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
Silver Spring Family Planning
1111 Spring Street, G2
Silver Spring, MD 20910

RE: NOTICE OF CURRENT DEFICIENCIES

Dear Administrator:

On September 13, 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
	SA000010	A. BUILDING: _____ B. WING _____	09/13/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SILVER SPRING FAMILY PLANNING	1111 SPRING STREET, G2 SILVER SPRING, MD 20910

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A 000	Initial Comments A re-licensure survey was conducted at Silver Spring Family Planning on 09/13/18. The survey included an initial unannounced site visit; an observational tour of the physical environment; interviews with clinical staff and physician; 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 staff performs medical and surgical abortion procedures and lithe facility includes two procedure rooms. Five 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 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:	A 420		

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A 420	Continued From page 1 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 four of four members of the clinical staff. This is a repeat deficiency from the survey completed on 08/18/15. The findings include: Personnel files for four clinical staff members were reviewed on 09/13/18. This review failed to reveal documentation of an orientation and/or competency assessment at the time of hire for four of four personnel.	A 420		
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 review of the policy manual, and review of personnel files, it was determined that the administration failed to ensure that all staff members received annual training on the facility's policies and procedures. This was evident for four of four clinical staff. This is a repeat deficiency from the survey completed on 08/18/15. The findings include: 1. Policies were reviewed on 09/13/18 and failed	A 450		

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A 450	Continued From page 2 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 09/013/18 and failed to reveal documentation of training in the facility's policies and procedures for four of four staff members.	A 450		
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 in place to provide oversight of the facility as mandated by state regulations. The findings include: Policy and procedure manuals were reviewed on 09/13/18 and failed to include the following policies, as outlined in regulation: - accountability of personnel involved in patient care; - job descriptions for all personnel; - procedures to ensure personnel are free from communicable diseases; - personnel policies or handbook; - documentation of staff training on facility policies and procedures;	A 530		

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A 530	Continued From page 3 - medication administration; - laboratory turn around time; - review of laboratory results; - confidentiality of medical records; and - staff training on the protocol of an emergency transfer	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, it was determined that the administration failed to ensure that all staff members had documentation of a signed job description. This was evident for four of four staff reviewed. The findings include: Personnel files were reviewed on 09/13/18 and failed to reveal documentation of a signed job description for four of four staff members.	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 on review of credentialing 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 four of four facility staff. The findings include:	A 570		

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A 570	Continued From page 4 1. Credentialing records and personnel files were reviewed on 09/13/18 and revealed the following: a. Documentation of baseline tuberculosis testing - missing for four of four staff members; b. Documentation of Hepatitis B vaccination or declination - missing for one of four staff members. 2. During interview with the medical director on 09/13/18, these findings were confirmed.	A 570		
A 600	.05(C)(5) .05 Administration (5) Infection control for patients and staff; This Regulation is not met as evidenced by: Based on the observational tour, review of policies and review of credentialing and personnel files, it was determined the administration failed to ensure all measures to prevent infection were practiced at the facility. These measures include the failure to properly prepare hinged surgical instruments for sterilization; the failure to monitor for and discard expired medical supplies; and the failure to provide annual training in infection prevention. This was evident for three of four members of the facility staff. The findings include: 1. During the observational tour conducted on 9/13/18, 21 sterilized peel packs were found with hinged surgical instruments (e.g., forceps) in a closed position. The peel packs were being stored in Procedure Rooms #1 and #2. All hinged instruments must be sterilized in the open position to effectively sterilize the hinged portions	A 600		

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A 600	Continued From page 5 of the instrument. 2. During the tour, the following expired items were discovered: A. In Procedure Room #1: a. 5 milliliter (ml.) Nipro Syringe, 1; expired 09/17; b. 7 millimeter (mm.) Rigid Curved Curette, 2; expired 11/17; c. 9 mm. Rigid Curved Curette, 4; expired 03/16; d. 9 mm. Curette, 2; expired 06/16; e. 9 mm. Curette, 9; expired 07/17; f. 9 mm. Vacuum Curette, 2; expired 08/15; g. 9 mm. Curette, 8; expired 10/15; h. 9 mm. Curette, 2; expired 11/16; i. 10 mm. Curette, 7; expired 04/17; j. 10 mm. Curette, 3; expired 05/15; k. 10 mm. Curette, 1; expired 05/18; l. 10 mm. Curette, 3; expired 06/16; m. 10 mm. Curette, 3; expired 07/17; n. 11 mm. Curette, 10; expired 11/16; o. 11 mm. Vacuum Curette, 8; expired 07/16; p. 11 mm. Curette, 21; expired 11/17; q. 12 mm. Curette, 5; expired 05/15; r. 12 mm. Curette, 6; expired 06/16; s. 12 mm. Curette, 16; expired 07/17; t. 12 mm. Curette, 5; expired 05/18; u. Aeromed Sterile Alcohol Prep Pads, 5 unopened boxes of 200; expired 11/16; v. Aeromed Sterile Alcohol Prep Pads, 3 unopened boxes of 200; expired 08/16; w. Aeromed Sterile Alcohol Prep Pads, 3 unopened boxes of 200; expired 08/17; x. Aeromed Sterile Alcohol Prep Pads, 3 unopened boxes of 200; expired 08/16; y. Aeromed Sterile Alcohol Prep Pads, 1 unopened box of 200; expired 11/15; z. Aeromed Sterile Alcohol Prep Pads, 1	A 600		

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A 600	Continued From page 6 unopened box of 200; expired 09/16; aa. Aeromed Sterile Alcohol Prep Pads, 1 unopened box of 100; expired 02/17; bb. Aeromed Sterile Alcohol Prep Pads, 200 pads; expired 03/17; cc. Terumo Safety IV Catheter, 20 gauge X 1 ¼ inch, 20; expired 01/18; dd. Terumo Needles, 25 gauge X 1 inch, unopened box of 100; expired 09/15; ee. Terumo Needles, 20 gauge X 1 inch, 68; expired 03/17; ff. Chlora Prep One-Step, 2; expired 09/15; gg. Miltex Biopsy Punch, 4 mm, 4; expired 08/17; hh. Miltex Biopsy Punch, 4 mm, 4; expired 08/13; ii. Sunshield Safety IV Catheter, 22 gauge X 1 ¼ inch, 3; expired 02/17; jj. Sunshield Safety IV Catheter, 20 gauge X 1 ¼ inch, 1; expired 01/18; kk. Select Non-Adherent Pad, 3 inches X 4 inches, 1; expired 09/17; ll. Telfa Non-Adherent Pad, 3 inches X 4 inches, 1; expired 06/18; mm. Ethicon Vicryl-Plus 3-0, 1; expired 01/16; nn. Ethicon Chromic Gut 3-0, 2; expired 01/15; oo. Preferred curette, 15; expired 09/16; pp. Select Intrauterine Insemination Catheter, 1; expired 04/18; qq. UtanLoop 15 mm X 12 mm, 16; expired 07/14; rr. 3M Electrosurgical Patient Plate: Split with Cord, 8; expired 12/15. B. In Procedure Room #2: a. Thin Prep Pap Test, 50; expired 04/25/18; b. Thin Prep Pap Test, 50; expired 06/25/17; c. Thin Prep Pap Test, 24; expired 07/16/17; d. Thin Prep Pap Test, 10; 01/25/18;	A 600		

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A 600	Continued From page 7 e. Preferred Curette, 5; expired 09/16; f. Instep Autoguard IV Catheter, 1; expired 06/13; g. Safety IV Catheter, 20 gauge, 3; expired 01/18; h. ICU Micro Clave, 3; 07/15; i. BD Vacutainer Safety Lok, 1; expired 12/14; j. BD Vacutainer Safety Lok, 3; expired 02/15; k. BD Vacutainer Safety Lok, 1; expired 10/16; l. Dilators, 12; unable to see indicator strips in sterile peel packs; m. Forceps, 6; unable to see indicator strips in sterile peel packs; n. Speculum, 3; unable to see indicator strips in sterile peel packs; o. Biopsy Punch, 1; expired 08/17; p. 7 mm. Vacuum Curette, 1; expired 08/14; q. 7 mm. Vacuum Curette, 1; 12/14; r. 7 mm. Curette, 3; expired 06/16; s. 7 mm. Curette, 1; expired 11/16; t. 7 mm. Curette, 3; expired 11/17; u. 9 mm. Curette, 13; expired 07/17; v. 10 mm. Curette, 3; expired 07/17; w. 10 mm. Curette, 1; expired 06/16; x. 10 mm. Curette, 1; expired 05/18; y. 11mm. Curette, 12; expired 07/17; z. 12 mm. curette, 4; expired 05/15. C. In Recovery Room (includes emergency equipment): a. Resuscitator - Adult, 1; expired 4/18; b. Extension Tubing, 1; expired 4/26/12; c. Laryngoscope not working. D. In Laboratory: a. Uroswab, 2; expired 7/18; b. Marble top vacutainers 8.5 ml, unopened	A 600		

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A 600	Continued From page 8 pack of 100; expired 7/31/18; c. Aeromed castile soap towelettes, 74; expired 10/16. 3. Review of credentialing and personnel files on 09/13/18 revealed that three of four members of the facility staff failed to have documentation of infection prevention training for 2018.	A 600		
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 review of facility documentation, it was determined that the facility staff did not follow their policy on emergency preparedness. The findings include: Review of facility documentation during the survey failed to reveal evidence that fire and disaster drills were being conducted as outlined in facility policy.	A 610		
A1270	.11 (A)(2) .11 Pharmaceutical Services (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice. This Regulation is not met as evidenced by: Based on review of the policy manual and observations, it was determined that the administration failed to develop and implement	A1270		

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A1270	Continued From page 9 policies regarding medication according to acceptable standards of practice. The administration failed to dispose of single dose vials after one time use. The findings include: 1. Review of policies on 09/13/18 failed to reveal policies on medication usage, preparation or administration. 2. An observational tour of the facility was conducted on 09/13/18 and revealed three used vials of Sodium Bicarbonate (used to replenish electrolytes) that were identified as 'Single Use Only' by the manufacturer. The vials had been previously used and each vial contained different amounts of medication. Patients are placed at risk for exposure to communicable disease by not discarding single dose vials after one time use regardless of the amount of medication remaining in the vial. This failure was evident during the tour by the discovery of multiple used single dose vials of Sodium Bicarbonate still available for continued use. This is a repeat deficiency from the survey completed on 08/18/15.	A1270		
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:	A1280		

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A1280	Continued From page 10	A1280		

Based on a review of the policy manual, observations, review of select clinical records, and interview, it was determined that the administration failed to develop and implement medication policies; failed to monitor for expired medication, topicals and solutions; failed to label all medication, solutions and fluids at the time of initial access; and failed to ensure that medication was ordered and administered according to acceptable standards of practice. The failure to have complete medication orders was evident for four of four clinical records selected for review during the survey. Patients #: 1, 2, 3, 4, 5 The findings include:

1. Review of policies on 09/13/18 failed to reveal policies on medication usage, preparation or administration.

2. The following expired medications, topicals and solutions were found during the observational tour on 09/13/18:

A. In Procedure Room #1:
a. Acetic Acid 3% (used in gynecologic testing), two 16 ounce (oz) bottles; expired 9/8/17;
b. Acetic Acid 3%, one 16 oz. bottle; expired 3/19/18;
c. Ferric Subsulfate (used to decrease bleeding), one 16 oz. bottle; expired 10/15;
d. Benzalkonium Chloride (used to decrease infection), one 16 oz. bottle; expired 7/12;
e. BAK (used to decrease infection) 1:750, one 16 oz. bottle; expired 12/16;
f. Bacteriostatic Water (sterile water), three 30 milliliter (ml.) vials; expired 5/1/18;
g. Bacteriostatic Water, two open 30 ml. vials; multi dose vials not dated;

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A1280	Continued From page 11	A1280		

h. Xylocaine 2% (anesthetic), two open 20 ml. vials; multi dose vials not dated;
i. Triple Antibiotic Ointment, one 0.33 oz. tube; expired 6/15;
j. Triad Lubricating Jelly, one 4 oz. tube; expired 6/11;
k. Henry Schein Lubricating Gel, one 4 oz. tube; expired 6/17;
l. Trichloroacetic Acid Solution (used in gynecologic testing), one 125 ml. bottle; expired 6/24/18;
m. One unlabeled brown solution in yellow top container with heavy layer of sediment.

B. In Procedure Room #2:
a. Bacteriostatic Water, 6; expired 5/18;
b. BAK 1:750, 1; expired 12/16;
c. Xylocaine 2%, 2 open multi dose vials; not dated.

C. In Recovery Room (includes emergency medications):
a. Methotrexate (used to induce abortion in ectopic pregnancy) Injection, 1; expired 7/16;
b. Hemabate (used to cause uterine contractions) Injection, 2; expired 2/18;
c. Hemabate Injection, 1; expired 7/17;
d. Hemabate Injection, 1; expired 3/15;
e. Hemabate Injection, 1; expired 6/18;
f. Epinephrine (used for blood pressure control) Injection 1 mg; 1, expired 11/15;
g. Epinephrine Injection 50 mg/ml, 2; expired 4/17;
h. Epinephrine Injection 50 mg/ml, 1; expired 9/16;
i. Epinephrine Injection 1 mg., 3; expired 8/17;
j. Naloxone Hcl Injection, 4; expired 1/18;
k. Naloxone Hcl Injection, 2; expired 6/18;
l. Naloxone Hcl (used to treat overdose)

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	SA000010	A. BUILDING: _____ B. WING _____	09/13/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SILVER SPRING FAMILY PLANNING	1111 SPRING STREET, G2 SILVER SPRING, MD 20910

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A1280	Continued From page 12	A1280		

0.4 mg/ml, 1; expired 8/18;
m. Diphenhydramine (used to treat allergic reaction) Injection 50 mg/ml, 2; expired 8/18;
n. Diphenhydramine Injection 50 mg/ml, 1; expired 2/18;
o. Ondansetron (used to treat nausea and vomiting) Injection 4 mg/2ml, 1; expired 4/18;
p. Ketorolac Tromethamine (pain reliever) Injection 30 mg/ml, 1; expired 6/18;
q. Albuterol Sulfate (used to open airways) Inhaler, 1; expired 11/16;
r. Sodium Bicarbonate (used to replenish electrolytes) Injection, 3 open/used single dose vials;
s. Oxytocin (used to cause uterine contractions) Injection 1 ml, 1; expired 2/16;
t. Oxytocin Injection 1 ml, 1; expired 3/16;
u. Oxytocin Injection 1 ml, 8; expired 9/17;
v. Oxytocin Injection 1 ml, 8; expired 10/17;
w. Oxytocin Injection 1 ml, 6; expired 8/18;
x. Oxytocin Injection 1 ml, 3; expired 4/18;
y. Oxytocin Injection 1 ml, 1; expired 6/18.

All of the expired items were reviewed with facility staff after discovery.

Patients are placed at risk for ineffective drug therapy related to decreased drug potency and serious side effects as a result of using expired medication. By failing to discard expired medication, the facility staff cannot ensure the viability of medication.

3. Select clinical records were chosen for review on 09/13/18 and revealed the following:

- Patient #1 - medicated pre-operatively with Motrin (pain reliever) 800 mg po (by mouth) and Mistoprostil (used to induce labor) 800 mcg po at

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A1280	Continued From page 13 0957; medicated intraoperatively with intravenous (IV) administration of Versed (used to cause relaxation prior to surgery) 2 mg and Fentanyl (opioid pain reliever) 100 mcg at 1222; - Patient #2 - medicated pre-operatively with Motrin 800 mg po and Doxycycline (antibiotic) 100 mg po at 1005; medicated intraoperatively with IV administration of Versed 3 mg and Fentanyl 100 mcg at 1132; - Patient #3 - medicated pre-operatively with Motrin 800 mg po at 0950; - Patient #4 - medicated pre-operatively with Motrin 800 mg po, Mistoprostil 400 mcg po, Xanax (used to relieve anxiety) 0.25 mg all given at 1003, and Amoxicillin (antibiotic) 125 mg po (time not noted); - Patient #5 - medicated pre-operatively with Motrin 800 mg po at 1104; medicated intra-operatively with IV Versed 2 mg and Fentanyl 100 mcg at 1152; also medicated with Albuterol 0.63 via inhalation nebulizer (time of administration not noted). However, there were no actual orders for the administered medication. All medical orders for any type of treatment, including medication, must be ordered by a physician, signed by the prescribing physician and signed off by a nurse. A complete order for medication must contain all of the following elements: - Drug name - Drug Dose - Route of administration - Frequency of administration - Date and time of order	A1280		

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A1280	Continued From page 14 - Signature of physician. A complete medication order must also contain the time and date of administration, the signature of the registered nurse (RN) who administered the medication with documentation of the patient's response to therapy.	A1280		
A1400	.13 (B)(2) .13 Medical Records (2) Significant medical history and results of a physical examination; This Regulation is not met as evidenced by: Based on policy review and review of clinical records, the administration failed to document significant elements of a patient's medical history and physical examination. This was evident for five of five clinical records reviewed during the survey. Patients #: 1, 2, 3, 4, 5 The findings include: Review of selected clinical records on 09/13/18 revealed that five of five clinical records were all missing the following information: - no documentation of family history; - no documentation of a complete physical examination except for the Gynecological system; - no documentation of an anesthesia risk assessment by the physician; - no documentation of the time post-operative vital signs were performed; and - no signature of the Registered Nurse who was responsible for post-operative assessment in the Recovery Room.	A1400		

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A1510	Continued From page 15	A1510		
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 an observational tour, it was determined that the administration failed to ensure that a safe, functional and sanitary environment was maintained for the provision of surgical services. These measures include the failure to appropriately maintain a sanitary environment and the failure to maintain furniture and equipment in the recovery room. The findings include: During the observational tour on 9/13/18, the following was noted: 1. A recliner and heating pads in the recovery areas were not intact. One recliner made of a faux leather material contained large cracks on the chair seat. Two heating pads with a vinyl covering contained multiple cracks. 2. The floor tiles inside and outside of Procedure Room #1 were no longer securely fastened to the floor. Flooring must be secure to ensure optimal cleaning and the safety of patients and staff; and 3. Wallpaper in the Patient Bathroom was coming apart from the wall at the sink and along baseboards.	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.	A1570		

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A1570	Continued From page 16 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 maintain a quality assurance program on a quarterly basis. This is a repeat deficiency from the survey completed on 08/18/15. The findings include: 1. On 09/13/18, the facility staff were unable to provide documentation that they had implemented a Quality Assessment and Performance Improvement program. 2. During an interview with the medical director on 09/13/18 at 11:00 AM, the findings were confirmed.	A1570		