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

August 11, 2015

, Administrator
Potomac family Planning Center
966 Hungerford Dr., Suite 24, Jackson Place
Rockville, MD 20850

Dear

Enclosed is a list of State deficiencies resulting from a relicensure survey that was completed at your facility on July 21, 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

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
	SA000011	A. BUILDING: _____ B. WING _____	07/21/2015

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POTOMAC FAMILY PLANNING CENTER	966 HUNGERFORD DRIVE, #24 ROCKVILLE, MD 20850

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A 000	Initial Comments A relicensure survey was conducted at Potomac Family Planning Center in Rockville, MD on 07/20-07/21/15. The survey included an unannounced on-site visit, an observational tour of the physical environment, observation of the patient laboratory (blood draw) process, observation of patient ultrasound process, observation of the pre-operative assessment, observation of patient counseling, observation of instrument cleaning/sterilization process; interviews, review of policy and procedure manuals, review of credentialing and personnel files, review of quality assurance program, and review of the infection control program. No surgical procedures were observed during the survey. The center performs surgical abortion procedures and includes two procedure rooms. Select clinical records were reviewed for procedures that had been performed between 01/07/15 and 07/21/15. 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		
A 600	.05(C)(5) .05 Administration (5) Infection control for patients and staff;	A 600		

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

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A 600	Continued From page 1	A 600		

This Regulation is not met as evidenced by:
Based on a tour of the facility, interview of the administrator and medical assistant and observations of instrument cleaning process, it was determined that measures to prevent infection were not practiced at the facility. These measures included failure to maintain and clean medical equipment, to maintain disinfection wipes, secure medical waste containers, to label solution containers, to maintain the surgical bed, and to prevent compromise of surgical wrapped sterile instruments. Staff: #5, #11, #14

The findings include.

An observational tour of the facility was conducted on July 20, 2015 starting at 10:00 AM. The findings are as follows:

1. A tour of procedure room #1 on July 20, 2015 at 10:45 AM revealed a laryngoscope (a light source used for direct visualization of the throat for placement of a tube for breathing) located in the drawer of the anesthesia cart. The laryngoscope had a coarse, white substance on the outside and inside the drawer of the anesthesia cart. Upon opening the laryngoscope the batteries were covered in the same substance. When tested, the laryngoscope was not working.

2. A tour of the facility included procedure rooms #1 and #2, the laboratory, and the recovery room, observations revealed the center uses PDI Sani Cloths Plus wipes for disinfection of patient equipment, the surgical beds and the surrounding patient touch areas in between each patient. Each area had at least one container of the wipes. All of the containers were opened

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A 600	Continued From page 2	A 600		

allowing the wipes to dry out thus decreasing the wipes effectiveness for disinfection. Interview of Staff #11 at 11:30 AM revealed the containers were opened last Saturday (two days ago).

3. A tour of procedure rooms #1 and #2 revealed that each room had one red medical waste container for used needles and syringes. The containers had syringes with needles attached. The containers did not have a lid on them to prevent anyone from reaching into the container and removing the needles and syringes.

4. A tour of the facility that included procedure rooms #1 and #2 and the laboratory revealed that each of the rooms contained a spray bottle filled with a purple solution. The spray bottle was not labeled with the name of the solution. Interview of Staff #11 at 11:30 AM revealed the solution is used after the room is cleaned with the PDI sani cloth plus wipes to make it smell better.

5. A tour of procedure room #2 revealed the surgical bed had multiple cracks and tears in the material exposing the material the bed is made of. The staff uses PDI Sani Cloth Plus wipes to disinfect the patient surgical bed in between each patient. The wipes are unable to penetrate the material to disinfect the surgical bed in between each patient allowing for cross contamination between patients.

6. Observation of the instrument cleaning process revealed after cleaning the instruments Staff #13 placed the instruments in a surgical tray, wrapped the instrument tray with blue wrap and wrote on the blue wrap with a sharpie pen allowing for bleeding of the ink into the surgical instruments and cross contamination of the

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A 600	Continued From page 3 surgical instruments.	A 600		
A 630	.05(C)(8) .05 Administration (8) The services and procedures specified in Regulations .07-.12 of this chapter. This Regulation is not met as evidenced by: Based on review of the facility's policy manual, observations and interview, it was determined that all required emergency equipment was not available for use in case of an emergency. The findings include: 1. Review of the policy manual on 07/20/15 revealed a policy entitled 'General Anesthesia Room' that stated, in part, "In addition to the basic equipment and medications listed for the operating rooms and the recovery room, the General Anesthesia Room will contain: 4. Tracheostomy set." 2. Observations during the facility tour on 07/20/15 at 10:15 AM revealed that the facility did not have a tracheostomy set. 3. Interview with Staff #5 and #14 on 07/21/15 at 3:15 PM revealed that they did not know whether or not the facility had a tracheostomy set.	A 630		
A1020	.07(D) .07 Surgical Abortion Services D. Before conducting a surgical procedure, a physician or other qualified health professional shall conduct a history and physical examination.	A1020		

