

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0607</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>05/02/2018</b>
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NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - READING</b>  STATE LICENSE NUMBER: <b>00228701</b>	STREET ADDRESS, CITY, STATE, ZIP CODE: <b>48 SOUTH FOURTH STREET READING, PA 19602</b>
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M 0000	INITIAL COMMENT	M 0000		

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

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M 0000	Continued from page 1  This report is the result of an Annual Registration survey conducted on April 18, 2018, at Planned Parenthood - Reading. 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		

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M 0032	Continued from page 3  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	Actions Taken the Day of of Inspection The 12 expired curretes were quarantined and disposed of according to manufacturer's instructions the day of inspection. Medications stored in the refrigerator were quarantined for disposal and the refrigerator was under close observation by the Director of Health Center Operations and the Director of Facilities prior to any new medications being stored.  On 4/30/2018 a new refrigerator was installed. Temperature monitoring was conducted daily to ensure the new unit was maintaining temperatures within the required range for one week.  On 5/9/2018 The documented temperatures were compliant to specification. The new stock of medications were placed in the new unit.  Training, Evaluation and Management	Completion Date: <b>05/30/2018</b> Status: <b>APPROVED</b> Date: <b>05/11/2018</b>

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M 0032	Continued from page 4	M 0032	<p>The Director of Health Center Operations (DHCO) and designee will be responsible for the center's compliance until staff have been trained. Training which will be held on or before 5/30/2018.</p> <p>The DHCO will retrain staff on the following by:</p> <ul style="list-style-type: none"> <li>Reviewing Expiration Date policy</li> <li>Performing center checks for expiry dates of medical supplies and documenting the monthly checks in the appropriate area on the "Daily Weekly Monthly" form.</li> <li>Reviewing the Refrigerator Temperature Monitoring policy</li> <li>Performing the daily check and documenting on the Refrigerator Temperature Log.</li> </ul> <p>A monthly effectiveness check of this training will be conducted by the Director of Health Center Operations to ensure compliance to policy. A summary of the effectiveness check will be provided to the Director of Risk and Quality Management by the end of each</p>	

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M 0032	Continued from page 5	M 0032	calendar month until each area consistently is compliant to policy.	

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M 0032	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 dispose of outdated supplies.  Findings include:  A review of facility policy, "EXPIRATION DATE POLICY" effective 12/5/2017, revealed, "PROCEDURE: Any chemical, laboratory testing supply, medical supply or substance used in the clinic will expire on the date of the container or stated on the manufacturer's literature. When product is expired it should be disposed of according to the manufacturer's instructions. EVAL/MGMT: Expiration dates are checked during center spot checks or by any member of the management team."  A tour of the facility on April 18, 2018, revealed the following expired supplies in Procedure Room 1:  (12) disposable rigid curettes expiration date Jan.	M 0032		

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M 0032	Continued from page 7  '18.  Interview on April 18, 2018, with EMP 1 and EMP2 at approximately 11:20AM confirmed that the supplies were expired.  _____  Based on review of facility policy, observation, and interview with staff (EMP), it was determined that the facility failed to maintain proper storage of patient medications by failing to record and continuously monitor medication refrigerator temperatures.  Review of facility policy, " <u>REFRIGERATOR TEMPERATURE MONITORING</u> , effective date 1/9/2018 [sic]", revealed "EVAL/MGT: The Center Manager will ensure all procedures are followed and the Director of Heath [sic] Center Operations (DHCO) and or the Director of Risk and Quality Management (DRQM) will conduct	M 0032		



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M 0032	Continued from page 8  periodical audits of the log sheet and refrigerator contents. <u>PROCEDURE</u> : 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 of the center on a daily basis. 2. To ensure proper storage conditions, the temperature must be between 36 and 46 degrees F. 3. Readings outside of the range must have action steps taken documented in the column and initialed. 4. If it is noted that the temperature is outside of the range, Director of RQM or the Lead Clinician must be notified to determine if the contents have been compromised based on manufacturer recommendations. All medications will be discarded based on the Medication Disposal policy..."  A tour of the facility on April 18, 2018, revealed a medication refrigerator in the patient recovery area. The thermometer on the outside of the refrigerator revealed a temperature of 51.8 degrees F.	M 0032		

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M 0032	<p>Continued from page 9</p> <p>Inside of the refrigerator were the following medications:</p> <p>(29) vials Vasostrict 20 units/ml (11) vials Rh Immune Globulin (1) vial Bicillin injectable (6) Methylergonovine maleate injections 0.2mg/ml</p> <p>All of the above medications had the storage temperature guideline of "store between 36-46 degrees F" printed on the label.</p> <p>Further review of the requested logs for January, February, March, and April revealed:</p> <p>January - no log received February - (4) days where the temperature was adjusted down, all days monitored as per policy. March - (4) days where the temperature was monitored as per policy.           (3) days where the temperature was monitored in the AM only.</p>	M 0032		

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M 0032	Continued from page 10  (14) days where no documentation was noted.  The last day monitored was March 20th with the temperature being 55.6 degrees F and the action taken was (#3) adjusted temp down. No further monitoring done for the month. April - (1) temperature was monitored April 9th in the AM reading was 48.9 degrees F. and the action taken was (#3) adjusted temp down. No further monitoring done.  Interview on April 18, 2018, at approximately 12:10PM with EMP1 confirmed that the temperatures were not being continuously monitored for the medication refrigerator in the post procedure area and the Director of RQM or the Lead Clinician were not notified to determine if the contents have been compromised .	M 0032		

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M 0032	Continued from page 11	M 0032			



# Certified End Page

**PLANNED PARENTHOOD KEYSTONE - READING**

**STATE LICENSE NUMBER: 00228701**

**SURVEY EXIT DATE: 05/02/2018**

**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**

Handwritten signature of Susan Coble in black ink on a light gray background.

*Susan Coble*  
*Deputy Secretary for Quality Assurance*

Handwritten signature of Rachel L. Levine, MD in black ink on a light gray background.

*Rachel L. Levine, MD*  
*Secretary of Health*



THIS IS A CERTIFICATION PAGE

**PLEASE DO NOT DETACH**

THIS PAGE IS NOW PART OF THIS SURVEY