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:	03/15/2018

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 March 15, 2018, at Planned Parenthood Keystone - Allentown (PPKey-Allentown). 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 0013		M 0013		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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M 0013	Continued from page 1 29.33(13) Requirements for Abortion Each patient shall be supervised constantly while recovering from surgery or anesthesia, until she is released from recovery by a registered nurse or a licensed practical nurse under the direction of a registered nurse or a physician. The nurse shall evaluate the condition of the patient and enter a report of the evaluation and orders in the medical record of the patient. This REGULATION is not met as evidenced by:	M 0013	Planned Parenthood Keystone's policy referenced in this deficiency is acknowledged as being accurate. In addition to the statements referenced, later in the same policy it also states the following: "Upon admission to the post procedure room...Vital signs are to be taken at this time (BP and pulse) and recorded on the flow sheet in the patient's chart." For the two patients referenced, vitals were taken by the licensed nurse under her login. This is evidence the nurse was present in the post procedure room as policy states. This was not adequately explained to surveyors at the time of the visit so there will be a training for the facility manager on how to illustrate compliance to policy and regulation. Additional training will be provided to licensed post procedure room staff. During this training, there will be instructions provided about an additional click in our electronic health record system that will	Completion Date: **04/30/2018** Status: **APPROVED** Date: **04/18/2018**

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M 0013	Continued from page 2	M 0013	provide an extra layer of assurance to surveyors of their presence in the post procedure room. This will be represented on the visit summary of each patient to whom we provide this service. Trainings will be completed by 4/30/2018 and an effectiveness check will be conducted by the Director of RQM by 5/30/2018 which will be comprised of a chart audit to verify the clicks are being made to ensure proper documentation. Findings will be reported to the CEO	

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M 0013	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 a licensed nurse was in attendance in the recovery room during the time the patient was recovering following a surgical abortion for two of 16 medical records reviewed (MR10 and MR15). Findings include: Review on March 15, 2018, of the facility's "Post Procedure Room and Patient Discharge" policy, effective December 27, 2017, revealed "Policy: To ensure that patients who receive an in-clinic abortion are stable to discharge from the facility. ... procedures: 1. At a minimum, the post procedure room is to be staffed by a licensed nurse. ... 5. A licensed health professional must staff the post procedure room and must not be assigned to any other duties or tasks that would interrupt or compromise the continuous observation and monitoring of recovering patients. ..."	M 0013		

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M 0013	Continued from page 4 Review of MR10 and MR15 on March 15, 2018, revealed these patients had surgical abortions at this facility. There was no documentation in MR10 and MR15 indicating a licensed nurse was in attendance in the recovery room following these patients' surgical abortion. Interview with EMP2 on March 15, 20128, at approximately 12:15 PM confirmed MR10 and MR15 had surgical abortions at this facility, and there was no documentation in these patient's medical records indicating a licensed nurse was in attendance in the recovery room following MR10 and MR15's surgical abortion.	M 0013		
M 0032		M 0032		

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M 0032	Continued from page 5 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	HibiClens is used in many amubulatory surgical facilities as well as hospitals. The type of procedures we perform do not involve electrocautery surgical devices which is where most of the risk is incurred with alcohol based pre-surgical preparations. To decrease the minimal risk to patients to zero, Planned Parenthood Keystone has decided in favor of a system-wide discontinuation of the use of HibiClens at all of its facilities. Sequestering of the product within the centers will be completed by 4/20/2018. We are currently working with our disposal company to arrange for a pick-up of the product. While we still await confirmation of a date, we will be supplied with evidence of the removal of the product as well as final disposition once completed. The Director of RQM or designee will ensure this process is complete by site inspection and review of documentation from disposal	Completion Date: **05/01/2018** Status: **APPROVED** Date: **04/18/2018**

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M 0032	Continued from page 6	M 0032	company.	

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M 0032	Continued from page 7 Based on review of facility documents, observation tour, and staff interview (EMP), it was determined the facility failed to ensure only nonflammable agents were used for pre-surgical skin preparations. Findings include: Review on March 14, 2018, of the "Safety Data Sheet," dated revised October 16, 2014, for "Product Name Hibiclens" revealed "...2. Hazards Identification Flammable liquids ... Keep away from heat/sparks/open flames/hot surfaces. ... Wear protective gloves/protective clothing/eye protection/face protection ... 3. Composition/Information On Ingredients Chemical Name Isopropyl alcohol ... 5. Fire-Fighting Measures Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical. Carbon dioxide (CO2). Water spray. Alcohol resistant foam. ... Specific Hazards Arising from the Chemical Keep product and empty	M 0032		

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M 0032	Continued from page 8 container away from heat and sources of ignition. ..." Observation tour on March 14, 2018, at approximately 10:45 AM revealed two 16-fluid ounce bottles of Hibiclens (chlorhexidine gluconate solution 4.0%) located in a storage cabinet in each procedure room. Interview with EMP1 on March 14, 2018, at approximately 10:45 AM confirmed there were two 16-fluid ounce bottles of Hibiclens in the storage cabinets in each procedure room. Interview with EMP3 on March 14, 2018, at approximately 11:45 AM revealed Hibiclens was used by the physician to prep the cervix prior to the surgical procedure. The surveyor requested a policy from EMP1 regarding Hibiclens being used as a surgical prep. No policy was provided related to Hibiclens being	M 0032		

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M 0032	Continued from page 9 used as a surgical prep.	M 0032		
M 3205		M 3205		

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M 3205	Continued from page 10 3205 Informed Consent 3205 Informed consent (a) General rule.--No abortion shall be performed or induced except with the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if and only if: (1) At least 24 hours prior to the abortion, the physician who is to perform the abortion or the referring physician has orally informed the woman of: (i) The nature of the proposed procedure or treatment and of those risks and alternatives to the procedure or treatment that a reasonable patient would consider material to the decision of whether or not to undergo the abortion. (ii) The probable gestational age of the unborn child at the time the abortion is to be performed. (iii) The medical risks associated with carrying her child to term. (2) At least 24 hours prior to the abortion, the physician who is to perform the abortion or the referring physician, or a qualified physician assistant, health care practitioner, technician or social worker to whom the responsibility has been delegated by either physician, has informed the pregnant woman that: (i) The department publishes printed materials which describe the unborn child and list agencies which offer alternatives to abortion and that she has a right to review the printed materials and that a copy will be provided to her	M 3205	Planned Parenthood Keystone during its counseling processes discusses all pregnancy options with the patient as a part of the 24 hour consent process. During the 24 hour counseling visit, the consent that contains the check box indicating whether the patient chose to receive the state's materials or chose not to receive the state's materials was not checked. It is however important to note that the 24 hour consent form was signed by the patients and witnessed by staff that this counseling session, including a consultation from the provider, was completed. To ensure proper documentation with respect to state related materials check box, on 3/29/2018 there was a retraining of all center staff on the importance of ensuring these check boxes have been clicked. As an extra measure, we had a system-wide retraining for all facility managers on 3/26/2018 on the importance of verifying this click has been made on	Completion Date: **04/30/2018** Status: **APPROVED** Date: **04/16/2018**

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M 3205	Continued from page 11 free of charge if she chooses to review it. (ii) Medical assistance benefits may be available for prenatal care, childbirth and neonatal care, and that more detailed information on the availability of such assistance is contained in the printed materials published by the department. (iii) The father of the unborn child is liable to assist in the support of her child, even in instances where he has offered to pay for the abortion. In the case of rape, this information may be omitted. (3) A copy of the printed materials has been provided to the pregnant woman if she chooses to view these materials. (4) The pregnant woman certifies in writing, prior to the abortion, that the information required to be provided under paragraphs (1), (2) and (3) has been provided. This REGULATION is not met as evidenced by:	M 3205	the 24 hour consent documentation. To follow-up on these retrainings, The Director of RQM will conduct an audit on the 24-hour consent visits to ensure we are achieving compliance on 4/30/2018 and will report findings to the CEO.	

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M 3205	Continued from page 12 Based on review of facility documents, medical records (MR) and staff interview (EMP), it was determined the facility failed to ensure women presenting to the facility for an abortion were provided the Department of Health printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; the right to review the printed materials; and a copy will be provided to her free of charge if she chooses to review it, for six of 16 medical records reviewed (MR6, MR7, MR9, MR12, MR15 and MR16). Findings include: Review on March 15, 2018, of the facility's "24 Hour Consent" policy effective January 10, 2018, revealed "Policy: In the state of Pennsylvania, the law requires that the following information is provided to patients who have either expressed interest in learning about abortion as an option or who have made the decision to have an abortion: 1. Types of abortion procedures, how they are performed as well as the risk and alternatives to an	M 3205		

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M 3205	Continued from page 13 abortion. 2. The probable gestational age of the fetus at the time of the abortion procedure and the medical risk of carrying the pregnancy to term are explored. ... Procedures: ... 8. Offer state materials to all patients. ..." Review on March 15, 2018, of the facility's "Proof of Compliance with 24 Hour Waiting Period" form, no review date, revealed "... I am satisfied with the information provided by the physician. I further state that at least 24 hours before the abortion I was informed by a physician or health care worker delegated by the physician that: The state publishes materials, which describe developmental stages of the fetus. They also list agencies, which offer alternatives to abortion. I have the right to review and/or receive these printed free of charge. ..." There was a block for the patient to check in front the following statement: "I chose not to receive the materials." There was a second block for the patient to check in front of the following statement: "I asked for and received a copy of the materials."	M 3205		

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M 3205	Continued from page 14 Review of MR6 on March 15, 2018, revealed the patient was admitted to the facility on January 30, 2018. The Proof of Compliance with 24 Hour Waiting Period form in MR6 revealed both check blocks were blank. There was no documentation in MR6 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses. Review of MR7 on March 15, 2018, revealed the patient was admitted to the facility on February 1, 2018. The Proof of Compliance with 24 Hour Waiting Period form in MR7 revealed both check blocks were blank. There was no documentation in MR7 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials	M 3205		

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M 3205	Continued from page 15 which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses. Review of MR9 on March 15, 2018, revealed the patient was admitted to the facility on February 12, 2018. The Proof of Compliance with 24 Hour Waiting Period form in MR9 revealed both check blocks were blank. There was no documentation in MR9 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses. Review of MR12 on March 15, 2018, revealed the patient was admitted to the facility on February 9, 2018. The Proof of Compliance with 24 Hour	M 3205		

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M 3205	Continued from page 16 Waiting Period form in MR12 revealed both check blocks were blank. There was no documentation in MR12 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses. Review of MR15 on March 15, 2018, revealed the patient was admitted to the facility on February 2, 2018. The Proof of Compliance with 24 Hour Waiting Period form in MR15 revealed both check blocks were blank. There was no documentation in MR15 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if	M 3205		

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:	03/15/2018

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 3205	Continued from page 17 she chooses. Review of MR16 on March 15, 2018, revealed the patient was admitted to the facility on February 9, 2018. The Proof of Compliance with 24 Hour Waiting Period form in MR16 revealed both check blocks were blank. There was no documentation in MR16 the patient chose not to receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses. Interview with EMP2 on March 15, 2018, at approximately 12:00 PM confirmed MR6, MR7, MR9, MR12, MR15 and MR16 presented to the facility for an abortion and signed the 24 hour waiting period form. EMP2 confirmed there was no documentation in MR6, MR7, MR9, MR12, MR15 and MR16's indicating the patients chose not to	M 3205		

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: _____	03/15/2018

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 3205	Continued from page 18 receive the materials or asked for and received a copy of the materials, i.e. the Department of Health's printed materials which describe the unborn child; the list of agencies which offer alternatives to abortion; that the patient had a right to review the printed materials and that a copy will be provided to the patient free of charge if she chooses.	M 3205		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - ALLENTOWN

STATE LICENSE NUMBER: 00218701

SURVEY EXIT DATE: 03/15/2018

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

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