STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Spring Grove Center • Bland Bryant Building
55 Wade Avenue • Catonsville, Maryland 21228-4663
Martin O'Malley, Governor –Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

March 26, 2013

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

**RE: NOTICE OF CURRENT DEFICIENCIES**

Dear

On March 5, 2013, 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.

III. 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.

IV. 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 Dr. Patricia Nay, Acting 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 Joyce Janssen at 410-402-8018 or fax 410-402-8213.

Sincerely,

Barbara Fagan
Program Manager

Enclosures: State Form

cc: License File

Office of Health Care Quality

PRINTED: 03/26/2013
FORM APPROVED

| 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 _____ | 03/05/2013 |

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

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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 DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|
| A 000 | Initial Comments<br><br>An initial survey of Metropolitan Family Planning Inst. Inc of Suitland was conducted on March 5, 2013. The Survey include the following: interview of the clinical staff; observational tour of the facility's physical environment; observation of the facility's sterilization equipment reprocessing; policy and procedure review; review of the facility's patient clinical records; review of the physicians credentialing; review of employee personnel files; review of the facility's Quality Assurance program and review of the facility's infection control program.<br><br>The facility has two procedure rooms.<br><br>A total of five patient clinical records were reviewed. The clinical patient records reviewed had procedures done between November 2012 and February 2013. | A 000 | | |
| A 790 | .06(B)(9) .06 Personnel<br><br>(9) Data provided by the National Practitioner Data Bank.<br><br>This Regulation is not met as evidenced by:<br>Based on review of the physician credentialing files and interview with the facility administrator, it was determined that the facility failed to collect, review and document data provided by the National Practitioners Data Bank (this is a database for physicians in connection with medical liability settlements or judgments as well as adverse peer review actions against licenses, clinical privileges) for the physician reviewed.<br>The findings include:<br>1. Review of the Physician Credentialing on 3/05/13 at 10:00 am revealed that the Physician's | A 790 | A790<br>(9) Data provided by the National Practitioner Data Bank:<br><br>1. Facility Administrator will contact the National Practitioner Data Bank to send appropriate documentation regarding physicians credentialing.<br>2. Facility Administrator will attach to this letter necessary credentialing paperwork, and will file a copy in the office | 4-10-13 |

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| A 790 | Continued From page 1<br>file contented no evidence to support that data provided by the National Practitioners Data Bank was collected, documented or review.<br>2. Interview of the Facility administrator on 3/05/13 at 10:30 am confirmed that no data had been collected, reviewed or documented from the National Practitioners data Bank on the Physicians. | A 790 | These will be monitored quarterly by the Administrator | |
| A1430 | .13 (B)(5) .13 Medical Records<br><br>(5) Discharge diagnosis.<br><br>This Regulation is not met as evidenced by:<br>Based on the review of patient clinical records and interview with the facility administrator, it was determined that the facility administrator failed to ensure that the patient medical records were complete and included a discharge diagnosis for five of five patients records reviewed.<br>The findings include:<br><br>Review on 3/05/13 at 9.00 am of patient clinical records revealed, that Patients #1, 2, 3, 4, and 5 medical records did not content any evidence that a discharge diagnosis was documented.<br><br>Interview on 3/05/13 at 09:30 am of the facility administrator manager revealed that there is not a discharge diagnosis done on the patients before they are discharged to home. | A1430 | A1430<br>(5) Discharge Diagnosis:<br><br>1. The facility administrator will audit each patient medical record upon their discharge to ensure inclusion of the following:<br>a. Chief complaint<br>b. History and physical<br>c. Procedure note<br>d. Discharge diagnosis<br>e. Discharge instructions/medications<br>f. Follow up, if indicated<br>2. At the quarterly staff meeting, the physicians were instructed to document all necessary documentation of the patient visit, including a discharge diagnosis/status. | 4-10-13 |
| A1510 | .15 (A) .15 Physical Environment<br><br>A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services. | A1510 | | |

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| A1510 | Continued From page 2<br><br>This Regulation is not met as evidenced by:<br>Based on observational tour, interview of clinical staff and policy review, it was determined that the facility failed to ensure the policies and procedures were implemented for instrument reprocessing, packaging of sterilized of instrument and surgical instruments were not expired.<br>The findings include:<br><br>1. Observational tour on 3/5/13 at 12:00 pm of procedure room #1 revealed eighteen expired single use Vacuum Curettes. Twelve Curettes expired 1/2007, one expired 11/2008 and five expired 12/2006.<br>a. Observation on 3/5/13 of Procedure room #1 at 12:00 pm, revealed fifty two packs of sterilized instruments that were not dated, had no initials or time of the person sterilizing and the facility lack a log to track sterilized packs.<br>Interview of Staff #3 on 3/5/13 at 12:30 PM, reveal that she was unaware of any expired surgical instruments and that she has no tracking method to what or when instruments are used.<br>2. Observation on 3/5/13 at 1:00 pm of the instrument reprocessing room revealed a basin of a yellowish substance with instruments in the basin. The reprocessing tech (Staff #4) stated that the basin contained Lysol and Water for cleaning the instruments. Lysol is not an enzymatic cleaner. An Enzymatic cleaner is for instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large | A1510 | These will be monitored quarterly by Office Administrator<br><br>A1510<br>Physical Environment<br><br>1. (a) All expired Vacuum Curettes have been discarded. Henceforth, all Vacuum Curettes will be labeled with the date of expiration upon sterilization to ensure no further issue with expired instruments/materials.<br>(b) All instrument packs set for sterilization will be labeled with the date, time and the initials of the staff members preparing the packages to be certain of sterilization dates. A sterilization log has also been created for entry of when the autoclave is being used, and to track date of sterilization for all packages. Each staff member was made aware of this addition to the policy and procedure manual at the quarterly staff meeting. | 4-10-13 |

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| A1510 | Continued From page 3<br>portion of common soil (e.g., blood, pus). Cleaning solutions also can contain lipases (enzymes active on fats) and amylases (enzymes active on starches). The enzymatic must be EPA (Environmental Protection Agency) approved. Further observation revealed that dirty bloody suction hose were in a bucket next to the clean hoses. The reprocessing tech identified this area as the clean area.<br><br>2. Observation of the sterilization processing room on 3/05/13 at 12:00 pm revealed Staff #4 took instruments from the procedure room into the reprocessing room and first cleaned the instruments with soft scrub with bleach (a house hold cleaner) that is not an EPA approved enzymatic cleaner. The staff then takes the instruments and places them in a basin with a cap off of the Lysol container full of Lysol and a 1/2 of basin full of water to soak the instrument.<br><br>3. Interview of the Staff #4 on 3/5/13 at 1:00 pm revealed that she could not remember who give her instructions on what solutions or measurements to use with instrument reprocessing. She further stated that spore testing is only done monthly. Monitoring of autoclaves sterilizers should be done at least weekly by using a biological indicator with a matching control (i.e., biological indicator.) A biological indicator-validates autoclave is spore free and sterilizing the instruments properly. | A1510 | 2. For the purposes of cleaning/sanitizing/sterilizing instruments, Amphyl 1% solution is now being used as the only solution for instrument. This enzymatic is EPA approved as an appropriate cleaning solution. All staff members have been made aware of this change and is no longer using previous cleaning solutions.<br>3. Staff #4 has been reminded of appropriate policies and procedures regarding cleaning of instruments and appropriate hand hygiene. Staff #4 and the rest of the facility staff have been informed that bleach and soft scrub are no longer to be used as "rinsing" solution, and all instruments are to be cleaned with Amphyl 1% prior to sterilization.<br>4. Spore testing of the autoclave will be done after each use. It is important to note as well that this facility also utilizes spore protecting tape on instrument packages as well as biological testing to ensure continued cleanliness, and spore free environment.<br>These will be monitored by Office Administrator. | |

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May 2, 2013

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

**RE: ACCEPTABLE PLAN OF CORRECTION**

Dear

We have reviewed and accepted the Plan of Correction submitted as a result of a initial survey completed at your facility on March 5, 2013.

Please be advised that an unannounced follow-up visit may occur prior to the standard survey to ensure continual compliance.

If there are any questions concerning this notice, please contact this Office at 410-402-8040.

Sincerely,

Barbara Fagan

Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality