MARYLAND
Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Office of Health Care Quality, 55 Wade Avenue, Catonsville, Maryland 21228

November 9, 2018

Administrator
Metropolitan Family Planning Inst Inc
5625 Allentown Road, Suite 203
Suitland, MD 20746

RE: NOTICE OF CURRENT DEFICIENCIES

Dear Administrator:

On September 6 and 18, 2018, a survey was conducted at your facility by the Office of Health Care Quality to determine if your facility was in compliance with State requirements for Surgical Abortion Facilities, Code of Maryland Regulations (COMAR) 10.12.01. This survey found that your facility was not in compliance with the requirements.

All references to regulatory requirements contained in this letter are found in COMAR Title 10.

I. PLAN OF CORRECTION (PoC)

A PoC for the deficiencies must be submitted within 10 days after the facility receives its State of Deficiencies State Form. Your PoC must contain the following:

- What corrective action will be accomplished for those patients found to have been affected by the deficient practice;
- How you will identify other patients having the potential to be affected by the same deficient practice and what corrective action will be taken;
- What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur;
- How the corrective action(s) will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place and;
- Specific date when the corrective action will be completed.

- References to staff or patient(s) by staff identifier only, as noted in the staff and patient rosters. This applies to the PoC as well as any attachments to the PoC. It is un-acceptable to include a staff or patient's name in these documents since the documents are released to the public.

II. ALLEGATION OF COMPLIANCE

If you believe that the deficiencies identified in the State Form have been corrected, you may contact me at the Office of Health Care Quality, Spring Grove Center, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228 with your plan of correction and any written credible evidence of compliance **(for example, attach lists of attendance at provided training and/or revised statements of policies/procedures).**

If you choose and so indicate, the PoC may constitute your allegation of compliance. We may accept the written allegation of compliance **and credible evidence** of your allegation of compliance until substantiated by a revisit or other means.

If, upon the subsequent revisit, your facility has not achieved compliance, we may take administrative action against your license or impose other remedies that will continue until compliance is achieved.

III. INFORMAL DISPUTE RESOLUTION

You have one opportunity to question cited deficiencies through an informal dispute resolution process. To be given such an opportunity, you are required to send your written request, along with the specific deficiency(ies) being disputed, and an explanation of why you are disputing those deficiencies, to me, Executive Director, Office of Health Care Quality, Bland Bryant Building, Spring Grove Center, 55 Wade Avenue, Catonsville, Maryland 21228. This request must be sent during the same 10 days you have for submitting a PoC for the cited deficiencies. An incomplete informal dispute resolution process will not delay the effective date of any enforcement action.

If you have any questions concerning the instructions contained in this letter, please contact me at 410-402-8055.

Sincerely,

Patricia Tomsko Nay, M.D.

Patricia Nay, M.D.
Executive Director

Enclosures: State Form

cc: License File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	SA000012	A. BUILDING: _____ B. WING _____	09/18/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METROPOLITAN FAMILY PLANNING INST INC	5625 ALLENTOWN ROAD, SUITE 203 SUITLAND, MD 20746

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A 000	Initial Comments A licensure survey was conducted at Metropolitan Family Planning Institute on 09/06/18 and 09/18/18. The survey included an unannounced site visit; an observational tour of the physical environment; demonstration of the process of instrument cleaning and sterilization; interviews with the administrator, consultant and clinical staff; review of clinical records; review of policy and procedure manuals; review of credentialing files; review of personnel records; review of quality assurance program; and review of the infection control program. The facility performs medical and surgical abortion procedures and includes four procedure rooms. Ten clinical records were selected for review during the survey. A key code for patients was provided to the facility administrator. Findings in this report are based on data present in the administrative records at the time of review. The facility's administrator was kept informed of the survey findings as the survey progressed. The administrator was given the opportunity to present information relative to the findings during the course of the survey.	A 000		
A 410	.05 (A)(1)(d) .05 Administration (d) Training the staff on the facility ' s policies and procedures and applicable federal, State, and local laws and regulations; and	A 410		

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A 410	Continued From page 1 This Regulation is not met as evidenced by: Based on review of the policy manual, review of personnel files, and interview, it was determined that the administration failed to ensure that all staff members received training on the facility's policies and procedures. This was evident for 6 of 6 clinical staff. The findings include: 1. Policies were reviewed on 09/06/18 and failed to reveal a policy on the need for all staff to be trained on the facility's policies and procedures. 2. Personnel files were reviewed on 09/06/18 and failed to reveal documentation of training in the facility's policies and procedures for 6 of 6 staff members. This is a repeat deficiency from the survey completed on 10/06/15.	A 410		
A 420	.05 (A)(1)(e)(i) .05 Administration (e) Ensuring that all personnel: (i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices; This Regulation is not met as evidenced by: Based on review of the policy manual, review of personnel files, and interview, it was determined that the administration failed to ensure that all staff members received orientation and competency assessments at the time of hire. This was evident for 6 of 6 staff. The findings include: Review of personnel files on 09/06/18 failed to	A 420		

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A 420	Continued From page 2 reveal documentation of an orientation and competency assessment at the time of hire for 6 of 6 personnel. During an interview with the administrator and consultant on 09/06/18 at 1:30 PM, the findings were confirmed. This is a repeat deficiency from the survey completed on 10/06/15.	A 420		
A 530	.05(C)(1) .05 Administration C. Policies and Procedures. The facility shall have policies and procedures concerning the following: (1) The scope and delivery of services provided by the facility either directly or through contractual arrangements; This Regulation is not met as evidenced by: Based on review of the policy manual, review of personnel files, and interview, it was determined that the administration failed to have all policies and procedures, mandated by regulation, in place to provide oversight of the facility. The findings include: Policy and procedure manuals were reviewed on 09/06/18 and failed to include the following policies, as outlined in regulation: - facility's scope and delivery of services; - accountability of personnel involved in patient care; - list of procedures approved for the facility; - verbal orders for medication;	A 530		

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A 530	Continued From page 3 - laboratory turn around time; and - staff training on the protocol of an emergency transfer. During an interview with the administrator and consultant on 09/06/18 at 1:30 PM, the findings were confirmed. This is a repeat deficiency from the survey completed on 10/06/15.	A 530		
A 560	.05(C)(2)(b) .05 Administration (b) Job descriptions on file for all personnel: and This Regulation is not met as evidenced by: Based on review of the policy manual, review of personnel files, and interview, it was determined that the administration failed to ensure that all staff members had documentation of a signed job description. This was evident for 2 of 6 staff. The findings include: 1. Policies were reviewed on 09/06/18 and failed to reveal a policy on the need for all staff to have a signed job description in their employee file. 2. Personnel files were reviewed on 09/06/18 and failed to reveal documentation of a signed job description for 2 of 6 staff members. This is a repeat deficiency from the survey completed on 10/06/15.	A 560		
A 570	.05(C)(2)(c) .05 Administration	A 570		

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A 570	Continued From page 4 (c) Procedures to ensure personnel are free from communicable diseases; This Regulation is not met as evidenced by: Based on review of credentialing records and personnel files, and interview, it was determined that the administration failed to ensure that all staff members were free of communicable diseases. This was evident for 5 of 8 facility staff. The findings include: Credentialing records and personnel files were reviewed on 09/06/18 and revealed the following: a. Documentation of initial tuberculosis screening - missing for 2 of 6 staff members; b. Documentation of Hepatitis B vaccination or declination - missing for 4 of 6 staff members. During an interview with the administrator and consultant on 09/06/18 at 1:30 PM, the findings were confirmed. This is a repeat deficiency from the survey completed on 10/06/15.	A 570		
A1250	.10 (B)(5) .10 Hospitalization (5) Appropriate training for staff in the facility 's written protocols and procedures. This Regulation is not met as evidenced by: Based on review of personnel files, and interview, it was determined that the administration failed to ensure that all staff members were trained in the protocol for	A1250		

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A1250	Continued From page 5 emergency transfer from the clinic to a hospital. This was evident for 6 of 6 staff. The findings include: Review of personnel records on 09/06/18 failed to reveal documentation of an orientation and competency assessment at the time of hire for 6 of 6 personnel. During an interview with the administrator and consultant on 09/06/18 at 1:30 PM, the findings were confirmed. This is a repeat deficiency from the survey completed on 10/06/15.	A1250		
A1280	.11 (B)(1) .11 Pharmaceutical Services B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice. This Regulation is not met as evidenced by: Based on review of the policy manual, review of select clinical records and interview, it was determined that the administration failed to have all medication ordered and signed by the prescribing physician and failed to have complete medication orders. Patients #: 1, 2, 4, 5, 7, 9, 10 The findings include: Select clinical records were reviewed on 09/06/18. Record review revealed that the facility staff failed to follow their own policy on documentation of medication administration.	A1280		

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A1280	Continued From page 6 A. Clinical records for Patients #1, 2, 4, 5, and 7 were stamped with the following medication order: "- Fentanyl (opioid pain reliever) 50 mcg - Versed (used for relaxation or sleep prior to surgery) 2.5 mg - Atropine (decreases saliva and fluid in respiratory tract) 0.4 mg IM - Given Sig:" B. Clinical records for Patients #9 and #10 were stamped with the following medication order: "- Fentanyl (opioid pain reliever) 50 mcg - Versed (used for relaxation or sleep prior to surgery) 2.5 mg IM - Given Sig:" The Atropine order had been crossed out in both clinical records. All medication orders were incomplete for the following reasons: - time and date of order not documented; - order not signed by prescribing physician; - site of administration not documented; - time and date of medication administration not documented; - signature of person administering medication not documented; - no documentation of patient response to medication. A time was handwritten next to each order but the time was not identified as either the time the order was written or the time the medications were administered. C. Additional medications, including Xanax (relieve anxiety), Aleve (pain reliever), Doxycycline (antibiotic), and Misoprostal (used to induce labor), ordered for Patient #s 1, 2, 4, 6, 7,	A1280		

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A1280	Continued From page 7 9, and 10 failed to have complete medication orders. These orders were also incomplete as there was no time and date of order; dosage and route of administration not included in the order; order not signed by prescribing physician; site of administration not documented; time and date of medication administration not documented; signature of person administering medication not documented; and no documentation of patient response to medication. During an interview with the administrator and consultant on 09/06/18 at 1:30 PM, the findings were confirmed.	A1280		
A1510	.15 (A) .15 Physical Environment A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services. This Regulation is not met as evidenced by: Based on review of policies, and observations, it was determined that the administration failed to ensure that all measures to prevent infection were practiced at the facility. These measures include the failure to provide annual infection prevention training for all staff; breaches in infection prevention observed during the process of precleaning and sterilization of surgical instruments; and the failure to monitor for discard and expired items. The lack of training was evident for 6 of 8 clinical staff. The findings include: 1. Review of personnel files on 09/06/18 failed to reveal documentation of initial or on-going annual training in Infection Prevention for 6 of 8 facility	A1510		

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A1510	Continued From page 8 staff. 2. Observations of the process of precleaning and sterilization of contaminated surgical equipment was completed on 09/06/18. Observations revealed the following breaches in infection prevention: A. The basin used to soak contaminated instruments was not marked to ensure accurate measurement of water to detergent ratio; and B. 38 sterilized peel packs contained an indicator strip with a date handwritten in ink; C. Peel packs taped on each end. 3. The following expired items were found during the tour: A. In the hallway storage area: a. Aeromed Castile Soap Towelettes, box of 100; 2 boxes; expired 12/16; b. Hygea Benzalkonium Chloride Antiseptic Towelettes, box of 100; 1; expired 11/16; c. Hygea Benzalkonium Chloride Antiseptic Towelettes, box of 100; 1; expired 07/14; d. Hygea Benzalkonium Chloride Antiseptic Towelettes; 11 individual towellettes; expired 11/14. B. In the Processing Area: a. Heat Seal View Pack Sterilization Pouch; 9 pouches; expired 03/06. C. In Procedure Room #3: a. BD Affirm VP 111 Ambient Temperature Transport Systems; 3; expired 04/05/18; b. BD Affirm VP 111 Ambient Temperature Transport Systems; 10; expired 12/17/15. D. In Procedure Room #4:	A1510		

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A1510	Continued From page 9 a. Hygea Benzalkonium Chloride Antiseptic Towelettes, box of 100; 1; expired 08/18. All expired items were reviewed with the administrator at the time of discovery. E. During the observational tour, it was noted that recliners in the recovery area were not intact. Four recliners made of a faux leather material contained cracks on the chair arms, back and seats. Two recliners were made of a soft material and each had a tear in the chair seat. This is a repeat deficiency from the surveys completed on 03/05/13 and 10/06/15.	A1510		
A1570	.16 (B) .16 Quality Assurance Program B. The facility shall conduct ongoing quality assurance activities and document the activities on a continuous basis, but not less than quarterly. This Regulation is not met as evidenced by: Based on review of the policy manual, review of facility documentation, and interview, it was determined that the administration failed to ensure an ongoing quality assurance program. The findings include: The only documentation of Quality Assurance activities noted during the survey were facility forms entitled 'Medical Record Compliance Evaluation' for 01/12/16, 03/01/16 and 08/19/16. Findings were reviewed with the administrator and consultant on 09/06/18 at 1:30 PM. This is a repeat deficiency from the survey	A1570		

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A1570	Continued From page 10 completed on 10/06/15.	A1570		