

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 8-0607	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED: 11/21/2017
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NAME OF PROVIDER OR SUPPLIER: PLANNED PARENTHOOD KEYSTONE - READING STATE LICENSE NUMBER: 00228701	STREET ADDRESS, CITY, STATE, ZIP CODE: 48 SOUTH FOURTH STREET READING, PA 19602
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M 0000	<p>INITIAL COMMENT</p> <p>This report is the result of an unannounced Special Monitoring Visit survey conducted on November 8, 2017, and completed on November 21, 2017, at Planned Parenthood Keystone - 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.</p>	M 0000		

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

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S 0000	INITIAL COMMENT	S 0000		
	This report is the result of a unannounced Special Monitoring Visit survey conducted on November 8, 2017, and completed November 21, 2017, at Planned Parenthood Keystone-Reading. 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 6142		S 6142		
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S 6142	Continued from page 1 561.25 Distressed drugs, devices and cosmetics 561.25 Distressed drugs, devices and cosmetics Drugs, devices and cosmetics which are outdated, visibly deteriorated, unlabeled or inadequately labeled, recalled, discontinued or obsolete shall be identified by the licensed pharmacist or responsible practitioner and shall be disposed of in compliance with applicable Commonwealth and Federal regulations. This REGULATION is not met as evidenced by:	S 6142	Although the organization has an expiration date policy and uses a center checklist (which is part of our official documentation program), we have made revisions to the policy to provide clarity around the expiration dates for general medical supplies. This policy's revision reflects a system wide change. 1. The policy for expiration dates was updated on 12/5/2017 to include the following statement: 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. 2. The Director of Risk and Quality Management conducted site visits during the week of 12/11/2017, and conducted training and education on the revision of this policy. 3. The Director of Risk and Quality Management will conduct an effectiveness check of this training with site visits during the week of	Completion Date: 01/22/2018 Status: APPROVED Date: 12/19/2017

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S 6142	Continued from page 2	S 6142	January 22, 2017.		

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S 6142	Continued from page 3 Based on observation, review of facility policy, and staff interviews (EMP), it was determined that the facility failed to dispose of outdated supplies. Findings include: Observation on November 8, 2017, at 12:45PM, in Procedure Room One, revealed 21 expired disposable rigid curettes with expiration dates of 06/16. A review of facility policies on November 8, 2017, revealed the facility did not provide a policy that addressed expired supplies. Interview conducted on November 8, 2017, at 12:46PM with EMP1 confirmed that the supplies were expired. Interview conducted on November 21, 2017, with EMP2 via email, revealed an "On-Site Center Checklist." " ...ITEM...Check that all medical	S 6142		

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S 6142	Continued from page 4 supplies are not expired (note if you find expired supplies)." EMP2 confirmed that the checklist "has acted as a policy in and of itself."	S 6142		
S 6747		S 6747		

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S 6747	Continued from page 5 567.43 Ventilation System The ventilation system shall be inspected and maintained in accordance with the written maintenance schedule to ensure that a properly conditioned air supply meeting minimum filtration, humidity and temperature requirements is provided in critical areas such as the surgical and recovery suites under Chapter 571 (relating to construction standards). This REGULATION is not met as evidenced by:	S 6747	The following plan of corrections contains system wide revisions that affect all of our ambulatory surgical facilities. 1. The Temperature and Humidity Log was revised on 12/5/2017 to require documentation of actions taken when out-of-range temperatures are noted. 2. The log was also revised with a column in which AM/PM can be circled to indicate two readings per procedure day must be taken. 3. The corresponding policy was revised on 12/5/2017 to include procedural instructions for the revised log. In addition, there is a requirement added to contact RQM personnel when more than two out of range temperatures are noted to ensure service can be provided to the center in a timely manner, if indicated. 4. On 12/5/2017 - Site managers received education and training on	Completion Date: 01/22/2018 Status: APPROVED Date: 12/19/2017

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S 6747	Continued from page 6	S 6747	<p>the above changes.</p> <p>5. Site visits were conducted the week of 12/11/2017 to ensure the use of the new temperature and humidity log and to reinforce the policy revisions.</p> <p>6. An effectiveness check will be conducted by the Director of Risk and Quality Management during the week of Jan 22,2017 to ensure adherence to policy.</p>	

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S 6747	Continued from page 7 Based on a review of facility policy, observation and interview with staff (EMP), it was determined that the facility failed to consistently maintain the required humidity and temperature levels in Procedure Room One and take corrective actions when the humidity and temperature levels were not within acceptable range. Findings include: On November 8, 2027, a review of facility policy "Temperature and Humidity Monitoring" last reviewed July 2012 revealed "...1. The temperature and humidity will be checked in the procedure rooms...before procedures begin and at the end of the day." "...a. Temperature should range between 68-73F (20-22.78C)...b. Humidity should range between 35-60%." "...If temperature and humidity [sic] the Center Manager will contact the Medical Services Support Team." On November 8, 2017, an observation of the	S 6747		

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S 6747	Continued from page 8 facility's "Temperature and Humidity Log" for "cab and room" (cab is short for cabinet) revealed that humidity levels were out of range for 22 of 28 days monitored (readings are documented one day per week) in the months of May 2017, June 2017, July 2017, August 2017, September 2017, October 2017 and November 2017. Further review revealed temperature levels were out of range for 18 of 28 days monitored (readings are documented one day per week) for the same seven month period. Further review revealed no documentation that actions were taken to correct out of range humidity and temperature levels for "cab and room". An interview conducted on November 8, 2017, at approximately 2:00 PM with EMP1 confirmed that the temperature and humidity levels were out of range. Further interview with EMP1 confirmed that "management takes care of that" and EMP1 was unable to confirm that corrective actions were taken.	S 6747		

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S 6747	Continued from page 9	S 6747			



Certified End Page

PLANNED PARENTHOOD KEYSTONE - READING

STATE LICENSE NUMBER: 00228701

SURVEY EXIT DATE: 11/21/2017

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

Handwritten signature of Susan Coble in cursive.

Susan Coble
Deputy Secretary for Quality Assurance

Handwritten signature of Rachel L. Levine, MD in cursive.

Rachel L. Levine, MD
Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY