Office of Health Care Quality

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 _____	08/18/2015

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 relicensure survey of Silver Spring Family Planning was conducted on August 7 and 18, 2015. The survey included: interview of the staff; an observational tour of the physical environment; observation of reprocessing of surgical equipment; review of the policy and procedure manual; review of clinical records; review of professional credentialing; review of personnel files and review of the quality assurance and infection control programs. The facility included two procedure rooms. A total of five patient clinical records were reviewed. The procedures were performed between February 2015 and June 2015. A key code for the patients and staff was provided to the facility staff. Findings in this report are based on data present at the time of review. The agency's staff was kept informed of the survey findings as the survey progressed. The agency staff 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		

OHCQ

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

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A 420	Continued From page 1 Based on review of staff personnel files and interview of Staff 1, the administrator did not ensure the clinical staff received orientation, to include proper infection control practice and skills competency demonstration to adequately perform patient care tasks for four of five staff reviewed. Staff: 2, 3, 5, 6 The findings include: Review of Staff 2, 3 and 6's personnel files revealed no documented evidence that they received orientation to the facility upon hire. Additionally, there was no documented evidence that Staff 2 and 3 performed a skills competency demonstration upon hire. New employees should participate in a skills competency demonstration, as it is a demonstration of the employee's ability to adequately perform patient care tasks. Review of Staff 5's personnel file revealed no documented evidence that her orientation to the facility included proper infection control practice. Interview of Staff 1 on 8/7/15 at 2:00 pm revealed that he acknowledged that there was no documented evidence that these staff received orientation, to include proper infection control practice and skills competency demonstration upon hire.	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	A 450		

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A 450	Continued From page 2 (ii) Available at all times for staff inspection and reference; and This Regulation is not met as evidenced by: Based on a review of policy and procedure manual and interview of Staff 1, the administrator did not ensure that staff reviewed and revised the policy and procedure manual as needed on an annual basis. The findings include: Review of the policy and procedure manual revealed no documented evidence that it had been reviewed, and revised by staff as needed on an annual basis. Interview of Staff 1 on 8/7/15 at 2:00 pm revealed that he acknowledged that the policy and procedure manual had not been reviewed, and revised by staff as needed on an annual basis.	A 450		
A 860	.06(D)(2)(e) .06 Personnel (e) Physician practice patterns as reviewed through the facility 's quality assurance program. This Regulation is not met as evidenced by: Based on review of the physician's credentialing file, review of the policy and procedure manual and interview of Staff 1, the administrator did not ensure the physician's performance pattern had been assessed through the quality assurance program, as part of the physician's biennial reappointment for one of one physician reviewed. Staff: 1	A 860		

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A 860	Continued From page 3 The findings include: Review of Staff 1's credentialing file revealed no documented evidence that his performance pattern had been assessed as part of his biennial reappointment to the facility. Review of the policy and procedure manual revealed, "Peer Review: Charts for peer review are selected at random and also related to specific cases, the later group including procedural complications and unusual sequelae; i.e. : vaso-vagal reaction, arrhythmia, drug reaction or hospital transfer. Random case charts will be reviewed on a quarterly basis by a member of the Silver Spring Gynecology staff. Two charts of 5% (whichever is larger) per physician of the previous quarters cases will be reviewed for any deficiencies, potential adverse outcomes, or positive outcomes." Interview of Staff 1 on 8/18/15 at 10:00 am revealed that a physician (colleague), who does not have privileges at the facility, is supposed to perform peer review of Staff 1 twice a year. This surveyor requested Staff 1 provide documentation of the peer review that was performed from August 2013 to current. Staff 1 stated the peer review had not been performed by the outside physician, and therefore he does not have documentation of the peer review.	A 860		
A1250	.10 (B)(5) .10 Hospitalization (5) Appropriate training for staff in the facility 's written protocols and procedures.	A1250		

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A1250	Continued From page 4 This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, review of staff personnel files and interview of Staff 1, the administrator did not ensure clinical staff were trained in the procedure for the transfer of patients to a nearby hospital in the event of a patient medical emergency for five of five staff reviewed. Staff: 2, 3, 4, 5, 6 The findings include: Review of the policy and procedure manual revealed, "Ongoing training of staff in the use of emergency equipment, the management of emergencies, and the indications for emergency transport will be conducted." Review of Staff 2, 3, 4, 5 and 6's personnel files revealed no documented evidence that they were trained in the transfer of patients to a hospital in the event of a patient medical emergency. Interview of Staff 1 on 8/7/15 at 2:00 pm revealed that he acknowledged that there was no documented evidence that these staff received training in the transfer of patients to a hospital in the event of a patient medical emergency.	A1250		
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 a tour of the facility and interview of	A1270		

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A1270	Continued From page 5 Staff 1, the agency staff did not secure and account for controlled medications, and did not appropriately utilize single dose medication vials. The findings include: 1. A tour of the facility on 8/18/15 at 10:30 am revealed there was one medication cabinet hanging on the wall located in the nursing area of the patient recovery room. This cabinet was unlocked, and contained several non-controlled medications, as well as Midazolam, Fentanyl and Alprazolam (controlled substances). There were 79 vials of Midazolam (schedule IV controlled substance), 63 ampules of Fentanyl (schedule II controlled substance), and 100 tablets of Alprazolam (schedule IV controlled substance). Review of the log book for the controlled substances revealed that a daily am (morning/beginning of shift) and pm (evening/end of shift) count was not performed and documented by two licensed staff for these three (Midazolam, Fentanyl and Alprazolam) controlled substances. Interview of Staff 1 on 8/18/15 at 10:30 am revealed that he maintains the key to the medication cabinet that is hanging on the wall located in the nursing area of the patient recovery room. Each morning, Staff 1 unlocks the medication cabinet so the medical assistants (non-licensed staff) may have access to the non-controlled medications in the cabinet. The medication cabinet remains unlocked throughout the day, as long as Staff 1 is present in the facility. At the end of the day, after patient care is complete, Staff 1 locks the medication cabinet. Staff 1 stated that he is the only one who accesses the controlled medications located in the medication cabinet. However, the controlled	A1270		

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A1270	Continued From page 6 substances are in the same cabinet as the non-controlled medications, and therefore, could be accessed by the medical assistants. The total amount of each controlled substance medication must be counted, documented, and signed by two licensed health care providers at the facility twice daily (am/beginning of shift and pm/end of shift) whenever those medications are accessed. This count must be performed before the first patient of the day receives any of the controlled medication, and after the last patient of the day receives any of the controlled medication. Additionally, controlled substances must be securely locked and maintained, so that they may not be accessed by unlicensed personnel. 2. A tour of the facility on 8/18/15 at 10:30 am revealed the following single dose vial of medication was observed in the medication cabinet hanging on the wall located in the nursing area of the patient recovery room: One vial of Sodium bicarbonate was previously opened and some of the medication had been used. Multiple patient uses of single dose vials contradict the manufacturer's instructions, and increases the risk of patient infection related to inadequate medication management. Interview of Staff 1 on 8/18/15 at 10:30 am revealed that he acknowledged that single dose vials of medication may not be used for multiple patients (used as multi-dose vials).	A1270		
A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis.	A1430		

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A1430	Continued From page 7 This Regulation is not met as evidenced by: Based on patient medical record review and interview of Staff 1, the administrator did not ensure that the patient's medical records included a discharge diagnosis for five of five patient records reviewed. Patients: A, B, C, D, E The findings include: Review of Patients A, B, C, D and E's medical records revealed there was no evidence that a discharge diagnosis was documented in the medical records. Interview of Staff 1 on 8/7/15 at 1:00 pm revealed that he acknowledged that a discharge diagnosis was not documented in the patient medical records.	A1430		
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 a tour of the facility, interview of Staff 1, observation of surgical instrument reprocessing and interview of Staff 6, the administrator did not ensure that a safe, functional and sanitary environment was maintained for the provision of surgical services. The findings include:	A1510		

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A1510	Continued From page 8	A1510		

1. A tour of the facility on 8/18/15 at 10:30 am revealed that a vital signs monitoring machine was located in procedure room one. The preventative maintenance sticker on the machine stated, "tested- 7/18/14, re-test 7/8/15." Additionally there was one ultrasound machine located in procedure room one, and one ultrasound machine located in procedure room two. There was no documented evidence that either of these two ultrasound machines had been checked for preventative maintenance.

Interview of Staff 1 on 8/18/15 at 10:30 am revealed that he acknowledged that these pieces of electrical medical equipment had not been checked on an annual basis for preventative maintenance. Preventative maintenance is required on all electrical medical equipment on an annual basis to ensure the equipment is functional, calibrated and safe.

2. A tour of the facility on 8/18/15 at 10:30 am revealed that a sharps container located in the recovery room was open and in use, and filled beyond its capacity (fill line).

Interview of Staff 1 on 8/18/15 at 10:30 am revealed that he acknowledged that the sharps container was filled beyond capacity, and should not have been in use. In order to prevent injury and infection to staff and patients, sharps containers must not be used beyond the fill line.

3. Observation of surgical instrument reprocessing on 8/18/15 at 11:30 am revealed that dirty surgical instruments were pre-cleaned in a bin of water, mixed with "Clorox Broad Spectrum Quarentary Disinfectant Cleaner." This Clorox cleaner was not an enzymatic detergent,

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A1510	Continued From page 9 and not manufactured to pre-clean dirty surgical instruments. Dirty surgical instruments must be pre-cleaned with an enzymatic detergent, according to the manufacturer's instructions. Interview of Staff 6 on 8/18/15 at 11:30 am revealed that when the facility staff ran out of the previous product they were using to pre-clean dirty surgical instruments, the supply company sent the facility the "Clorox Broad Spectrum Quarentary Disinfectant Cleaner." Staff 6 was unaware that this Colorox cleaner was not manufactured to pre-clean dirty surgical instruments.	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 and procedure manual, review of the quality assurance documentation and interview of Staff 1, the administrator did not maintain a quality assurance program on a quarterly basis. The findings include: Review of the policy and procedure manual revealed, "Quality Assessment and Performance Improvement (QAPI)- Peer Review: Charts for peer review are selected at random and also related to specific cases, the later group including procedural complications and unusual sequelae; i.e. : vaso-vagal reaction, arrhythmia, drug reaction or hospital transfer. Random case charts	A1570		

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A1570	Continued From page 10 will be reviewed on a quarterly basis by a member of the Silver Spring Gynecology staff. Two charts of 5% (whichever is larger) per physician of the previous quarters cases will be reviewed for any deficiencies, potential adverse outcomes, or positive outcomes...Any minor deviations from quality patient care will be documented by the QAPI nurse (second nurse reviewer) and brought to the attention of the attending physician and/or nurse immediately. The case will be flagged for discussion and review at the next QAPI committee meeting, at which time corrective action will be defined. QAPI meetings will be held no less than quarterly." Review of the quality assurance documentation revealed no documented evidence that peer review and QAPI meetings had been conducted and documented on a quarterly basis. Interview of Staff 1 on 8/18/15 at 10:00 am revealed that peer review had not been performed and documented on a quarterly basis. Informal staff meetings are held with the facility staff, but meeting minutes are not documented.	A1570		
A9999	Final Comments An exit conference was conducted with the medical director on August 18, 2015. The survey findings were reviewed. The facility staff was directed to submit a written plan of correction in response to the Maryland State 2567 form and following the attached guidelines, within ten days. Failure to submit an acceptable plan of correction may result in revocation of licensure from the Surgical Abortion Facilities program.	A9999		