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
Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

March 28, 2016

Administrator
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 Re-licensure survey completed at your facility on October 6, 2015.

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

STATE OF MARYLAND
DHMH

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Office of Health Care Quality
Spring Grove Center • Bland Bryant Building
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Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

February 22, 2016

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

Dear

We have received your facility's response to the list of deficiencies resulting from the Re-licensure survey completed at your facility on October 6, 2015.

Please note that an acceptable Plan of Correction (POC) for the identified deficiencies must contain the following information:

1. State what process changes the management team will make to correct each specific deficiency cited.

2. State what process changes the management team will make to correct each specific deficiency identified.

3. Define the projected timeline for each step in the corrective action plan for each deficiency cited.

4. Define the projected completion date for each deficiency cited.

5. Identify who will be responsible for assuring each step in the plan of correction is implemented.

6. State what specific quality indicators the management team will monitor to evaluate the effectiveness of the correction actions.

7. Define what will be the on-going schedule of the quality monitoring activities for each deficiency cited.

NOTE: PLEASE DOCUMENT THE SPECIFIC CORRECTIVE ACTION ACCOMPLISHED FOR EACH PATIENT IDENTIFIED BY TAG NUMBER AND PATIENT IDENTIFIER.

After careful review of your POC, the following component(s) of an acceptable POC were not addressed:

_ Scope of Deficiencies not evaluated by the management team;
Tags:

_ Process changes not identified to correct each deficiency by the management team;
Tags:

_ Timeline for each step of corrective action not defined for each deficiency;
Tags:

_ Projected completion date not indicated for each deficiency;
Tags:

x Person responsible for each corrective action is not identified;
Tags: A1510 - Please remove staff name and replace with title.

_ Specify quality indicators for monitoring the corrective action were not identified;
Tags:

_ The schedule for on-going quality monitoring was not stated.
Tags:

x **Please sign and date page 1 of Statement of Deficiency.**

If there are any questions concerning these instructions, please call this office at (410) 402-8040.

Sincerely,

Barbara Fagan

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

STATE OF MARYLAND
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November 10, 2015

Metropolitan Family Planning Inst
Administrator
5625 Allentown Rd., Suite 203
Suitland, MD 20746

Dear

Enclosed is a list of State deficiencies resulting from a relicensure survey that was completed at your facility on October 7, 2015.

Please note that an Acceptable Plan of Correction (POC) for the identified deficiencies must include the following information:

1. **State how the management team will evaluate the scope of each deficiency cited.**

2. **State what process changes the management team will make to correct each specific deficiency identified.**

3. **Define the projected time line for each step in the corrective action plan for each deficiency cited.**

4. **Define the projected completion date for each deficiency cited.**

5. **Identify who will be responsible for assuring each step in the plan of correction is implemented.**

6. **State what specific quality indicators that the management team will monitor and evaluate the effectiveness of the corrective actions.**

7. **Define what will be the on-going schedule of the quality monitoring activities for each deficiency cited.**

IT IS IMPERATIVE THAT YOUR POC CONTAIN THE ABOVE COMPONENTS.

Please complete Forms CMS 2567 as follows:

1. **Use the official form provided to you for your response.**
2. **Your Plan of Correction must be entered in the appropriate column on the right.**
3. **An authorized representative of your facility must sign and date the form in the designated space provided.**

PLEASE RETURN COMPLETED CMS 2567:

Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality
Spring Grove Center
Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228

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. Tricia Nay, 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.

Please submit a Plan of Correction within 10 calendar days of receipt of this letter. Please be advised that failure to submit an acceptable POC could result in a recommendation to terminate your facility from the Medicare program.

If you have any questions regarding these instructions, please call the undersigned at (410) 402-8040.

Sincerely,

Barbara Fagan

Barbara Fagan
Program Manager
Ambulatory Care
Office of Health Care Quality

Cc: 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 _____	10/06/2015

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 re-licensure survey was conducted at Metropolitan Family Planning on October 6 and 7, 2015. An exit interview was conducted on October 7, 2015. The center performs surgical abortion procedures. The facility includes two procedure rooms. The survey included an on-site visit, an observational tour of the physical environment, demonstration of the instrument cleaning/sterilization process, interview of the facility's administrator, physician, registered nurse, counselor, and medical assistants, review of the policy and procedure manual, review of the personnel files, review of quality assurance and infection control program, and review of professional credentialing. There were no surgical procedures performed at the facility during this survey. A total of six clinical records were reviewed. The surgical abortion procedures that were performed between April 2015 through September 2015 were reviewed. Findings in this report are based on data present in the administrative records at the time of review. The agency's administrator was kept informed of the survey findings as the survey progressed. The agency administrator was given the opportunity to present information relative to the findings during the course of the survey. A key code for patients, medical staff and employees contained herein was provided to the agency administrator.	A 000	MAR - 8 2016	
A 410	.05 (A)(1)(d) .05 Administration	A 410		

OHCQ
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Office Administrator | (X6) DATE: 3/2/16

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A 410	Continued From page 1 (d) Training the staff on the facility ' s policies and procedures and applicable federal, State, and local laws and regulations; and This Regulation is not met as evidenced by: Based on review of personnel files and interview of the administrator, it was determined that there was no evidence that two of three staff members (E, F, C) received training on the facility policies and procedures. The findings include. Review of staff members E and F's personnel files revealed there was no evidence that the staff members received training on the facility policies and procedures. Interview of the administrator (C) on October 7, 2015 at 10 AM revealed the administrator was not aware that the staff needed the training.	A 410	A410 1. The facility manager will review training procedures, and audit each employee's personal file. 2. Each employee will receive the current policy and procedure manual, and will have to sign an acknowledgement that they have received and read all of the applicable policies and procedures. 3. This will go into effect immediately 4. All employee's will be compliant by December 31, 2015 5. Facility manager will be responsible for implementation, and will keep a copy of signed acknowledgement in each employees personal file 6. Insuring each member of the facility team has received and read the policies and procedures outlined in the manual, will better facility office practices, and reiterate job descriptions 7. This will be completed on an annual basis, or as necessary if addendums are added, or revisions made.	
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 training files, review of the policy and procedure manual and interview of the administrator it was determined that five of five staff members did not have orientation that demonstrates competency to perform patient care and training in infection control. Staff: A, B, C, D, E, F The findings include:	A 420	A420 1. Facility manager will audit employee files to determine scope of current training of all employees, to include competency in patient care and training in infection control 2. Facility manager will identify qualified member of the team to perform training to all employees regarding patient care, and proper infection control 3. Effective immediately 4. December 31, 2015	

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A 420	Continued From page 2 Review of staff E, date of hire [redacted] and F's, date of hire [redacted] training file revealed there was no documentation the staff members had orientation that demonstrates competency to perform patient care and infection control training. Review of staff A and B's training file revealed there was no documentation the staff members had infection control training. Interview of the administrator (C) on October 7, 2015 at 10 AM revealed the administrator was not aware that there is no orientation and infection control training for the staff members.	A 420	A420 cont. 5. The office manager will perform annual audits, and addend policy and procedure manual to include all required training for patient care and infection control, as standards deem necessary 6. Employee will be required to take, and pass a standard quiz to illustrate competency regarding this measure, and a certificate will be placed in their file 7. Identified trainer will perform biannual surprise evaluations to insure procedures set forth are being followed and report back to the office facilitator who will update employee training log	
A 450	.05 (A)(2)(a) .05 Administration (2) The administrator shall ensure that: (a) The facility's policies and procedures as described in §C of this regulation are: (i) Reviewed by staff at least annually and are revised as necessary; and (ii) Available at all times for staff inspection and reference; and This Regulation is not met as evidenced by: Based on a review of policies, review of facility documentation and interview, it was determined that the facility did not ensure that the policy and procedure manual was reviewed, revised and approved, as necessary, on an annual basis. Staff: C The findings include: Review of the policy manual on 10/06/15 revealed that there is no documented policy or procedure to review, revised and approve the manual on any	A 450	A450 1. Facility manager will revise and audit current policy and procedure manual. 2. Facility manager will update policy and procedure manual in order to correct, addend or update policies that have been changed or discarded from the manual since last revision 3. Effective immediately 4. Revisions will be completed by January 31, 2016 5. Facility manager is designated for implementation 6. Facility manager will be charged with annual review of policy and procedure manual, and for addendums if deemed necessary prior to annual revisions 7. Annual review and revisions	

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A 450	Continued From page 3 annual basis. Review of facility documentation revealed that the last date of an annual policy review was 07/01/12. The names are typed and there are no collaborating signatures next to the typed names and date. Interview with the administrator (C) on 10/06/15 at 12:30 PM revealed that the policy manual has not been reviewed on an annual basis.	A 450	A530	
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 upon review of the policy manual, it was determined that the facility did not have policies and procedures in place to provide oversight of the center. The findings include: Review of the policy manuals on 10/06/15 revealed that they were incomplete. A facility is expected to ensure that it is in regulatory compliance for all of the facility's areas of operation. Missing policies, as outlined in regulation, include the following: 1. Annual review and revision of policies and procedures;	A 530	1. Facility manager will identify policies and procedures that are missing or require revision to reflect current practices at this facility 2. During this process, facility manager will be sure to include the following policies that are currently missing from the manual: a. Job descriptions for all employees b. Pre-operative testing and examination c. Obtaining lab data to meet the needs of the patient d. Lab turn around time e. Review of lab reports f. Documentation of laboratory results 3. Effective immediately 4. Completion by January 31, 2016 5. Facility manager will be responsible for insuring and obtaining approval for changes to policies put forth above 6. Will audit random charts for above quality indicators 7. Annual quality monitoring	

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A 530	Continued From page 4 2. Job descriptions for all personnel; 3. Pre-operative testing and examination; 4. Obtaining routine and emergency laboratory and radiological services to meet the needs of patients; 5. Laboratory turn around time; 6. Review of lab reports 7. Documentation of laboratory results.	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 personnel files and interview of the administrator, it was determined that the administrator did not provide a job description to three of three staff members that includes their duties and qualifications. Staff: C, D, E, F The findings include. Review of personnel file for staff member D revealed that the staff member was hired on [redacted]. There was no evidence that the staff member received a job description that includes the duties and qualifications. Review of personnel file for staff member E revealed that the staff member was hired on [redacted]. There was no evidence that the staff member received a job description that includes the duties and qualifications. Review of personnel file for staff member F revealed that the staff member was hired on [redacted] There was no evidence that the staff member received a job description that	A 560	A560 1. Facility manager will review and revise all job descriptions given to employees 2. Each employee will be required to sign and date their job description, which will be placed in their personal file 3. Effective immediately 4. Completion by January 31, 2016 5. Facility manager will be responsible for implementing this procedure 6. If changes to job description are made, an addendum will be added, and both facility manager and employee will need to sign and date 7. Job descriptions will be reassessed and evaluated per discretion of the facility manager	

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A 560	Continued From page 5 includes the duties and qualifications. Interview of the administrator (C) on October 7, 2015 at 10 AM revealed the administrator was not aware the staff did not receive a job description.	A 560		
A 570	.05(C)(2)(c) .05 Administration (c) Procedures to ensure personnel are free from communicable diseases; This Regulation is not met as evidenced by: Based upon review of policies, review of credentialing and personnel files, and interview, it was determined that the administrator did not comply with regulations to ensure that all medical personnel are free from communicable diseases. Staff: C, D, E, F The findings include: 1. Policy manuals were reviewed on 10/06/15 and revealed a policy entitled 'Communicable Disease' that stated "All medical personnel that work within the facility, regardless of patient interaction, must be free from communicable disease. This includes tuberculosis and hepatitis B and C. 2. Review of personnel file for staff member D revealed, staff member D was hired on [redacted]. There is no documented tuberculosis skin test in the file. Review of personnel file for staff member E revealed, staff member E was hired on [redacted]. The last documented tuberculosis skin test was March 7, 2013. Review of personnel file for staff member F	A 570	A570 1. Facility manager will be charged with updating each employee file to insure all vaccinations and testing are up to date 2. Facility manager will request from each employee documentation of vaccination and/or supplemental documentation and place in employee file 3. Effective immediately 4. Completion by January 31, 2016 5. Facility manager is assigned to insuring this policy is effectively implemented 6. Will monitor annual vaccination and TB testing 7. Each employee chart will be audited October of each year to insure compliance with above	

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A 570	Continued From page 6 revealed, staff member F was hired on [redacted]. The last documented tuberculosis skin test was March 1, 2013. 3. Interview of the administrator (C) on October 7, 2015 at 12 PM revealed the administrator was not aware that the annual tuberculosis testing had not been done.	A 570		
A 610	.05(C)(6) .05 Administration (6) Pertinent safety practices, including the control of fire and mechanical hazards; This Regulation is not met as evidenced by: Based on review of policies and interview, it was determined that the administrator did not follow their policy on emergency preparedness. The findings include: 1. Review of policies on 10/06/15 revealed a policy entitled 'Emergency Preparedness (Disaster) Plan' that stated under the heading 'Facility Manger', in part, that "Ensure that drills are conducted biannually (or as required by your accreditor or other regulator)." The policy continued under the heading 'Emergency drills' and stated, in part, "Emergency drill shall be conducted to ensure employee familiarity with appropriate procedures to be followed during emergencies. Both fire drills and disaster drills shall be conducted regularly, as required by your accreditor or other regulatory body." 2. Copies of fire and disaster drills were requested during the survey. Interview with the	A 610	A610 1-2 1. Facility manager is responsible for reviewing policy and procedures regarding "Emergency preparedness". 2. Facility manager will be charged with creating a new procedure to reflect office procedures, and will insure all state guidelines are met in this policy. The facility manager will also educate all employees on appropriate emergency plans, including exit strategy in case of a fire or natural disaster. 3. Effective immediately 4. Completion January 31, 2016 5. Facility manager will be responsible for educating the employees, and maintaining safety guidelines outlined by state regulation 6. Will log and document employee education, and ensure all members are updated 7. Annual quality monitoring to insure all employees are prepared in case of an emergency to facilitate exit strategies and insure patient care and safety.	

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A 610	Continued From page 7 administrator on 10/06/15 at 12:35 PM revealed that the facility was not conducting fire or disaster drills. 3. Review of policies revealed a policy entitled 'Life Safety Management' that stated under the heading 'Inspection, testing and maintenance of fire detection, alarm, and protection equipment', in part, that "All portable fire extinguishers shall be clearly identified, inspected, and maintained monthly and annually." Another policy entitled 'Orientation to the center' stated, in part, that during orientation to the facility staff would learn about "Emergency procedures 1. Fire 2. Evacuation procedures 3. Environmental disaster (e.g., tornado, ice/snow, hurricane) procedures 4. Disaster plan." 4. During the observational tour on 10/06/15, a portable fire extinguisher was observed in the hallway outside of Procedure Room 1. The tag on the fire extinguisher had not been updated since 2012.	A 610	A610 3-4 1. Will audit all safety equipment in the facility including but not limited to the following: a. Fire extinguisher b. Fire detectors/alarms 2. Facility manager will update, and rid facility of outdated or non-working equipment 3. Effective immediately 4. Completion November 30, 2015 5. Facility manager will be responsible for checking safety equipment mentioned above 6. Will perform testing for functionality, and battery testing. 7. This will be conducted every 3-6 months to insure this equipment is in working condition, and/or is not expired	
A 620	.05(C)(7) .05 Administration (7) Preventive maintenance for equipment to ensure proper operation and safety; and This Regulation is not met as evidenced by: Based on interview of the administrator, a tour of the facility and review of the policy and procedure manual, it was determined that the administrator did not provide preventative maintenance to emergency equipment.	A 620		

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A 620	Continued From page 8 Staff: C The finding include. 1. A tour of procedure room two on October 6, 2015 at 10:40 AM revealed the ultrasound machine had not had preventative maintenance performed to assure the ultrasound was functioning properly. During a tour of the instrument cleaning room on October 6, 2015 at 11:06 AM it was revealed the autoclave had not had preventative maintenance performed to assure the autoclave was functioning properly. 2. Interview of the administrator (C) on October 6, 2015 at 11:15 AM revealed they were not aware that the autoclave had not been inspected. 3. Review of the policy and procedure for preventative maintenance revealed, "The facility shall have an ongoing program to monitor the safety and performance of all biomedical equipment via annual inspection performed by biomed tech." Review of policies on 10/06/15 revealed a policy entitled 'Medical Equipment Management Plan' that stated, in part, "It is the policy of this facility to manage a program to assess and control the facility and the physical risks associated with medical devices and their usage by scheduling routine inspections, providing reports to track inspection schedule compliance and device failure history, and reporting results to the safety steering committee." Review of the existing policy revealed that it did not address the need for annual inspections of all electrical equipment used to provide patient care.	A 620	A620 1. All maintenance of equipment will be audited by medical doctor, and assistants working in facility to insure completion of maintenance by Atlantic Bio Medical. 2. The team will log maintenance check on monthly bases for all equipment, and will audit annual maintenance by above company. 3. Effective immediately 4. Completion by November 30, 2015 5. The medical doctor of the facility will be responsible in accordance with the facility manager that all medical equipment is maintained and working optimally, as well as communicating with Atlantic Bio Medical about necessary annual maintenance. 6. The team will utilize log sheets that will be audited to insure quality and effectiveness, as well as alert for when annual maintenance is due by Atlantic Bio Medical. 7. Audits will take place every three months, and on an annual basis by Atlantic Bio Medical 620-1: Ultrasound machine is less than 1 year old, and was not due for maintenance. Per contract if machine malfunctions for any reason, a loner will be sent to the practice, while the machine is being repaired/evaluated. 620-2: Autoclave will be inspected on annual bases, with weekly spore testing, and annually for proper function 620-3: Updated logs have been added to the facility manual for proper weekly, monthly and annual testing	

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A 650	Continued From page 9	A 650		
A 650	.06(B)(1) .06 Personnel B. Credentialing of Physicians. The facility shall collect, review, and document the following information concerning a physician licensed under Health Occupations Article, Title 14, Annotated Code of Maryland: (1) The physician ' s education; This Regulation is not met as evidenced by: Based on review of physicians credentialing files and interview of the administrator it was determined that one of two physicians credentialing files do not include a resume. Staff: B, C The finding include. Review of physician B's credentialing file revealed that files do not include a resume of the physician's education, board certification, post graduate training, any hospital the physician has an appointment or employed in the past ten years, and disciplinary action. Interview of the administrator (C) on October 7, 2015 at 11:45 AM revealed the administrator was not aware that the resume was missing from the files.	A 650	A650 1. Review of physician files will be conducted 2. Facility manager will obtain, organize, and update each credentialing file of the physicians employed by the facility 3. Effective immediately 4. Files will be completed by January 31, 2016 5. Facility manager will be responsible for requesting and organizing this information 6. Files will be updated if new information is provided, and new physicians will be required to have a completed file before they are permitted to work in the facility 7. Once physician files are completed, the file will be updated as reappointments, re certification's, and/or changes are made on a biannual basis.	
A 790	.06(B)(9) .06 Personnel (9) Data provided by the National Practitioner Data Bank. This Regulation is not met as evidenced by: Based on review of professional credentialing files for physicians and surgeons, review of policies and procedures and interview of the administrator, it was determined that two of two	A 790		

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A 790	Continued From page 10 physician credentialing files reviewed were incomplete and did not contain National Practitioner Data Bank information. This deficiency was cited on the previous survey performed on March 5, 2013. Staff: A, B, C The findings include. 1. Review of physician's A and B's credentialing files revealed, the file did not include information from the National Practitioner Data Bank regarding claims against physicians. 2. Review of the POC from the survey completed 03/05/13 revealed that the facility was previously cited for not having physician data provided by the National Practitioners Data Bank. The POC stated: "1. Facility Administrator will contact the National Practitioner Data Bank to send appropriate documentation regarding physicians credentialing. 2. Facility Administrator will attach to this letter necessary credentialing paperwork, and will file a copy in the office." 3. The policy manual was reviewed on 10/06/15 and revealed a policy entitled 'Confidential Credentialing Information' that stated, in part, "The types of individual provider credentialing information that are considered confidential and restricted from review and disclosure include but are not limited to - credentialing checklists that contain any of the above mentioned information and National Practitioner Data Bank reports (which are prohibited from release by federal regulations)." 4. Interview of the administrator (C) on October 7, 2015 at 10:30 AM revealed, the administrator was not aware that the items are missing from the	A 790	A790 1. This will be included during the review of that physicians credentialing file 2. Facility manager will obtain national practitioners data bank profile as provided by the national website 3. Effective immediately 4. Completed October 31, 2015 5. Facility manager will be responsible for updating information with credentialing packet 6. File will be updated during credentialing file audit 7. Once physician files are completed, new information will be updated as it becomes available, or on biennial basis *A790 1 – National Practitioner Data Bank Files updated to each physician file *A790-2 – National Practitioner Data Bank Files were obtained from official website. Policy and Procedure manual will be updated regarding this change in procedure	

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A 790	Continued From page 11 credentialing files.	A 790	A810	
A 810	.06(D)(1) .06 Personnel D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes: (1) An update of the information required in §B of this regulation; and This Regulation is not met as evidenced by: Based on review of policies, credentialing files and interview of the administrator it was determined that the administrator did not implement a procedure for the reappraisal of two of two physicians. Staff: A, B, C, The findings included: 1. Review of physician's A and B's credentialing file on October 7, 2015 at 10:30 AM revealed the files failed to included evidence of a review of physician's A and B's performance, including review of complications of the surgical procedures performed. The file did not contain a list of the surgical procedures the physician was privileged to perform at the ambulatory surgical center. The file did not contain reappointment letters for each physician to practice at the facility. 2. Review of policies on October 6, 2015 did not reveal policies addressing credentialing or re-appointment. 3. Interview of the administrator (C) on October 7, 2015 at 10:30 AM revealed the administrator was not aware that the information was needed.	A 810	1. Policy will be reviewed and updated to reflect necessary reappointment of the staff 2. Policy will be followed to include peer review, and reappointment status 3. Effective immediately 4. Completed by January 31, 2016 5. Facility manager will be responsible for updating the policy and procedure manual to reflect above procedure necessary for reappointment 6. Review of the policy, and adhering to procedure for reappointment, to include periodic auditing of physician credentialing packet 7. Monitoring to be concluded biennially with reappointment of physicians *A810-1 – Will have new forms to document peer review of physicians, including complications during surgical procedures. This will also include a list of surgical procedures physicians are privileged to perform within the surgery center under current policy and credentialing. *A80-2 – With policy and procedure revision will include policies regarding credentialing and re-appointment	

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A 980	Continued From page 12	A 980		
A 980	.07(B)(6) .07 Surgical Abortion Services (6) Emergency services; This Regulation is not met as evidenced by: Based on interview of the administrator, review of personnel files and policy and procedures it was determined that two of two non-anesthesia personnel did not have current ACLS (advanced cardiac life support) training and certification. Staff: A, C, D The findings include: 1. Interview of the administrator (C) on October 6, 2015 at 10:15 AM revealed that the physician administers moderate sedation. The medications used are fentanyl 50 mcg (fifty micrograms), versed 2.5 mg (two point five milligrams) and atropine 4 mg (point four milligrams). The administrator stated that the staff members are not ACLS certified. 2. Review of personnel files of staff A and D revealed the staff members are not ACLS certified. 3. Review of policies on 10/06/15 revealed a policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' that stated, in part under the heading 'Management of emergencies/complications', that "- For patients who receive moderate sedation by non-anesthesia personnel, an ACLS-certified healthcare provider must be in attendance."	A 980	A980 1. Biennial review of physician credentialing will include audit of ACLS/BLS training for physicians, as well as BLS training for the staff involved in patient care. 2. The management team will insure that each employee per their job description will have current ACLS/BLS certification 3. Effective Immediately 4. Completed by January 31, 2016 5. Facility manager will be responsible for biennial audit of certifications 6. All employees per job description will need to be certified either in BLS or BLS/ACLS 7. Biennial audit of physician and employee file to insure current status for certifications	
A1080	.09(A) .09 Emergency Services A. Basic Life Support. Licensed personnel employed by the facility shall have certification in	A1080		

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A1080	Continued From page 13 basic life support. A licensed staff individual trained in basic life support shall be on duty whenever there is a patient in the facility. This Regulation is not met as evidenced by: Based on review of personnel files, review of policy's and procedures and interview of the administrator, it was determined that the administrator did not assure five of five personnel received certification in basic life support. Staff: A, B, C, D, E, F The findings include. 1. Review of policy and procedure for emergency services revealed, "All personnel employed by the facility shall have certification in basic life support." 2. Review of five personal files for staff (A, B, D, E, F) revealed there is no current certification in basic life support. 3. Interview of the administrator (C) on October 07, 2015 at 12:30 PM revealed that the administrator was not aware that training for basic life support was needed.	A1080	A1080 1. Biennial review of physician and employee files to determine BLS certification status 2. Will provide resources for personnel to obtain appropriate certification 3. Effective immediately 4. All office staff must be certified by January 31, 2016 5. Facility manager will be responsible for insuring all personnel have current certification 6. All employees per job description will require certification 7. Biennial audit of physician and employee file to insure current certification status. *Employee D has current certification in BLS. Expires June 2016	
A1110	.09(C)(1) .09 Emergency Service C. When sedation or general anesthesia is administered, the facility shall have at least the following emergency equipment available to the procedure rooms: (1) Oxygen; This Regulation is not met as evidenced by: Based on a tour of the facility and interview of the administrator it was determined that the	A1110		

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A1110	Continued From page 14 administrator did not to secure the oxygen tanks. Staff: C The findings include. 1. Review of policies on 10/06/15 revealed a policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' that stated, in part, "The environment where the induction of sedation occurs will have provisions for emergency power for lighting, resuscitation equipment, monitoring equipment, and telephone. All equipment and supplies must be suitable for the age and size of the patients being treated and located to provide immediate access to the patient. On-site equipment requirements include - blood pressure monitoring system, automatic or manual - oxygen supply with masks and nasal cannulas, including positive pressure oxygen delivery device." The existing policy does not include instructions on how to store gas tanks. 2. During the observational tour on 10/06/15, it was noted that: a. Nitrous oxide blue gas tank not tethered to wall or in a carrier in the GYN room; b. During a tour of the storage room on October 6, 2015 at 12 PM revealed an unsecured oxygen tank. For safety purposes, all gas tanks must either be secured/tethered to a wall or in a tank carrier. 3. Interview of the administrator (C) on October 6, 2015 at 12:30 PM revealed the administrator was not aware that the gas tanks had to be secured.	A1110	A1110 1. Facility manager will be responsible for designating an employee to inspect availability, functionality and/or expiration of necessary emergency equipment 2. All emergency equipment will be audited by the facility manager biannually to inspect expiration date, and check functionality 3. Effective immediately 4. All audits will be completed by November 30, 2015 5. Facility manager will be responsible for assuring implementation 6. Manager will check log sheets filled by employees who are charged with checking equipment 7. Quality monitoring will occur biannual basis *Oxygen updated, and secured appropriately 10/26/15 to this site. A1110-1 – Blood pressure equipment, oxygen mask, nasal cannulas and ambu bag provided to this site A1110-2 – Nitrous oxide blue gas tank removed from the facility, and all oxygen tanks at this location are secured in the oxygen trolley	

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A1130	Continued From page 15	A1130		
A1130	.09(C)(3) .09 Emergency Services (3) Automated external defibrillator (AED); This Regulation is not met as evidenced by: Based on a tour of the facility and interview of the administrator it was determined that the administrator did not to obtain an automatic external defibrillator (AED) for emergencies. Staff: C The findings include. 1. During a tour performed on October 6, 2015 at 10:30 AM it was revealed that the facility did not have an AED to use in emergencies. 2. Review of policies on 10/06/15 revealed a policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' that stated, in part, "The environment where the induction of sedation occurs will have provisions for emergency power for lighting, resuscitation equipment, monitoring equipment, and telephone. All equipment and supplies must be suitable for the age and size of the patients being treated and located to provide immediate access to the patient. The existing policy does not include the need for an automated external defibrillator (AED). 3. Interview of the administrator (C) on October 6, 2015 at 11:30 AM revealed the administrator was not aware that an AED was needed.	A1130	A1130 1. Facility manager will be responsible for designating an employee to inspect availability, functionality and/or expiration of necessary emergency equipment. 2. All emergency equipment will be audited by the facility manager biannually to inspect expiration date, and check functionality 3. Effective immediately 4. All audits will be completed by November 30, 2015 5. Facility manager will be responsible for assuring implementation 6. Manager will check log sheets filled by employees who are charged with checking equipment 7. Quality monitoring will occur biannual basis A1130-1 – "AED" was purchased and placed onsite at this facility October 2015 A1130-2 – With revision of policy and procedure manual, will add "use and requirement" for AED in the facility	
A1140	.09(C)(4) .09 Emergency Services (4) Equipment to monitor blood pressure, pulse, and oxygen levels;	A1140		

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A1140	Continued From page 16 This Regulation is not met as evidenced by: Based on a tour of the facility, review of policies and procedures and interview of the administrator, it was determined that the administrator did not to have equipment to monitor the patient's oxygen level. Staff: C The findings include: 1. During a tour performed on October 6, 2015 between 10:35 AM and 12 PM revealed that there was no equipment to monitor the patient oxygen level. 2. Interview of the administrator (C) on October 6, 2015 at 12:30 PM revealed the administrator was not aware that equipment to monitor the patient oxygen level was needed. 3. Review of policies on 10/06/15 revealed a policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' that stated, in part, "The environment where the induction of sedation occurs will have provisions for emergency power for lighting, resuscitation equipment, monitoring equipment, and telephone. All equipment and supplies must be suitable for the age and size of the patients being treated and located to provide immediate access to the patient. The existing policy does not include the need for equipment to monitor oxygen levels. Another policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' stated, in part under the heading 'Preprocedure', that "Assessment is the responsibility of the physician who is performing the procedure, in collaboration with the registered nurse who will provide the moderate sedation under the supervision of the	A1140	A1140 1. Facility manager will be responsible for designating an employee to inspect availability, functionality and/or expiration of necessary emergency equipment 2. All emergency equipment will be audited by the facility manager biannually to inspect expiration date, and check functionality 3. Effective immediately 4. All audits will be completed by November 30, 2015 5. Facility manager will be responsible for assuring implementation 6. Manager will check log sheets filled by employees who are charged with checking equipment 7. Quality monitoring will occur biannual basis A1140-1 – Pulse oximeter available for use at this facility October 31, 2015 A1140-2 – Will add "necessity of oxygen monitoring" to emergency services section of policy and procedure manual. Will also revise current policy and procedure regarding "Moderate Sedation, Non-Anesthesia Personnel" to reflect current emergency procedures.	

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A1140	Continued From page 17 physician. The assessment will be completed and documented in the patient's record prior to the elective sedative procedure. The assessment includes - required equipment is assembled at bedside and is in good working order - baseline vital signs, O2 saturation, and level of consciousness."	A1140		
A1150	.09(C)(5) .09 Emergency Services (5) Suction equipment; and This Regulation is not met as evidenced by: Based on a tour of the facility, review of the policy and procedure manual and interview of the administrator it was determined that the administrator did not to obtain a suction machine for patient emergencies. Staff: C The findings include: 1. During a tour performed on October 6, 2015 between 10:35 AM and 12 PM, it was revealed that there was no suction machine for patient emergencies. 2. Interview of the administrator (C) on October 6, 2015 at 12:30 PM revealed the administrator was not aware that a suction machine was needed for patient emergencies. 3. Review of policies on 10/06/15 revealed a policy entitled 'Moderate Sedation, Non-Anesthesia Personnel' that stated, in part, "The environment where the induction of sedation occurs will have provisions for emergency power for lighting, resuscitation equipment, monitoring equipment, and telephone. All equipment and	A1150	A1150 1. Facility manager will be responsible for designating an employee to inspect availability, functionality and/or expiration of necessary emergency equipment 2. All emergency equipment will be audited by the facility manager biannually to inspect expiration date, and check functionality 3. Effective immediately 4. All audits will be completed by November 30, 2015 5. Facility manager will be responsible for assuring implementation 6. Manager will check log sheets filled by employees who are charged with checking equipment 7. Quality monitoring will occur biannual basis A1150-1 – A suction machine will be available by January 1, 2016 for use in emergencies at this facility. Policy and procedure manual will reflect requirement for suction machine.	

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A1150	Continued From page 18 supplies must be suitable for the age and size of the patients being treated and located to provide immediate access to the patient. The existing policy does not include the need for suction equipment.	A1150		
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 a review of policies, interview of the administrator and review of personnel files, it was determined that the administrator did not provide emergency training for patient transfers to the hospital for three of three employees. Staff: C, D, E, F The findings include. 1. Review of personnel files for staff members D, E and F revealed that there is no documentary evidence that the members received training for emergency patient transfer's to the hospital. 2. Interview of the administrator (C) on October 7, 2015 at 10 AM revealed the administrator was not aware that this type of training needed to be provided. 3. Review of policies revealed that there were none related to the emergency transfer of a patient to a hospital.	A1250	A1250 1. Facility manager will meet with each employee to identify the training needed for appropriate hospital transfer. 2. Facility manager will be responsible for designating a qualified employee to train the staff on appropriate hospital transfer protocol 3. Effective immediately 4. All training to be completed by all employees by January 1, 2016 5. Designated trainer will be responsible for insuring all staff is appropriately trained in hospital transfer 6. Each employee will need to sign a document stating that they have received this training 7. This will be monitored on a biennial review	
A1280	.11 (B)(1) .11 Pharmaceutical Services B. Administration of Drugs. (1) Staff shall prepare and administer drugs	A1280		

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A1280	Continued From page 19 according to established policies and acceptable standards of practice. This Regulation is not met as evidenced by: Based on the observational tour of the facility and interview, it was determined that the registered nurse did not identify and discard expired medications and solutions. This deficiency was cited on the previous survey performed on March 5. 2013. Staff: C The findings include: 1. During an observational tour on 10/06/15 at 10:30 AM revealed the following solutions and medications were expired: 1. In the GYN room: a. Ferric Subsulfate Solution or Monsel's Solution (used to help stop bleeding), 4 fl oz bottle, undated and appeared old (from Walter Reed Hospital in Washington, DC); lid was cracked, label stained; b. Podophyllin 25% in Tincture of Benzoin (topical treatment for genital warts), 2 fl oz bottle, directions on label said to discard after 08/05/1987; c. dark brown bottle, 16 fl oz, approximately 1/3 full of unidentified liquid, no label; d. small container with an orange lid containing a dark liquid, not labeled, not dated; e. pump container - 1/2 full of clear gel, not labeled, not dated. 2. Procedure Room #1: a. Monsel's Ferric Sulfate solution, 1 bottle, expired 09/14; b. 3% Acetic Acid, 8 fl oz bottle, not dated; c. Tindamax (antibiotic) 500 mg sample box, 12 packs, expired 03/27/14.	A1280	A1280 1. Facility manager will be responsible for designating an employee to audit expiration, and appropriate labeling of all pharmaceutical agents within each examination room in the facility. All materials no longer used by facility will be properly discarded 2. All rooms will be inspected by designated employee on a weekly basis 3. Effective immediately 4. Completion by October 31, 2015 5. Facility manager will be responsible for assuring implementation 6. Facility manager will be inspecting proper labeling techniques, cleanliness, and expiration of any/all pharmaceutical agents currently used at the facility 7. The facility manager will perform inspection with designated employee on a monthly basis A1280-1 – All expired, and unlabeled agents properly discarded by October 31, 2015 A1280-2 – All expired, and unlabeled agents properly discarded by October 31, 2015 A1280-3 – All expired, and unlabeled agents properly discarded by October 31, 2015 A1280-4 – Unused or partial used medications properly disposed of by October 31, 2015 A1280-5 – All expired agents properly disposed of by October 31, 2015	

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A1280	Continued From page 20 3. During a tour of the procedure room two on October 6, 2015 at 10:40 AM revealed the following medications were expired. a. Seven ammonia inhalant's expired on August 2000. b. Two five hundred milliliter intravenous bags of lactated ringers solution expired on August 2013. c. Six syringes had ten milliliters of a clear solution. The syringes were not labeled with the name of the solution(s), the date drawn and who drew the solutions. d. Located in the locked emergency container was one vasopressin one milliliter expired on November 2014. 4. During a tour of the instrument cleaning room on October 6, 2015 at 11:06 AM revealed the following medication was expired. a. One fifty milliliter multiple dose vial of 2% lidocaine (anesthetic) expired on August 1, 2011. Some of the medication had been used. The remaining expired medication had not been disposed of. 5. During a tour of the storage room on October 6, 2015 at 12 PM revealed the following medications were expired. a. Four five hundred milliliter intravenous bags of lactated ringers solution expired on August 2013. Interview of the administrator (C) on October 6, 2015 at 11:10 AM revealed the administrator was not aware that the supplies were expired.	A1280		
A1510	.15 (A) .15 Physical Environment A. The administrator shall ensure that the facility	A1510		

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	SA000012	A. BUILDING: _____ B. WING _____	10/06/2015

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A1510	Continued From page 21	A1510		

has a safe, functional, and sanitary environment for the provision of surgical services.

This Regulation is not met as evidenced by:
Based on interview of the administrator and observations, it was determined that the registered nurse did not discard expired supplies, did not implement infection control policies and did not ensure that measures to prevent infection were practiced at the facility. These measures include not using chemical indicators in each sterilized package of sterilized instrument and not performing spore testing on the autoclave. This deficiency was cited on a survey performed on March 5, 2013.
Staff: C, F The findings include:

1. During a tour of procedure room 2 on October 6, 2015 at 10:40 AM revealed that thirty-one wrapped surgical instrument packs do not include internal steam indicator strips to ensure sterilization of the surgical instruments.

Interview of the administrator (C) on October 6, 2015 at 11 AM revealed that the administrator was not aware that chemical indicators needed to be used inside the instrument packets.

2. Review of spore testing documentation for the autoclave (machine used for the reprocessing/sterilization of surgical instrument) revealed that spore testing was not performed in April, May, July, August and September of 2015. Spore testing was not performed weekly January through September 2015. The Centers for Disease Control (CDC) recommends weekly use of biological indicators (spore testing) to ensure the efficacy of an autoclave machine in the sterilization process.

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A1510	Continued From page 22 Interview of the medical assistant (F) on October 6, 2015 at 1:45 PM revealed that spore testing is performed monthly and not weekly on the autoclave. The medical assistant was unaware that spore testing needed to be performed weekly on the autoclave machines. 3. Review of the POC (plan of correction) from the survey completed on 03/05/13 revealed that the facility was previously cited for this regulation. The POC stated, in part, that: "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. (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." The POC continued: "4. Spore testing of the autoclave will be done after each use. It is important to note as well that this facility also utilizes sport protecting tape on instrument packages as well as biological testing to ensure continued cleanliness, and spore free environment." 4. During an observational tour on 10/06/15 at 10:30 AM revealed the following surgical supplies were expired: In the Sonogram Room:	A1510	~~A1510~~ 1. Facility manager has identified the registered nurse to perform sanitary measures and implement infection control 2. Designated employee will be responsible for insuring all instruments are appropriately sanitized, including the use of chemical indicators, and assuring all expired curettes have been properly discarded. 3. Effective immediately 4. New strategies implemented October 31, 2015 5. Facility manager and registered nurse, are responsible for assuring implementation 6. Will evaluate spore testing, and inspect sterilization packets for appropriate technique 7. Spore testing will be conducted weekly, with associated log sheet to document testing, and results. Policy and procedure manual will also be updated to reflect weekly spore testing and new sterilization technique. A1510-3 – All expired curettes have been properly discarded by October 31, 2015 A1510-4 – The use of hospital grade sanitization wipes are being used, and cracked exam tables have been replaced. All instruments have been inspected, and those that were expired were properly disposed of. All instrument packs are properly labeled, and appropriately stored.	

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A1510	Continued From page 23 a. Clorox Disinfecting wipes - household use wipes not Hospital grade; b. Examination table with cracks in upholstered cover; cracks covered with tape; c. drawers in exam table are dirty with stains and blackish debris. In the GYN Room: a. InPouch TV Test Kit, 1 kit, expired 05/08/15; e. Transystem Sterile Transport Swabs, 19 sets, all expired 08/15; f. sterilized instrument packs, 1 with rust stains, 6 other packs with stained or discolored packaging; g. Female Endocervical Collection swabs, 4 swabs, expired 11/14; j. Female Endocervical Collection swabs, 4 swabs, expired 09/15; k. Sterile swabs, 6 swabs, expired 04/09; l. Transystem Sterile Transport Swabs, 11 swabs, expired 08/15; m. Gen Probe Aptima Unisex Swabs, 4 swabs, expired 06/30/15. Storage cabinets in the hallway: a. Antibacterial foaming hand sanitizer, 9.0 fl oz, 1 container, expired 06/09; b. BD Vacutainer marble top blood collection tubes, 8 tubes, expired 07/15. Procedure Room #1: a. autoclaved surgical instrument pack, 1 pack, stained; b. gray colored plastic containers of curettes, vacurettes; bottoms of containers dirty with stains and blackish debris; c. curette (rigid/curved) 11 mm, 4 curettes, expired 03/15; d. autoclaved instrument packs, 6 packs,	A1510		

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A1510	Continued From page 24 stained, 1 pack partially opened; blue wrap written on with black marker; e. autoclaved instrument trays, 4 trays, dates written on blue wrap in black marker; f. Exam table with an approximate 7 inch rip in upholstered cover; g. drawers in exam table stained are dirty with stains and blackish debris. Procedure Room #2: a. Thirty synevac vacuum curetts (used to remove tissue from the uterus) expired on December 2006. Instrument cleaning room: a. One gallon container of betadine solution (topical antiseptic) expired on July 2005. Interview of the administrator (C) on October 6, 2015 at 11:10 AM revealed the administrator was not aware that the supplies were expired.	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 administrator has not maintained an ongoing quality assurance program as outlined. Staff: C The findings include: 1. Review of policies on 10/06/15 revealed a policy entitled 'Performance Improvement' that	A1570		

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A1570	Continued From page 25 stated, in part, "The PI (performance improvement) program written plan is a document that describes the PI activities and initiatives within the facility. The written plan recommendation is generated from the facility's PI steering committee. The PI steering committee will review annually those PI activities to identify areas that continue to be high-risk, high-volume, and problem prone. In addition, the PI steering has identified other areas that need ongoing monitoring and have been included in the PI plan. The PI plan is revised when applicable." Under the heading 'Objectives', the policy continued "The PI plan describes the program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities. PI steering is responsible for planning the annual PI improvement objectives. Continuous monitoring of performance and quality indicators is performed to provide ongoing evaluation of clinical and administrative processes. Progress toward attaining the annual objectives of the PI plan is monitored through formal reporting mechanisms. The PI steering committee reviews activities during the monthly meetings established for this purpose. Revisions to the objectives of the PI plan are ongoing as evolving factors are taken into account and priorities change." 2. Minutes of Steering Committee meetings were requested during the survey. Interview with the administrator (C) on 10/06/15 at 12:30 PM revealed that the facility did not currently have a Steering Committee. Current PI monitoring includes 'Patient Satisfaction Survey' and monthly 'Medical Record Compliance Evaluation'.	A1570	A1570 1. Facility manager will review and revise current performance improvement program 2. To assure performance improvement within the scope of the facility, facility manager will revise current policy to reflect current practices within the facility, and including employees 3. Effective immediately 4. Completed by January 31, 2016 5. Facility manager will be responsible for implementing above revisions 6. Will monitor employee participation and commitment to revised performance improvement strategies 7. Once revisions are completed, and staff made aware, will monitor on annual basis.	

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A9999	Continued From page 26	A9999		
A9999	Final Comments An exit conference was conducted with the administrator on October 7, 2015. The survey findings were reviewed. The administrator was directed to submit a written plan of correction in response to the 2567 form, following the attached guidelines, within ten calendar days. Failure to submit an acceptable plan of correction may result in revocation of your license from the Department of Health and Mental Hygiene Surgical Abortion Facilities program.	A9999		