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:	11/30/2017

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**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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 This report is the result of an unannounced revisit survey conducted on November 30, 2017, at Planned Parenthood Keystone - Allentown (PPKey-Allentown) as the result of a previous Special Monitoring survey conducted on August 23, 2017. 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 0032		M 0032		

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

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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	Warminster POC - rejected 12/21/2017 responed 12/26/2017 A new Patient Safety Officer (PSO) was named during the 3rd week of November 2017 and has been going through the training process when this deficiency was noted. It took some time for the change to be recognized and logins to the PSRs website set up. Once this was completed, the PSO learned that PA-PSRs website does not allow revisions to reports that are older than 90 days. As a result, the organization was advised by the PA-PSRs help desk to enter it as a new event and reference the initial report. On 12/15/2017, the new PSRs report was re-entered as a serious event. Additionally, on the same day, the serious event written notification was sent to the patient from the PSO. A review of Planned Parenthood	Completion Date: **12/31/2018** Status: **APPROVED** Date: **01/02/2018**

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M 0032	Continued from page 2	M 0032	Keystone's Patient Safety Plan (which is a required policy based on regulations outlined by ACT 13) was conducted. On 12/26/2017 it was confirmed by the Director of RQM that the Plan included instruction regarding written notifications to patients who experience serious events. A system wide training module will be sent to all appropriate staff, including the new PSO, regarding written notifications. This correspondence will be completed by the Director of RQM by 12/31/2017. Planned Parenthood Keystone does not experience incidents considered to be serious events often, but to ensure the affiliate is in compliance with respect to written notifications, the Director of RQM will monitor this activity ongoing via the affiliate's Patient Safety Committee which meets quarterly. The Director of RQM will be	

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M 0032	Continued from page 3	M 0032	responsible for the oversight of this POC and will report to the CEO when plan is completed.	

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M 0032	Continued from page 4 Based on review of facility documents, medical records (MR), and staff interview (EMP), it was determined the facility failed to conform to all applicable State Laws. Planned Parenthood Keystone - Allentown (PPKey - Allentown) was not in compliance with the following state law: Act 13 of 2002, Medical Care Availability and Reduction of Error (MCARE) Act 40.§1303.310 Patient safety committee and 1303.313 Medical facility reports and notifications. Section 302. Definitions. "Incident." An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. "Infrastructure failure." An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service	M 0032		

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M 0032	Continued from page 5 which could seriously compromise patient safety. "Serious event." An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident. Section 308 Reporting and notification. (b) Duty to notify patient. A medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee, within seven days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian shall be notified in accordance with this subsection. The notification	M 0032		

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M 0032	Continued from page 6 requirements of this subsection shall not be subject to the provisions of Section 311 (a). Notification under this subsection shall not constitute an acknowledgement or admission of liability. Section 313. Medical facility reports and notifications. (a) Serious event reports. A medical facility shall report the occurrence of a serious event to the department and the authority within 24 hours of the medical facility's confirmation of the occurrence of the serious event. ... (c) Infrastructure failure reports. A medical facility shall report the occurrence of an infrastructure failure to the department within 24 hours of the medical facility's confirmation of the occurrence or discovery of the infrastructure failure. ... (e) Notification to licensure boards. --If a medical facility discovers that a licensee providing health care services in the medical facility during a serious event failed to report the event in accordance with section 308 (a), the medical facility shall notify the licensee's licensing board of the failure to do report. (f) Failure to report or notify. --Failure to report a serious event	M 0032		

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M 0032	Continued from page 7 or an infrastructure failure as required by this section or to develop and comply with the patient safety plan in accordance with section 307 or to notify the patient in accordance with section 308 (b) shall be a violation of the Health Care Facilities Act. In addition to any penalty which may be imposed under the Health Care Facilities Act, a medical facility which fails to report a serious event or an infrastructure failure or to notify a licensure board in accordance with this chapter may be subject to an administrative penalty of $1,000 per day imposed by the Department. This is not met as evidenced by: Based on review of facility documents, medical records (MR) and staff interview (EMP), it was determined the facility failed to ensure a patient with a confirmed uterine perforation following a surgical abortion was provide written notification following determination of a serious event for one of one applicable medical record reviewed (MR1).	M 0032		

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M 0032	Continued from page 8 Findings include: Review on November 30, 2017, of the facility's "Patient Safety Plan," effective February 29, 2016, revealed "Policy: In compliance with Act 13, the Medical Care Availability and Reduction of Error (MCare) Act, of the Commonwealth of Pennsylvania, Planned Parenthood has established a Patient Safety Plan which designates a Patient Safety Officer (PSO), establishes a Patient Safety Committee, identifies a system for the reporting of incidents and serious events, prohibits retaliatory action against health care workers for reporting incidents or serious events, and provides for the written notification to clients affected by s serious event. Definitions: A. Patient Safety Authority (PSA): an independent state agency Created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (MCare) Act. In 2006, the law was amended to require free standing abortion facilities to report certain events that may or do compromise the safety of clients. ... C. Patient Safety Reporting System (PSRS): a mandatory,	M 0032		

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M 0032	Continued from page 9 confidential, statewide information system for reporting of events, occurrences or situations that have (or could have) resulted in unanticipated injury to a patient in an Act 13-covered medical facility. D. Harm Score: a measure of the extent to which an incident "reached" the patient and the degree of harm caused to the patient. ... G. Incident: an event, occurrence or situation involving the clinical care of an Abortion Services client that could have injured the client but did not either cause an unanticipated injury or require the delivery of additional health care services to the client. ... I. Serious Event: an event, occurrence or situation involving the clinical care of a client in the abortion facility that results in death or compromises client safety and results in an unanticipated injury requiring the delivery of additional health services to the client. Procedure: ... C. Reporting of Incidents ... 2. After ensuring all reports are investigated, the Patient Safety officer will determine if the incident meets any of the following criteria for reporting. These criteria are meant to be guidelines only. a. Incidents i. Is the incident a "near miss" which involved the clinical	M 0032		

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M 0032	Continued from page 10 care of a client, and has the potential for serious harm to the client? ii. Were unanticipated injuries or additional health care services to the client avoided? iii. Is the event a medication error or an adverse drug reaction? This could also be a serious event. Review the details on a case-by case basis b. Serious Events i. Did the event result in patient death, injury or hospitalization? ii. Was the event an aggressive episode? iii. Is the event a medication error or an adverse drug reaction? iv. Did the event result in clients being exposed to a health acquired infection? ... E. Notification of Clients 1. Clients with have been affected by a serious event will be notified in writing within seven days of the occurrence or discovery of the serious event. ..." 1) Review on November 30, 2017, of MR1 revealed the patient was admitted to the facility on November 3, 2017, for a surgical abortion. The physician documented that a uterine perforation occurred during the suction part of the abortion procedure. Documentation revealed MR1 was transferred from the facility to the local hospital for	M 0032		

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M 0032	Continued from page 11 further evaluation and treatment. MR1 was admitted and underwent surgical intervention for the uterine perforation. Interview with EMP1 and phone interview with EMP2 on November 30, 2017, at approximately 12:15 PM confirmed MR1 was admitted to the facility for a surgical abortion; the physician documented a uterine perforation occurred during the suction part of the abortion procedure; MR1 was transferred to the local hospital for further evaluation and treatment and MR1 required surgical intervention for the uterine perforation. Review on November 30, 2017, of facility provided documentation revealed the facility determined MR1 experienced an event requiring the delivery of additional health care services and the facility determined MR1's event met the definition of a serious event. The facility was not able to provide documentation the patient received written notification regarding the serious event as required by the facility's Patient Safety Plan and Act 13, the	M 0032		

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M 0032	Continued from page 12 Medical Care Availability and Reduction of Error (MCare) Act, of the Commonwealth of Pennsylvania. Interview with EMP1 and phone interview with EMP2 on November 30, 2017, at approximately 12:25 PM confirmed MR1 experienced an event requiring the delivery of additional health care services, and MR1's event met the definition of a serious event. EMP2 confirmed the facility did not provide written notification to MR1 regarding this patient's serious event as required by the facility's Patient Safety Plan and Act 13, the Medical Care Availability and Reduction of Error (MCare) Act, of the Commonwealth of Pennsylvania.	M 0032		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - ALLENTOWN

STATE LICENSE NUMBER: 00218701

SURVEY EXIT DATE: 11/30/2017

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

THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY