

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
--	---	---	--

NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>  STATE LICENSE NUMBER: <b>00188701</b>	STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>
---	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0000	INITIAL COMMENT	M 0000		
M 0032	<p>This report is the result of an unannounced Special Monitoring survey conducted on July 7, 2016, at Planned Parenthood Keystone - Warminster (PPKey - Warminster). 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 0032		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 1  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	Planned Parenthood has not failed to ensure the maximum recommended dose of Lidocaine is administered to patients, and in fact has not subjected, and is not subjecting, patients to excessive doses of Lidocaine, as evidenced by the following:  1. a review of records from the previous 12 months shows that patients are not administered dosages greater than 20mL of 1% concentration. 2. a dosage of 20 mL of 1% concentration does not approach the recommended maximum dosage for patients weighing more than 85 pounds. 3. a review of patient records shows no evidence of complications resulting from the administration of Lidocaine.  In order to further ensure that patients are not receiving more than the recommended dose of Lidocaine, medical center staff will collect	Completion Date: <b>07/30/2016</b> Status: <b>APPROVED</b> Date: <b>08/03/2016</b>

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 2	M 0032	weights on patients presenting for an abortion to confirm that their weight is in fact in excess of 85 pounds. The physician will evaluate whether the standard dosage of 20mL may need adjustment. The effective date of this procedural modification is July 30, 2016. The RQM Coordinator will review patient records quarterly for the correlation of Lidocaine dosage to weight, in conjunction with the review of patient records selected as a part of the overall internal auditing program. This addition to the RQM process will begin with the review of patient records for the quarter ended September 30, 2016.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 3  Based on review of facility documents, medical records (MR) and staff interview (EMP), it was determined the facility failed to ensure the maximum recommended dose of Lidocaine (an anesthetic) was not exceeded when administered as a paracervical block (regional anesthesia causing a loss of sensation in a region of the body which results from the injection of a local anesthetic on each side of the cervix) for eight of 10 medical records reviewed (MR1, MR4, MR5, MR6, MR7, MR8, MR9 and MR10).  Findings include:  Review on July 7, 2016, of the facility's "Use of Local Anesthesia" policy, effective January 19, 2015, revealed "Policy: Planned Parenthood Keystone (PPKey) provides only local anesthesia in the form of a paracervical block for surgical abortion procedures. PPKey also provides oral analgesia in the form of either acetaminophen or NSAID's (nonsteroidal anti-inflammatory medications). No controlled substances are	M 0032		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 4  provided onsite to patients. Responsibility: Planned Parenthood Physicians Procedure: 1. The paracervical block is administered by a Physician as part of the abortion procedure. 2. For Analgesia, patients receive [name of NSAID] orally prior to the surgical abortion procedure unless contraindicated. [Name of NSAID] may be given if [name of NSAID] is contraindicated. EVAL/MGT: the Medical Services support Team will oversee this policy".  Review on July 7, 2016, of the facility's "Chapter 2: Analgesia and Sedation," Revised June 2014 / PPKeystone implemented March 31, 2015, revealed the following table titled "... 2.6.d. Table: Local Anesthetic." The following table headings and information were contained in the table: "Local Anesthetic Generic name (Trade name) - Action Lidocaine (such as Xylocaine) Mode of Administration Injection Maximum Recommended Dose (MRD) 4.5 mg (milligram) / kg (kilogram) Onset of Action Varies	M 0032		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	<p>Continued from page 5</p> <p>Half-Life Varies Duration Varies Comments Clinicians should be aware of both toxic, non-allergic reactions resulting from direct intravascular injection and allergic reactions including anaphylaxis (a systemic allergic reaction). FYI - Local Anesthesia Toxicity".</p> <p>The following medical records were reviewed on July 7, 2016:</p> <p>Review of MR1 revealed the patient was admitted to the facility on April 15, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 millimeters (ml) of Lidocaine 1 percent 10 milligrams (mg)/ml to the patient prior to the procedure. No weight was obtained on MR1 prior to the administration of the 20 ml of Lidocaine 1 percent.</p> <p>Review of MR4 revealed the patient was admitted to the facility on April 15, 2016, for a surgical abortion. CF1 administered a paracervical block</p>	M 0032		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	<p>Continued from page 6</p> <p>using 20 millimeters (ml) of Lidocaine 1 percent 10 milligrams (mg)/ml to the patient prior to the procedure. No weight was obtained on MR4 prior to the administration of the 20 ml of Lidocaine 1 percent.</p> <p>Review of MR5 revealed the patient was admitted to the facility on July 1, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR5 prior to the administration of the 20 ml of Lidocaine 1 percent.</p> <p>Review of MR6 revealed the patient was admitted to the facility on June 7, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR6 prior to the administration of the 20 ml of Lidocaine 1 percent.</p> <p>Review of MR8 revealed the patient was admitted</p>	M 0032		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 7  to the facility on June 7, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR8 prior to the administration of the 20 ml of Lidocaine 1 percent.  Review of MR7 revealed the patient was admitted to the facility on June 17, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR7 prior to the administration of the 20 ml of Lidocaine 1 percent.  Review of MR9 revealed the patient was admitted to the facility on June 17, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR9 prior to the administration of the 20 ml of Lidocaine 1 percent.	M 0032		



STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
M 0032	Continued from page 8  Review of MR10 revealed the patient was admitted to the facility on June 24, 2016, for a surgical abortion. CF1 administered a paracervical block using 20 ml of Lidocaine 1 percent 10 mg/ml to the patient prior to the procedure. No weight was obtained on MR10 prior to the administration of the 20 ml of Lidocaine 1 percent.  Interview on July 7, 2016, with EMP1 at approximately 3:00 PM confirmed weights were not obtained on MR1, MR4, MR5, MR6, MR7, MR8, MR9 and MR10 prior to administering the paracervical block of 20 ml of Lidocaine 1 percent. EMP1 revealed the effects of administering too much Lidocaine is the loss of sensation in the pelvic area, the legs and arms. EMP1 confirmed without a documented weight on MR1, MR4, MR5, MR6, MR7, MR8, MR9 and MR10, the facility was not able to determine if the patients received more than the recommended maximum dose of Lidocaine 4.5 mg/kg.	M 0032		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>8-0908</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED:  <b>07/07/2016</b>
NAME OF PROVIDER OR SUPPLIER: <b>PLANNED PARENTHOOD KEYSTONE - WARMINSTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE: <b>610 LOUIS DRIVE SUITE 303 WARMINSTER, PA 18974</b>		
STATE LICENSE NUMBER: <b>00188701</b>					
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE	
M 0032	Continued from page 9	M 0032			



# Certified End Page

**PLANNED PARENTHOOD KEYSTONE - WARMINSTER**

**STATE LICENSE NUMBER: 00188701**

**SURVEY EXIT DATE: 07/07/2016**

**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 Nancy J. Lescavage in black ink on a light gray background.

*Nancy J. Lescavage*  
*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