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:	04/01/2014

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**

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M 0000	INITIAL COMMENT This report is the result of an annual Registration survey conducted on February 27, 2014, at the Planned Parenthood of Northeast and Mid-Penn - Allentown Health Center. It was determined the facility was not in substantial 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	The Patient Safety Officer and Associate Medical Director of Planned Parenthood Keystone (PPKey) have always carefully reviewed the Patient Safety Authority definitions of serious event and incident reports, and had previously determined that this event did not constitute a serious event or an incident. This was based upon a review of the patient safety reporting system, indicating that an incident needs to have ALL of the following components: involved the clinical care of a patient in a medical facility (yes), compromised patient safety (no), resulted in an unanticipated injury that required additional health care services (no). Abnormal bleeding after a surgical abortion is not unusual nor is it unanticipated. It has been PPKey policy to report on incidents that have compromised patient safety or resulted in an unanticipated injury (e.g. perforated uterus or hemorrhaging requiring a blood transfusion).	Completion Date: **04/10/2014** Status: **APPROVED** Date: **05/08/2014**

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M 0032	Continued from page 2	M 0032	In response to a recent communication from officials at the Department of Health , Planned Parenthood Keystone will modify its current practice to include reporting on any ambulance transfer as a serious event. This will begin 04/10/14 The Center Manager or Regional Manager of the facility will be responsible to report any ambulance transfer , in addition to any other action that may compromise patient safety to the Patient Safety Officer and/or the Associate Medical Director. The Patient Safety Officer and Associate Medical Director will review the case and submit a report to the Patient Safety Authority in the time frame required. A Plan of Correction will be determined and communicated to the PPKey medical facility involved. The Plan of Correction will also be discussed at the Abortion Center Managers' regular conference call and be added to the agenda of both the Patient Safety Committee and the	

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M 0032	Continued from page 3	M 0032	Risk and Quality Management committee meetings. Those committee agenda results are also shared at the affiliate's Board of Directors meetings. This will be monitored by the Regional Managers. Failure to file events as specified will result in disciplinary action Findings re storage of charts: 1) Lids were immediately placed on the box containing file folders while the surveyors were on site. 2) The file folder boxes will be moved by 4/18/14 to another location which is secure from water damage – a locked office. This will be carried out by the Center Manager and monitored by the Regional Manager. 3) Failure to secure confidentiality and safety of files will result in disciplinary action	

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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 of Northeast, Mid-Penn, and Bucks County Planned Parenthood Central 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	M 0032		

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M 0032	Continued from page 5 discontinuation or significant disruption of a service 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 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	M 0032		

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M 0032	Continued from page 6 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 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 transfer from the facility to an acute care hospital	M 0032		

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M 0032	Continued from page 7 emergency department was reported to the Department for one of one medical records reviewed (MR6). Findings include: Review on February 27, 2014, of the facility's "Patient Safety Plan," dated January 2013, revealed "Describe responsibilities of the PSO [Patient Safety Officer] 1. To handle all reports of serious events within 24 hours 2. To ensure the investigation of all reports of incidents and serious events 3. To take action as is immediately necessary to ensure patient safety against any harm identified from the investigation of a report of an incident or serious event which includes developing a plan, notifying PSA [Patient Safety Authority] (if appropriate) and providing written notification o [sic] the patient of a serious event within 7 days (as per 40 PS.1303.302, 35PS 10101-10105, 18 Ps C.S.A. 3206) 4. Report to the PSC [Patient Safety Committee] regarding any action taken to promote patient safety as a result of an investigation of a report of an incident or serious event. ..."	M 0032		

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M 0032	Continued from page 8 Review of MR6 on February 27, 2014, revealed the patient presented to the facility on March 15, 2013, for an elective in-clinic abortion. CF1 performed internal suction and documented no products of conception were found. CF1 requested an ultrasound be performed. Further review revealed CF1 documented the patient's uterus was empty. CF1 completed a second internal suction of the patient's uterus. CF1 documented no products of conception were found and requested a second ultrasound be performed. CF1 documented no products of conception were found. Continued review of MR6 revealed the patient began with excessive bleeding with noticeable large clots. CF1 instructed CF2 to administer Methergine (medication used to manage hemorrhage) 0.2 milligrams (mg) intramuscularly (IM). The patient's excessive bleeding continued and CF1 instructed EMP3 to call 911 to request ambulance transport of MR6 to the hospital's emergency department (ED). Interview with EMP2 and EMP3 on February 27,	M 0032		

