STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
		A. BLDG: 00 B. WING:	10/23/2013

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
PLANNED PARENTHOOD OF WESTERN PENNSYLVANIA, INC. STATE LICENSE NUMBER: **00248701**	**933 LIBERTY AVENUE PITTSBURGH, PA 15222**

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M 0000	INITIAL COMMENT This report is the result of the annual registration survey conducted on October 23, 2013, at Planned Parenthood of Western PA (WHS). It was determined the facility was 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		

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

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S 0000	INITIAL COMMENT This report is the result of a full State Licensure survey conducted on October 23, 2013, at Planned Parenthood of Western PA (WHS). 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 0000		
S 0110		S 0110		

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S 0110	Continued from page 1 551.21 (e)(1-3) Criteria for ambulatory surgery 551.21 Criteria for ambulatory surgery (e) In obtaining informed consent, the practitioner performing the surgery shall be responsible for disclosure of: (1) The risks, benefits and alternatives associated with the anesthesia which will be administered. (2) The risks, benefits and alternatives associated with the procedure which will be performed. (3) The comparative risks, benefits and alternatives associated with performing the procedure in the ambulatory surgical facility instead of in a hospital. This REGULATION is not met as evidenced by:	S 0110	The Client Information for Informed Consent (CIIC), created and amended by the Planned Parenthood Federation of America (PPFA) after the last survey and the deficiency with PA DOH observations were sent on 10/28/13, to our Consortium of Abortion Providers to assist with further modifications and PPFA approval because Planned Parenthood affiliates are not permitted to independently modify any of the CIIC's for any services. The modified CIIC was approved on 11/5/13 and was implemented on the next day of service, 11/9/13. The new CIIC's include the risks, benefits, and alternatives to having the procedure performed in an ASF versus the hospital. The Surgical Site Supervisor will conduct an audit of 100% of the surgical abortion electronic medical records for three months to monitor that the correct CIIC's are being utilized. The PPWP RQM Oversight Committee will be informed of the change and the Governing Body will be made aware of the deficient practice and	Completion Date: **11/30/2013** Status: **APPROVED** Date: **11/19/2013**

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S 0110	Continued from page 2	S 0110	corrective action. If audit results are less than 100%, future monitoring will be based on the actual results and recommendations of the Risk and Quality Management Oversight Committee.	

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S 0110	Continued from page 3 Based on review medical records (MR) and staff interviews (EMP), it was determined the facility staff failed to ensure that informed consent forms contained the risks, benefits and alternatives associated with performing the procedure in the ambulatory surgical facility instead of in a hospital for 20 of 20 closed medical records. (MR1 - MR20). Findings include. On October 24, 2013, at 2:00 PM, the facility's policy, "Abortion Section Surgical Abortion Services - PPWP," revised December 2012, was reviewed. The policy states, " ... Informed Consent Process ... In obtaining the informed consent, the physician performing the surgery is responsible for disclosure of: ... 3. The comparative risks, benefits, and alternatives associated with performing the procedure in an ASF instead of in a hospital ... " 1. Review of the facility's consent form titled, "Client Information for Informed Consent," states, " ...	S 0110		

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S 0110	Continued from page 4 Besides an in-clinic abortion, what other choices do I have? ... You can also have an abortion in a hospital or by another doctor, now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion ..." 2. Review of medical records, on October 23, 2013, at approximately 12:00 PM, revealed consent forms for MR1 - MR20, did not include the risks, benefits and alternatives associated with performing the procedure in the ambulatory surgical facility instead of in a hospital. 3. Interview with EMP2 on October 23, 2013, at approximately 2:00 PM confirmed the above findings and revealed, " ... Our Legal team put the verbiage in "... You can also have an abortion in a hospital or by another doctor now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion,] to satisfy that regulation." Repeat deficiency	S 0110		

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S 0110	Continued from page 5	S 0110		
S 0142		S 0142		

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S 0142	Continued from page 6 551.52 ASF Responsibilities 551.52 ASF Responsibilities An ASF shall comply with applicable standards which are required by Federal, State, and local authorities. This includes, but is not limited to, standards at 49 Pa. Code Chapters 17, 21 and 27 (relating to State Board of Medicine, Nursing and Pharmacy) in addition to standards related to radiologic health, sanitation, food, service, electric wiring and life safety code compliance. When the ASF has been inspected by another regulatory agency, it shall have available during the survey by the Department written confirmation of compliance as required by the other regulatory agency. This REGULATION is not met as evidenced by:	S 0142	Staff training has been conducted by the CEO for all supervisors regarding the procedures for the collection and review of background check results. Supervisors have been instructed that the original background check must be reviewed, and the original or copy retained in the personnel file must be dated and initialed by the supervisor who reviewed the documents. 100% of new employee personnel files will be audited for six months from the date of the survey to ensure the procedure is followed. The administrative assistant will be responsible for the audit and maintain an audit record documenting whether background checks were reviewed according to procedure. The results of the audit will be submitted to the Risk and Quality Management Committee for further recommendations on monitoring frequency.	Completion Date: **11/30/2013** Status: **APPROVED** Date: **11/19/2013**

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S 0142	Continued from page 7 Based on review of facility documents and staff interviews (EMP), it was determined the facility failed to conform to all applicable State laws. The facility was not in compliance with the following State law: The Child Protective Services Law (CPSL), 23 Pa. C.S. §6344.2 requires that employees hired after July 1, 2008, who have a significant likelihood of regular contact with children in the form of care, guidance, supervision, or training must obtain three background checks as condition of employment: Pennsylvania State Police Clearance, Department of Public Welfare (DPW) Childline Clearance and Federal (FBI) Criminal Background Check. Act 179 of 2006 and Act 73 of 2007 amended the Child Protective Services Law (CPSL). CSPL now requires that hospital and ambulatory surgical facility (ASF) employees hired after July 1, 2008 that have "significant likelihood of regular contact with children	S 0142		

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S 0142	Continued from page 8 in the form of care, guidance, supervision or training" obtain three background checks as a condition of employment: To assure compliance with the requirements of the Law, facilities must: ... Retain a copy of each of the background clearances and notate that the original documents have been reviewed. This is not met as evidenced by: Based on review of facility documents and personnel files (PF), and staff interview (EMP), it was determined that the facility failed to notate that the original documents [background checks] have been reviewed in two of 3 personnel files (PF2, and PF3). Findings Include: Review of "References, Pre-Employment Testing and Background Checks" no date provided revealed, "6. A copy of the background and	S 0142		

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S 0142	Continued from page 9 reference checks must be filed in the employee personnel file. The original document must be reviewed by a supervisor. If a copy and not the original of the background check is retained for the personnel file, it must be notated on the copy by responsible staff that the original document has been reviewed..." 1. On October 23, 2013, PF review revealed that PF2, and PF3, did not contain evidence that the original CPSL background check document was reviewed. 2. EMP1 confirmed the above and stated, "I didn't know that I supposed to notate that I saw the originals."	S 0142		

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S 6124	561.11 Pharmaceutical Facilities - Principle 561.11 Principle The ASF shall provide equipment and supplies for the pharmaceutical service to implement its professional and administrative functions and to ensure patient safety through the proper storage and dispensing of drugs. Facilities shall be provided for the storage, safeguarding, preparation, and dispensing of drugs. This REGULATION is not met as evidenced by:	S 6124	The Surgical Site Supervisor educated all staff responsible for noting temperatures and correcting improper temperatures about the issue and what actions they need to take in order for the issue to be resolved (see below) on (10/23/13.) Responsible staffs are health care assistants that have lab duties, the Physician Assistant and Clinic Coordinators. - A corrective action sheet was posted next to the temperature log to detail when corrective actions are taken and the resulting outcome (10/23/13) - The Surgical Site Supervisor will conduct a once daily audit to ensure that staff are recording temperatures within acceptable limits for three months. The audit will begin on 10/24/13 and conclude on 1/27/14. Expected compliance is 100% The results of monitoring will be shared with the RQM oversight and governing body. If audit results are less than 100%, future monitoring will be based on the actual results and recommendations of the Risk and Quality Management Oversight Committee.	Completion Date: **11/30/2013** Status: **APPROVED** Date: **11/19/2013**

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S 6124	Continued from page 11 Based on review of facility documents, observation and employee interviews (EMP), it was determined that the facility failed to maintain medications within the recommended temperature ranges noted on the manufacturer packaging for four out of four medications. Findings include: 1. Review of the facility policy on October 23, 2013, at approximately 11:30 AM, "Pharmaceutical Services" updated on June 2012, revealed, " ... b. The following drug/products must be stored in the refrigerator (36 F -45 F)." 2. Tour of the fourth floor on October 23, 2013, at 10:30 AM revealed a medication refrigerator containing Promethegan (Phenergan), Methergine (Methylergonovine Maleate), and Rho(D) Immune Globulin and Phenadoz (Promethegan rectal). The manufacturer label on all of the listed medications indicated, "store at 2-8 degrees C (36-44 F)."	S 6124		

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S 6124	Continued from page 12 3. A review of the temperature log for the medication refrigerator revealed, "Report Readings Outside of Acceptable Limits As Out of Control Condition...Acceptable Limits: 36 to 44 F ..." Further review of the log temperatures for June 2013 revealed 9 out of 24 days to be below 36 degrees Fahrenheit. Review of the log temperatures for July 2013, revealed 16 out of 23 days below 36 degrees Fahrenheit. Review of August temperatures revealed 23 out of 23 days that the temperature was below the acceptable limit. Review of September 2013 revealed that 25 out of 25 days that the temperatures were below the acceptable limits, and the log for October revealed 18 out of 18 days that the medications were stored below the acceptable ranges. During an interview on October 23, 2013, at approximately 10:40 AM, EMP1 confirmed that the temperatures on the refrigerator log were below the acceptable levels.	S 6124		

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S 6124	Continued from page 13	S 6124		

Certified End Page

PLANNED PARENTHOOD OF WESTERN PENNSYLVANIA, INC.

STATE LICENSE NUMBER: 00248701

SURVEY EXIT DATE: 10/23/2013

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

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