance with applicable State and Federal laws as well as with nationally recognized expressed in the clinical use of drugs and biologicals. Review of the Lidocaine usage policy - "To ensure proper handling of Lidocaine in all Surgical Abortion sites. Responsibility: Advanced Practice Clinician (APC) and Physicians. Eval/ Mgt: This process is overseen by the Center Manager and Director of Health Center Operations. Procedure: 3. The Lidocaine is logged on the Lidocaine Inventory Log by a staff member." Review of the Lidocaine log revealed there has been no documentation from August 16, 2018 - May 22, 2019. Interview with EMP 4 at 1:30PM could not state why there was no documentation on the log and could not provide evidence of usage or any remaining amounts.	S 0119		

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S 0119	Continued from page 14 Based on a review of facility policy, observation and interview with staff (EMP), it was determined that the facility failed to meet the minimum Medicare standard 416.51(a)Standard: Sanitary Environment. In order for the Center to be recognized by the accrediting organization, the facility must comply with the minimum Medicare Standards. 416.51(a) Standard: Sanitary Environment: Must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. Review of the Refrigerator Temperature Monitoring last reviewed 1/9/2018 -Refrigerator temperatures are monitored continuously to maintain proper storage conditions for refrigerated medications and lab specimens. Refrigerators for medication storage or specimens must not contain food and refrigerators for food storage must not contain medication or specimens. Responsibility: Center Manager and Center Staff. Eval/Mgt: The Center Manager will ensure all	S 0119		

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S 0119	Continued from page 15 procedures are followed and the Director of Health Center Operations (DHCO) and or the Director of Risk and Quality Management (DRQM) will conduct periodical audits of the log sheets and refrigerator contents. Procedure: Refrigerator Temperature Log Sheet. 1. A log sheet will be placed on all medication refrigerators. It will be used to record the temperature at opening and closing on a daily basis. 5. A thermometer with a memory should be used to keep track of temperatures when the center is closed. Review of daily task log for February 2019 revealed 15 days no documentation of refrigerator temp to include the days the facility was closed. Daily task log for May 2019 revealed 22 days no refrigerator temperature documentation, to include days the facility was closed. March 2019 Weekly Task sheet revealed no temperature documentation for the freezer.	S 0119		

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S 0119	Continued from page 16	S 0119		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - YORK

STATE LICENSE NUMBER: 00198701

SURVEY EXIT DATE: 06/06/2019

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

Susan Coble
Deputy Secretary for Quality Assurance

Rachel L. Levine, MD
Secretary of Health

pennsylvania
DEPARTMENT OF HEALTH

THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY