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:	08/22/2011

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
PLANNED PARENTHOOD KEYSTONE - WARMINSTER STATE LICENSE NUMBER: **00188701**	**610 LOUIS DRIVE SUITE 301 WARMINSTER, PA 18974**

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M 0000	INITIAL COMMENT This report is the result of an unannounced initial registration survey conducted on August 22, 2011, at the Planned Parenthood Association of Bucks County. It was determined that 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. Additional recommendations were provided to the facility in Tag 9999 - Recommendations. The facility is encouraged to provide a plan of correction.	M 0000		
M 0007		M 0007		

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

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M 0007	Continued from page 1 29.33(7) Requirements for Abortion Rho (D) - - immune globin (human) shall be administered to each Rh-negative patient at the time of any abortion, unless contraindicated. Evidence of compliance with this paragraph shall appear in the medical record of the patient. If for any reason the patient refuses the administration of Rh immune globulin when recommended, this refusal shall be noted in the clinical record of the patient. This REGULATION is not met as evidenced by:	M 0007	Planned Parenthood Association of Bucks County (PPABC) has entered into a management contract with a neighbor affiliate effective July 1, 2011. While all charts and practices reviewed during the survey were prior to the commencement of this contract, the corrective actions below are ones that the new management have determined appropriate to ensure that PPABC polices, procedures and practices are compliant with the requirements of the Pennsylvania Department of Health Regulations § 28 Pa Code, Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. All staff will be retrained to ensure compliance. Completing and monitoring this plan of corrective action is the responsibility of the Vice President for Medical Services and the Associate Medical Director. The	Completion Date: **10/21/2011** Status: **APPROVED** Date: **09/29/2011**

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M 0007	Continued from page 2	M 0007	plan will be shared with the PPABC Board of Directors and the board will be kept apprised of its status. M 0007 29.33(7) 1)PPABC has policies and procedures for Rhogam administration. PPABC Medical Standards and Guidelines VII-A-1-page 9. They will be reviewed and revised (where necessary) by Associate Medical Director and Director of Center Operations. Training to medical center staff will be provided by the Associate Medical Director. - Audits will be added to the Risk & Quality Management calendar and performed weekly by RQM Coordinator for three months. -Any non-compliance will have a required action plan and will be re-audited more frequently. -All non-compliance will be on the agenda of the Patient Safety Committee -Non-compliance by staff will result	

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M 0007	Continued from page 3	M 0007	in disciplinary action consistent with PPABC personnel policies. 2)Both patients associated with the records cited as lacking documentation have been contacted three times as per PPFA (Planned Parenthood Federation of America) notification protocols. The patients have not responded to this notification. -The issue was reported to the Patient Safety Committee August 29, 2011 -To ensure there are two "flags" for Rh negative patients, they will have their chart in a color-coded jacket. -To ensure accountability for administering Rhogam , it will be given in the recovery room and be the responsibility of the recovery room nurse. 3) No action needed	

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M 0007	Continued from page 4 Based on review of medical records and interview with staff (EMP), it was determined that the facility failed to ensure that there was documentation of Rhogam administration to Rh negative patients for two of sixteen medical records reviewed. (MR1, MR6) Findings include: 1) Surveyor requested facility policies and procedures during the survey for Rhogam administration. None were provided. 2) Review of MR1 and MR6 revealed that these patients had no documented evidence that Rhogam was administered for these RH-negative patients. 3) Interview with EMP2 on August 23, 2011, at approximately 2:00 PM confirmed that there was no documented evidence of of Rhogam administration for the RH-negative patients in MR1 and MR6.	M 0007		

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M 9999		M 9999		

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M 9999	Continued from page 6 Recommendation This REGULATION is not met as evidenced by:	M 9999	M 9999 Patient care was never compromised in this regulation, yet PPABC intends to address all of these issues in a swift and appropriate manner to ensure complete compliance. 1) * Training Manager will review (and revise where necessary) all storage policies (food, equipment and medications) and an audit will be done monthly by the Risk & Quality Management (RQM)Coordinator. * Training Manager will provide repeat training to the PPABC staff on confidentiality. Periodic walk-through audits by the RQM Coordinator will be performed. - The succinylcholine has been disposed of and is no longer a component of the emergency kit. * The equipment temperature range log	Completion Date: **10/21/2011** Status: **APPROVED** Date: **09/29/2011**

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M 9999	Continued from page 7	M 9999	policy was reviewed with PPABC staff by the PPABC Medical Services Project Manager and the RQM Coordinator will audit it monthly. NOTE: Patient nutrition refrigerator contains soda which does not need to have temperature regulated. 2) - Equipment logs are reviewed by PPABC staff for service dates -Service has been requested for the ultra-sound machines. -AED has new pads - All expired drugs and equipment were disposed of immediately by PPABC staff. - The expired drug policy will be reviewed and revised (as necessary) and an update will be presented to staff by Associate Medical Director.	

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M 9999	Continued from page 8	M 9999	* The PPABC Medical Services Project Manager will review the monthly equipment and drug check list with PPABC staff. The RQM Coordinator will audit it monthly - Conscious sedation services were suspended after this audit until management could be assured that all proper drug protocols were in place, staff trained, and procedures tested for compliance - A revised drug/narcotics policy is being developed by Associate Medical Director and Chief Operating Office. -The Training Manager and Associate Medical Director will ensure that all staff working in abortion care facility have mandatory training on the new policy before conscious sedation services are resumed. - The emesis basin was discarded by PPABC staff as the stains could not	

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M 9999	Continued from page 9	M 9999	be removed. Disposable cups will be used for betadine solution due to its staining property. 3) - The PPABC Medical Services Project Manager reviewed all storage regulations with staff and supplies have been moved to their proper locations. NOTE: The policy and procedure for washing/drying linens was presented to the inspection team during the inspection. 4) - All expired drugs and equipment were disposed of. - The expired drug policy will be reviewed and revised (as necessary) and an update will be presented to staff by Associate Medical Director. - All instruments have been properly sterilized and labeled according to PPABC Infection	

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M 9999	Continued from page 10	M 9999	Control Manual (Chapter 5) -The RQM Coordinator will do a weekly audit for three months. - The four colored speculums are specialty speculums that are specifically coated for use during LEEP procedures to prevent conduction of electricity. NOTE: Plastic urinal was previously used to hold cidex (a disinfectant) for the ultra-sound probe; cleaning and disinfectant has been changed to a spray and probe covers 5) - The PPABC Medical Services Project Manager will review the cleaning contract and meet with the contractor to discuss major cleaning to include pulling equipment from walls on a regular basis. - The 2nd balancing tube has been ordered. NOTE: It is recommended to use another tube filled with water (no	

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M 9999	Continued from page 11	M 9999	special balancing tube is needed) as a counter balance in the centrifuge. Since Abortion services were not being provided on the day of the audit, there was no counter weight in the centrifuge. - PPABC staff has properly sanitized, sterilized and labeled all equipment and supplies according to PPABC Infection Control Manual procedures (Chapter 5). 6) - All first aid kit components are up to date - All food supplies and medical supplies have been separated -The RQM Coordinator will add this to the monthly facility audit. 7) - The PPABC staff have disposed of expired meds and supplies. - The expired drug policy will be reviewed and revised (as necessary)	

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M 9999	Continued from page 12	M 9999	and an update will be presented to staff by Associate Medical Director. - The RQM Coordinator will add this to the monthly facility audit. 8) No action needed 9) - PPABC staff has disposed of expired meds and supplies. - The expired drug policy will be reviewed and revised (as necessary) and an update will be presented to staff by Associate Medical Director. - A revised drug/narcotics policy is being developed by Associate Medical Director and Chief Operating Officer. -The Training Manager and Associate Medical Director will ensure that all staff working in the abortion facility have mandatory training on the policy before conscious sedation services are resumed.	

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M 9999	Continued from page 13	M 9999	- Finance staff compared orders, invoices and shipments to verify that there were no discrepancies between quantities ordered, shipped, and paid for. 10) No action needed 11) No action needed	

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M 9999	Continued from page 14 Based on an observation tour of the facility and interviews with staff (EMP), (OTH), it was determined that facility failed to maintain a safe and sanitary environment. Findings: Observation tour of the facility on August 22, 2011, between approximately 11:30 AM and 2:30 PM revealed: 1) Observation of the Recovery Room revealed the following: - Food was stored in cabinet with medical supplies. - Recovery Room schedule dated July 1, 2011, through July 28, 2011, with patient names was on the counter. - Succinylcholine 200 mg. 25 vials stored in the medication refrigerator were frozen. - Patient nutrition refrigerator did not have a temperature log.	M 9999		

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M 9999	Continued from page 15 2) Observation of the IV Sedation Room revealed: - Ultrasound equipment had a preventative maintenance sticker "Next due PM 3/5/10." - 3 Suture kits with expiration dates 1/14/11 - 2 packages of 6 Ft tubing with expiration dates 7/11 - vial of Naloxone HCL expired August 1, 2011 - one 250 ml bag of 0.9% Sodium Chloride had a taped label on it that read "Medication Added Epinephrine .3 mg/250 ml." The label was not completed for that date and time of the medication added. - one Fentanyl 2,500mcg/50 ml with 26 ml not dated when it was opened. - one Midazolam hydrochloride (Versed) not dated when it was opened. - one box of 10 multidose vials of Valium 5mg/ml, 10 ml each that was expired November 2010 (not logged in the "Controlled Drug Log" for the Locked Safe) and one unexpired box of Valium 100mg prefilled syringes, strength 10mg/2ml. These two different concentrations of Valium were documented	M 9999		

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M 9999	Continued from page 16 together on the IV Procedure Room "Controlled Drug Log" under the Propofol column. - EKG monitor had a preventative maintenance sticker with "Next inspection due 12/10." - one bottle of Betadine with expiration date of 5/5/11 - Automated External Defibrillator had expired pads. - cabinet contained a blue emesis basin with dried red brown flakes on the sides and bottom. - Lidocaine 2.5%/Prilocaine 2.5% cream expired September 2008. - three suture kits expired 3/11. 3) Observation of the Supply Closet/Laundry Area/Hallway/Biohazard Closet revealed: - Supply Closet had boxes stored directly on floor. - Supply Closet had paper and medical supplies stored directly underneath electrical/telephone panel. - Bleach stored directly on floor in Laundry Room. - Lint in the dryer in Laundry Room. - Policy and procedures were requested for washing/drying of linens. None was provided.	M 9999		

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M 9999	Continued from page 17 - A pair of socks were stored on the hot water heater in Laundry Room. - Box of IV tubing was stored on top of the water fountain in the hallway. - Container of Metricide in Biohazard Closet had an expiration date of 1/00. 4) Observation of the Local Anesthesia Room revealed: - Six Tegaderm dressings with expiration date 11/2005 - one Tegaderm dressing with expiration date 1/2005 - Exam table supply drawer had 8 speculums stored it; four of these speculums were blue/green colored and two of the four speculums had tan colored tape wrapped around parts of the equipment. - plastic bin labeled "Sterile Individual Wrapped Instruments" had wrapped speculum with expiration 8/11/11, one dilator with expiration 7/1/11, one forceps with 7/18/11 - Ultrasound equipment needed preventative maintenance sticker/documentation of service.	M 9999		

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(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 9999	Continued from page 18 - Plastic urinal on counter that was half filled with a green liquid and labeled "Cidex" that was used for cleaning of vaginal ultrasound probe. - Vaginal probe for the ultrasound equipment was stained with yellow, reddish pink color at the proximal end of the probe. - Ultrasound probe care log dated 8/19/11 at 1:15 PM was not documented for "Rinse with distilled water." There was documentation "test strips on order." - Two opened multidose sterile water bottles that were not dated. 5) Observation of the Sterilization Room revealed: - Specimen refrigerator had been pulled away from wall due to power outage. There was dust and debris in the area where the refrigerator had been located. - Lab equipment for spinning blood specimens was located in this area. The equipment contained only one balancing tube and not the required two. - one package labeled "Calpo" with expiration date 1/29/11	M 9999		

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: _____	**08/22/2011**

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M 9999	Continued from page 19 - one package labeled "FP Dilators" expired 2/4/11 - one gallon of enzymatic detergent not dated when opened. - Citraguard glass jars unlabeled and not dated. 6) Observation of the Laboratory Area revealed: - First Aid Kit contained one triple antibiotic ointment expired 4/2010, and one bottle of eye wash expired 1/11. - Five packets of triple antibiotic ointment expired 2/2010 - 12 antiseptic cleaning wipes expired 1/10 - 3 insect sting relief packages expired 3/11 - cabinets near the sink contained food with supplies on the 2nd shelf - orange/tangerine juice, and lollipop and candy sticks were located next to pregnancy tests. 7) Observation of the Ultrasound/Examination Room revealed: - Exam table had storage drawer that was against a heating pad wire. The heating pad located inside of the storage drawer contained paper on top of it to	M 9999		

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M 9999	Continued from page 20 warm speculums that were being stored. - two boxes of hemoccult test slides with expiration 2/11 - eight bottle of Ampicillin 500 mg capsules expiration date 7/11 8) Interviews with EMP1 and EMP2 on August 22, 2011, between approximately 10:45 AM and 3:00 PM confirmed the above findings during the observation tour. 9) Observation of the Locked Medication Storage Room revealed: - one bottle of Hibiclens with expiration 7/20/11 - The "Narcotics Control Log" from the locked safe had entry discrepancies versus the actual supply on hand. - The "Controlled Drug Log" from the locked safe contained entries dated 12/3/10, 12/31/10, 4/15/11, 4/29/11, 5/27/11, 6/3/11, 7/1/11. The "Controlled	M 9999		

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M 9999	Continued from page 21 Drug Log" from the locked medication storage in the IV Procedure Room contained entries dated 6/23/10, 7/1/11, 7/22/11, 7/29/11, 8/5/11, 8/12/11, 8/19/11. There was no documentation of a reconciliation of the movement of controlled drugs from the locked safe storage to the locked storage in the IV Procedure Room on the dates listed. - The "Controlled Drug Log" from the safe had a column labeled "Propofol" (Diprivan 20 mg) that was crossed out and labeled "Valium." There was no propofol supply onsite noted during the survey. (Reference #2) - Discrepancy was noted between "Controlled Drug Log" from the Locked Medication storage versus the actual on hand medication of 10 multidose vials of Valium 5mg/ml, 10 ml each that was expired November 2010. (Reference #2) - Discrepancy noted between "Controlled Drug Log" from Locked Medication storage and IV Sedation Room of one 50 ml multidose vial of	M 9999		

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M 9999	Continued from page 22 Fentanyl. 10) Telephone interview with OTH1 on August 22, 2011, at approximately 1:00 PM confirmed that propofol had not been used at the facility for approximately seven months. OTH1 confirmed that they and EMP1 reconcile the narcotic log every morning and it was correct. 11) Interview with EMP1 on August 22, 2011, at approximately 12:30 PM confirmed they forgot to make an entry into the inventory on the "Controlled Drug Log" for IV Sedation Room.	M 9999		

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M 9999	Continued from page 23	M 9999		

Certified End Page

PLANNED PARENTHOOD KEYSTONE - WARMINSTER

STATE LICENSE NUMBER: 00188701

SURVEY EXIT DATE: 08/22/2011

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

Michael Wolf

Michael Wolf
Acting Deputy Secretary For Quality Assurance

Eli N. Avila

Eli N. Avila, MD, JD, MPH, FCLM
Secretary of Health

Pennsylvania
Department of Health

THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY