Planned Parenthood
Care. No matter what.

Planned Parenthood of Greater Ohio

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July 13, 2018

Wanda L. Iacovetta, R.N., Supervisor
Ohio Department of Health
Office of Health Assurance and Licensing
246 North High Street
Columbus, OH 43215

RE: Planned Parenthood Bedford Heights – License: 1014AS
Survey Completed on May 1, 2018
Written Facility Inspection Report Received on July 5, 2018

Dear Ms. Iacovetta,

Planned Parenthood of Greater Ohio is committed to ensuring our patients receive safe, high quality health care, no matter what.

In compliance with Ohio's licensing requirements, attached you will find the completed Statement of Deficiency that contains Planned Parenthood's comprehensive plan of correction in response to the cited violations at our Bedford Heights surgical facility that we received on July 5, 2018.

The enclosed plan of correction details what actions Planned Parenthood has taken to correct the situation, and clearly identifies what systematic, ongoing processes will be launched in order to maintain our compliant status.

In support of our corrective action plan, you will also find supplementary documentation within the attachments that serves as additional evidence of Planned Parenthood's ongoing commitment to our patients and full compliance with the Ohio Revised Codes associated with Health Care Facilities.

Planned Parenthood looks forward to receiving your recommendation of ongoing licensure for our Bedford Heights Regional Medical Care Facility.

If you have any questions regarding our Plan of Correction and/or our documented evidence, please feel free to contact me at (330)535-2674 or Holly.Myers@ppoh.org.

Sincerely,

Holly Myers
Director of Compliance Risk and Quality Management

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	1014AS	A. BUILDING: _____ B. WING _____	05/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD BEDFORD HEIGHTS	25350 ROCKSIDE ROAD BEDFORD HEIGHTS, OH 44146

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C 000	Initial Comments Licensure Compliance Inspection Administrator: Naneesha Pitts County: Cuyahoga Number of ORs: 3 The following violations are issued as a result of the licensure compliance inspection completed on 05/02/18..	C 000	cooo As a preliminary matter, Planned Parenthood of Greater Ohio ("PPGO") respectfully requests that ODH's Summary Statement of Deficiencies be revised to accurately identify the total number of surgical procedures performed at the Bedford Heights facility from 04/01/17 - 3/31/18. On pages 1, 5, and 9 of the Summary Statement of Deficiencies, ODH states that the Bedford Heights facility conducted "a total of 6,213 surgical procedures between 04/01/17 - 03/31/2018" This statement is factually incorrect. Instead, the Bedford Heights facility only performed 1,561 surgical procedures out of a total of 2,657 total procedures for the time period between 04/01/17 - 03/31/18. This information was provided to the surveyors when they were on-site for the licensure survey and can be made available for further on-site review at the health center upon request by ODH.	
C 139	O.A.C. 3701-83-10 (B) Safety & Sanitation The HCF shall be maintained in a safe and sanitary manner. This Rule is not met as evidenced by: Based on observations and staff interview, the facility failed to ensure products used as skin dressings, for hand hygiene and disinfection of surfaces were not expired, and failed to ensure cardboard boxes were stored in a safe manner. This could potentially affect all patients in the facility. The facility conducted a total of 6,213 surgical procedures between 04/01/17-03/31/18. Findings include: On 05/01/18 between 9:02 AM and 10:35 AM a tour was conducted with Staff A, B and C. The following was observed on tour and confirmed with Staff A, B and C at the time of observations.	C 139		

Ohio Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Director of Compliance, Risk and Quality Management 7/13/18

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C 139	Continued From page 1 a) In the first floor receptionist office a container of Hydrogen Peroxide disinfectant wipes was observed with an expiration date of 01/15/17. Staff C confirmed the expiration date and stated the wipes were used to disinfect surfaces in the receptionist area and waiting room. b) An alcohol based hand rub container used for hand hygiene was observed expired in examination room 3 on the second floor. The expiration date on the container was July 2017. c) Two unused transparent dressings were observed in Operating room #2. The packaging of the dressings had an expiration date of 04/18. d) On the second floor in the operating room hallway the storage/electrical room was observed with a battery backup (UPS) system and a circuit breaker box electrical panel on the wall. Large unused cardboard boxes were observed in direct contact with the UPS system and the bottom 2-3 inches of the electrical panel.	C 139	C139 PPGO strives to ensure that our patients receive safe, high quality health care at each of our facilities, and that our facilities are maintained in a safe and sanitary manner in compliance with O.A.C. § 3701-83-10(B). As a part of our Risk and Quality Management Program, routine monthly checks are conducted throughout the center to both monitor expiration dates and ensure expired products are removed from patient care areas. PPGO has reviewed ODH's findings in C139(a) and (b) related to expired products. PPGO determined that: (a) the container of hydrogen peroxide disinfectant wipes with an expiration date of 01/15/17 found in the receptionist office (a non-patient care area that is routinely cleaned and surfaces disinfected by a contracted cleaning company) and (b) an alcohol based hand rub container with an expiration date of July 2017 which was found in examination room 3 on the second floor (a room that is not utilized for patient care), were missed by staff during their routine quality assurance checks, which are performed and documented monthly. Continued on next page:	55/02/18
C 201	O.A.C. 3701-83-16 (B) Governing Body Duties The governing body shall: (1) At least every twenty-four months review, update, and approve the surgical procedures that may be performed at the facility and maintain an up-to-date listing of these procedures; (2) Grant or deny clinical (medical-surgical and anesthesia) privileges, in writing and reviewed or re-approved at least every twenty-four months, to physicians and other appropriately licensed or	C 201		

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C 201	Continued From page 2 certified health care professionals based on documented professional peer advice and on recommendations from appropriate professional staff. These actions shall be consistent with applicable law and based on documented evidence of the following: (a) Current licensure and certification, if applicable; (b) Relevant education, training, and experience; and (c) Competence in performance of the procedures for which privileges are requested, as indicated in part by relevant findings of quality assessment and improvement activities and other reasonable indicators of current competency. (3) In the case of an ASF owned and operated by a single individual, provide for an external peer review by an unrelated person not otherwise affiliated or associated with the individual. The external peer review shall consist of a quarterly audit of a random sample of surgical cases. This Rule is not met as evidenced by: Based on personnel file review and staff interviews, the facility failed to provide documented evidence one of three practicing physicians was privileged to provide clinical services for a period of time. This affected Staff F and 440 procedures performed. Findings include:	C 201	Both expired products noted in C139 (a) and (b) were immediately removed and discarded. Further, on May 1, 2018, PPGO reminded all staff that they are required to check the first floor reception area and exam room 3 (both of which, as an aside, is never used for patient care) during their expired product checks which occur at the beginning of each month. PPGO has reviewed ODH's findings in C139(C) related to the expiration date on the unused transparent dressings in operating room #2. The two unused transparent dressings found in operating room #2 had an expiration date of 04/18. Therefore, this product was good through 04/30/18, and then would have been discarded on 05/01/18, as PPGO staff perform their expired product checks (which occur at the beginning of each month). However, since staff were busy working with the ODH surveyors on May 1, 2018, PPGO staff had not yet identified the expiration of this product. This expired product noted in C139(c) was immediately removed and discarded. Finally, PPGO, on May 1, 2018 in response to ODH's findings that certain large cardboard boxes were observed in direct contact with the UPS system Continued on next page:	

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C 201	Continued From page 3 Review of Staff F's (physician) credentialing and privileging was begun the afternoon of 04/30/18. Review of said documents revealed privileges were granted to Staff F for the period 04/22/15 to 04/22/17 by a representative of the Governing Body on 04/22/15. Clinical privileges were then granted to Staff F for the period 07/01/17-07/01/19 by a representative of the Governing Body on 08/08/17. There was no documented evidenced Staff F was privileged to provide services for the interim period of 04/23/17 to 06/30/17. During a Governing Body Meeting held on 06/28/17 the re-privileging of Staff F, and other facility physicians, was discussed. The Governing Body then voted and approved said privileges on 07/05/17. Staff A, interim Practice Manager, was made aware of the apparent lapse in Staff F's privileging on 05/01/18 at 12:31 PM. At that time Staff A was shown the privileging documents in question. At 2:15 PM on 05/01/18 Staff A and Staff D were asked about the lapse in Staff F's privileging. Staff A stated she had Staff F's file, at which time she was asked to locate within the file evidence that Staff F was privileged for the period 04/23/17-06/30/17. No supporting documentation was provided. On 5/2/18 at 9:32 AM Staff A was asked again about the lapse in Staff F's clinical privileging. Staff F stated there was nothing more documented related to the lapse. Staff A was then asked if Staff F was providing services during that time (04/23/17-06/30/17) and stated yes. Staff A	C 201	and the bottom 2-3 inches of the panel, staff immediately removed the boxes in direct contact with the UPS system and electrical panel, as evidenced by attachment A. On May 1, 2018, staff was reminded to keep the UPS system and the electrical panel clear of any interference, including cardboard boxes. This area will be routinely monitored by the Practice Manager to ensure ongoing compliance. C201 PPGO reviewed our policy and procedure around where physician privileging documents are stored as well as ensuring the appropriate staff in the surgery center has easy access to these records to provide a quicker turn around time for ODH site surveyor's to review in the future. The Practice Manager will be responsible to ensure all physician privileging forms are accessible in real time at the surgery center level and will monitor ongoing for compliance with this regulation. Please see attachment B as evidence that Staff F's privileges were granted by the governing body and there was no lapse in documentation during the time period in question between 04/23/17-06/30/17.	55/02/18

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C 201	Continued From page 4 was then asked to determine the total number of procedures Staff F performed during that time. Staff A provided a list of procedures performed by Staff F between 04/23/17 and 06/30/17 that revealed a total of 440 procedures were performed.	C 201	C231 PPGO has reviewed ODH's findings related to access to and security around the narcotics storage container. On May 4, 2018, PPGO changed the code to the noted lock box and only authorized licensed personnel, per PPGO's internal policy, have access to the new code. Please see attachment C as evidence of PPGO's code change. PPGO also reviewed its policies for re-packaging medicine upon ODH's finding that PPGO had failed to follow its own policy for repackaging medicine when it received a bulk container of Vicodin in error and was unable to return it. We discontinued use of the noted vials and are working with Medflats Medical Return and Disposal System to have them removed and destroyed. Going forward, PPGO will continue to only order individual blister packs for ease of dispensing to patients as well as ensure ongoing compliance. If a bulk container is ever received again it will be returned (if possible) or destroyed. Staff have been re-educated on this policy and will be supervised going forward by the Practice Manager to ensure ongoing compliance.	5/04/18
C 231	O.A.C. 3701-83-19 (B) Drug Control & Accountability Each ASF shall: (1) Provide adequate space, equipment, and staff for storage and the administration of drugs in compliance with state and federal laws and regulations. (2) Establish and implement a program for the control and accountability of drug products throughout the facility and maintain a list of medications that are always available. This Rule is not met as evidenced by: Based on observations, interviews and policy review the facility failed to ensure unauthorized persons were unable to access narcotic medications and failed to follow their policy for repacking of medications. This could potentially affect all patients who receive services. The facility conducted a total of 6,213 surgical procedures between 04/01/17-03/31/18. Findings include:	C 231		

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C 231	Continued From page 5 a) On 05/02/18 a review of the facility policy titled "Narcotics Management", approved 10/06/17, revealed the following documentation: "Only licensed staff may have access tot he narcotic cabinet, keys and medications." b) On 05/01/18 between 9:02 AM and 10:35 AM a tour was conducted with Staff A and B. The second floor was observed with a lock box on the wall near the recovery room. The lock box contained keys which were used to unlock the narcotic storage lock box located inside a cabinet behind an open rolling metal cage door. According to Staff B the metal rolling cage door could be locked in place to keep unauthorized persons from accessing the medications. Staff B was observed using the keypad on the lock box to obtain keys for the locked narcotic storage container. Narcotic medications were observed inside the box. When asked who has access to the keys for the narcotic and medication storage, Staff B stated the former Practice Manager and the Security Guard knew the code of the lock box and could access the keys. Staff B confirmed these persons were not licensed or authorized to access the narcotics and medications. c) On 05/02/18 at 9:40 AM a review of the facility policy titled "Drug Control System", approved 10/06/17, contained the following documentation: " Clinicians may repackage multiple containers of a particular drug from a bulk container (for example, repackaging a bottle of 21 metronidazole pills from a bottle of 100 pills) to dispense to individual patients."	C 231		

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C 231	Continued From page 6 "Each container must have the following information and labels applied: Standard PPGOH labeling with patient name, name & address of affiliate, name and strength of drug, directions for usage, date dispensed, and name of prescribing clinician." On 05/01/18 at 10:00 AM the interior of the narcotic storage container was observed with ten amber colored medication bottles which each contained ten pills of medication. An eleventh amber colored medication bottle contained two additional pills. The medication containers were observed with a strip of security tape and were labeled with the lot number, name and strength of medication and the employee's initials and date when the repacking occurred. There was no patient information or prescribing clinician, or directions for usage information on the containers of pills. Staff B stated the pills were Vicodin 5 mg/325 mg and were repackaged from a container of 100 pills into the containers in order to count the medications easier during narcotic drug count reconciliation and this process had been in effect since November 2017. In an additional interview on 05/02/18 at 9:40 AM with Staff B, the employee stated the repackaging was for convenience due to the medication had not been ordered correctly. Staff B was made aware the facility policy provided for review was not followed by the facility for repackaging of the Vicodin medication.	C 231		
C 255	O.A.C. 3701-83-21 (A) - (E) Medical Records	C 255		

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C 255	Continued From page 7 Each medical record required by paragraph (A) of rule 3701-83-11 of the Administrative Code shall contain at least the following information as applicable for the surgery to be performed: (A) Admission data: (1) Name, address, date of birth, gender, and race or ethnicity; (2) Date and time of admission; and (3) Pre-operative diagnosis, which shall be recorded prior to or at the time of admission. (B) History and physical examination data: (1) Personal medical history, including but not limited to allergies, current medications and past adverse drug reactions; (2) Family medical history; and (3) Physical examination. (C) Treatment data: (1) Physician's, podiatrist's or dentist's orders; (2) Physician's, podiatrist's or dentist's notes; (3) Physician assistant's notes, if applicable; (4) Nurse's notes; (5) Medications; (6) temperature, pulse, and respiration; (7) Any special examination or report, including but not limited to, x-ray, laboratory, or pathology reports; (8) Signed informed consent form; (9) Evidence of advanced directives, if applicable; (10) Operative record; (11) Anesthesia record, if applicable; and (12) Consultation record, if applicable. (D) Discharge data: (1) Final diagnosis; (2) Procedures and surgeries performed; (3) Condition upon discharge; (4) Post-treatment care and instructions; and (5) Attending physician's, podiatrist's or dentist's signature. (E) Other information required by law.	C 255	C 25555 Regarding C255(a), PPGO has revised its operating procedures around the documentation in the patient's medical record to specifically indicate all the names of the individuals who participated in the time out before the procedure begins. Staff were trained on this new procedure on 09/05/18, as evidenced by the signed training log in attachment D. The Practice Manager will be responsible to monitor for adherence to this updated operating procedure and the standard will also be added to the surgery centers chart review audit procedures to ensure ongoing compliance for complete and accurate medical records. In C255(b), ODH, determined that Patient #4 had a surgical abortion on 01/30/18. The patient was discharged later that day, and PPGO gave her discharge paperwork. However, the medical record did not document the time of the discharge. PPGO recognizes that this was an error in documentation by its staff member. On May 8, 2018, PPGO provided the staff with refresher training regarding medical record documentation, as evidence by attachment E. Ongoing monitoring for compliance will be the responsibility of the Practice Manager and this standard will also be added to the surgery centers chart review audit	99/05/18 55/08/18

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C 255	Continued From page 8 This Rule is not met as evidenced by: Based on medical record review and staff interview, the facility failed to ensure 5 of 5 sampled patients' (Patients #1, #2, #3, #4, and #5) medical records were accurate and complete. The facility conducted a total of 6,213 surgical procedures between 04/01/17-03/31/18. Findings include: On 05/01/18 medical record reviews were conducted with and confirmed by Staff I. This review revealed the following: a) Four of four sampled patients (Patients #2-#5) had surgical abortions performed by Staff F in the facility. Patient #2's abortion was on 04/19/18. Patient #3's abortion was on 04/20/18. Patient #4's abortion was on 01/30/18, and Patient #5 (minor patient) was on 03/09/18. This review revealed a timeout verification was conducted prior to the procedure; however, the medical record listed only the physician (Staff F) as performing the timeout. Staff I stated the timeout was conducted with all staff present in the operating room but the electronic record would only permit documentation of one person's name. b) Patient #4 had a D & C surgical abortion on 1/30/18. Although the discharge information was given to the patient at 11:24 AM on that date, the medical record did not document the time of discharge from the facility. c) Patient #1 had a medical abortion on 02/12/18 by Staff H. The medical record was silent to vital sign assessment on that date. This finding was	C 255	procedures to ensure ongoing compliance for complete and accurate medical records. In regards to C255(c), PPGO provided the staff with refresher training regarding medical record documentation on 09/05/18, as evidenced by attachment D. Ongoing monitoring for compliance will be the responsibility of the Practice Manager and this standard will also be added to the surgery centers chart review audit procedures to ensure ongoing compliance for complete and accurate medical records.	9/05/18

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C 255	Continued From page 9 confirmed by Staff I during the medical record review who verified vital signs should have been obtained on that date.	C 255		