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M 0032	Continued from page 9 2014, at approximately 2:00 PM confirmed CF1 performed internal suction two times on MR6, and each time there were no products of conception found. Continued interview confirmed the patient had excessive bleeding, was given Methergine, and transferred to the hospital ED for excessive bleeding following an in-clinic abortion. A request was made of EMP1 and EMP2 on February 27, 2014, for the facility's internal investigation and the facility's report of MR6's transfer from the facility to an acute care hospital emergency department. No investigation or facility report to the Department or Patient Safety Authority were provided. Phone interview with EMP1 on February 27, 2014, at approximately 2:15 PM revealed if the facility did submit this occurrence, it would have been submitted as an incident and not a serious event. _____	M 0032		

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M 0032	Continued from page 10 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 of Northeast, Mid-Penn, and Bucks County Planned Parenthood Central 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 310. Patient safety committee. (b) Responsibilities.--A patient safety committee of a medical facility shall do all of the following: (1) Receive reports from the patient safety officer pursuant to section 309. (2) Evaluate investigations and actions of the patient safety officer on all reports. (3) Review and evaluate the quality of patient safety measures utilized by the medical facility. A review shall include the consideration of reports made	M 0032		

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M 0032	Continued from page 11 under sections 304(a)(5) and (b), 307(b)(3) and 308(a). (4) Make recommendations to eliminate future serious events and incidents. (5) Report to the administrative officer and governing body of the medical facility on a quarterly basis regarding the number of serious events and incidents and its recommendations to eliminate future serious events and incidents. 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 review, evaluate and make recommendations regarding a patient's transfer from the facility to an acute care hospital emergency department for one of one medical records reviewed (MR6). Findings include: Review on February 27, 2014, of the facility's "Patient Safety Plan," dated January 2013, revealed	M 0032		

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M 0032	Continued from page 12 "... Responsibilities 1. Receive reports/investigations and log for PSO [Patient Safety Officer] 2. Evaluate any investigations 3. Review [and] evaluate the quality of patient safety measures utilized by the agency 4. Establish a system for health care workers to reports serious events and incidents 24/7 ..." Review of MR6 on February 27, 2014, revealed this patient presented to the facility on March 15, 2013, for an elective in-clinic abortion, this patient began with excessive bleeding with noticeable large clots and was transported by ambulance transport to the hospital emergency department (ED). A request was made of EMP1 and EMP2 on February 27, 2014, for the facility's internal investigation and the facility's report of MR6's transfer from the facility to an acute care hospital emergency department. No investigation or report to the Department and Patient Safety Authority were provided. Review on February 27, 2014, of the facility's	M 0032		

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M 0032	Continued from page 13 Patient Safety Committee Meeting minutes from January 2013 through January 2014 revealed no documentation MR6's transfer to the hospital ED was discussed at the facility's Patient Safety Committee meeting or that the facility reviewed, evaluated or made recommendations regarding MR6's excessive bleeding following an in-clinic abortion. Interview with EMP2 and EMP3 on February 27, 2014, at approximately 2:25 PM confirmed the facility's Patient Safety Committee Meeting minutes did not include a discussion regarding MR6's transfer to the hospital ED or that the facility reviewed, evaluated or made recommendations regarding MR6's excessive bleeding following an in-clinic abortion. _____ Based on review of facility documents, observation and staff interview (EMP), it was determined the facility failed to ensure patient medical records were	M 0032		

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M 0032	Continued from page 14 stored in a manner to protect from damage. Finding include: Review on February 27, 2014, of the facility's "Abortion Medical Records" policy, last revised June 2012, revealed "Policy: A confidential medical record is established for every client. The medical record will be completed accurately and legibly at each patient encounter, and will be stored in a secure and confidential manner that is consistent with HIPAA regulations. ..." 1) Observation of the facility's storage room on February 27, 2014, revealed eight boxes containing file folders labeled with patient names on a plastic shelving unit. Further observation revealed the name of the patient on the first file folder was clearly visible. Interview with EMP2 and EMP3 on February 27, 2014, at the time of the observation revealed these file folders contain information of patients who had	M 0032		

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M 0032	Continued from page 15 abortions over the last three years. Further interview with EMP2 confirmed these boxes containing confidential patient information should be covered with a box cover to protect patient privacy and prevent disclosure of a patient's name. 2) Observation of the facility's storage room on February 27, 2014, revealed three water-stained ceiling tiles directly above 59 storage boxes stored on plastic shelving units. Interview with EMP2 and EMP3 on February 27, 2014, at the time of the observation revealed these file folders contain information of patients who had abortions over the last three years. Further interview with EMP2 and EMP3 confirmed these boxes containing patient medical records were not stored in a manner to protect from water damage.	M 0032		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - ALLENTOWN

STATE LICENSE NUMBER: 00218701

SURVEY EXIT DATE: 04/01/2014

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