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A1020	Continued From page 4 This Regulation is not met as evidenced by: Based on interview of the administrator and the medical assistant, and review of medical records, it was determined that a history and physical examination before conducting the patient's surgical procedure for eight of ten patients receiving local, intravenous sedation or general anesthesia was not done. Staff: #5, 14 Patients: #1, 2, 3, 5, 6, 7, 8, 10 The findings include: Review of patient's #1, 2, 3, 5, 6, 7, 8, and 10's medical records revealed that before conducting a surgical procedure, the physician failed to assess the patient's heart and/or lung sounds. The physician failed to document the findings to establish the patient's baseline and to determine if the patient had any abnormal findings. Interview of Staff #5 and Staff #14 on July 21, 2015 at 3:15 PM revealed they were not aware the history and physical had not been completed.	A1020		
A1030	.07(E) .07 Surgical Abortion Services E. If anything other than an unsupplemented local anesthetic is needed to accomplish a surgical procedure, a health practitioner as described in Regulation .08 of this chapter shall conduct a pre-anesthesia evaluation and document the anesthetic risk to the patient.	A1030		

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A1030	Continued From page 5 This Regulation is not met as evidenced by: Based on review of clinical records and interview of staff, it was determined that there was no pre-anesthetic evaluation for six out of ten patients reviewed. Staff: #5, 14 Patients: #1, 3, 5, 6, 8, 10 Review of records for Patients #1, 3, 5, 6, 8, and 10 revealed the patients received general or intravenous sedation for their procedures. The patients received Fentanyl (anesthetic, pain control), Versed (sedative, anesthetic) and/or Propofol (anesthetic). The anesthesiologist failed to perform an assessment and document the assessment prior to induction to determine the risk of the anesthetics to the patient. Interview of Staff #5 and 14 on July 21, 2015 at 3:15 PM revealed they were not aware the anesthesia provider needed to perform a pre-anesthesia assessment of the patients.	A1030		
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 interview of staff, observations, and review of policies it was determined that policies to count all medication deemed by the facility to be in need of control was not done. Staff: #5, #14 The findings include:	A1270		

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A1270	Continued From page 6 1. Policy review failed to reveal policies that addressed the need to conduct counts of controlled medication, address who is authorized to conduct a count, address the frequency of counts, or how to witness substance waste. Any medication, deemed by the facility to be in need of control, must be counted on a regular basis. By failing to properly count and document medication usage, the surgical abortion facility cannot ensure security and prevent abuse and/or misuse. When not in use, emergency medications must be secured and accessed by a double locked mechanism Only licensed medical personnel can perform a narcotic count. This can be a physician or a nurse. Narcotic counts and witnessing of medication wastage can only be performed by licensed medical personnel. 2. Observations of the medication storage closet conducted on 07/20/15 at 10:25 AM revealed a clip board with a drug inventory log that included Versed, Propofol, Narcan, Fentanyl, Valium and Dilaudid. The form included the start of day and end of day count of each mediation and the signature of the professional licensed personnel performing the count. 3. Interview of staff #5 and #14 on July 21, 2015 at 11:30 AM revealed that no counts of narcotics or medications deemed in need of counting by the facility have been performed since 2012.	A1270		
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 7 according to established policies and acceptable standards of practice. This Regulation is not met as evidenced by: Based on review of clinical records, review of policies and interview, it was determined there was no documentation of physician orders for the administration of medication, no physician orders for the initiation of intravenous (IV) fluids for all patients and no policies and procedures for medication administration. This was evident for 10 of 10 patients. Staff: #5, #14 Patients #1, 2, 3, 4, 5, 6, 7, 8, 9, 10 The findings include: 1. Clinical record review revealed that the facility uses a double sided form that is made up of sections with information on demographics, medical history, physical findings, reevaluation, laboratory, pre-operative checklist, operating room, operative findings, post anesthesia care unit, and cancellation note. Under the heading 'Operative Findings', there are two columns of medications to be checked off by the physician; one column identified as 'Drugs Given' and the other as 'Drugs Prescribed'. This section contained a space for a physician's signature. The facility also uses forms entitled 'Anesthesia Record' and 'Post Anesthesia Recovery Room Record'. The anesthesia form documents information particular to the procedure, medications administered, intravenous (IV) fluids given, and vital signs. The recovery room (RR) record documents post-op vital signs, recovery score, drugs given, nurses notes, and discharge criteria.	A1280		

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A1280	Continued From page 8	A1280		

Review of clinical records on 07/21/15 revealed the following:

a. Patient #1 - According to the clinical record form, no medications were given. The anesthesia record revealed that an IV of Lactated Ringers (LR) solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle used to start the IV and no documentation of where the IV was placed.

Review of the recovery room (RR) record revealed that the patient was medicated with Ibuprofen (pain reliever) 800 mg PO (by mouth) at 10:30 AM and Micrhogam (used to prevent problems that may occur during pregnancy or blood transfusions) IM (intramuscular injection) in the left thigh. Neither drug was ordered by the physician and there was no notation of when the IM had been given.

b. Patient #2 - According to the clinical record form, Ibuprofen 800 mg PO and Methergine (used to prevent and control post partum hemorrhage) 0.2 mg IM were given. However, there was no note from the nurse to document when the medications were administered, the site of the IM injection or signature of the nurse who administered the medications.

c. Patient #3 - According to the clinical record form, no medications were given. The anesthesia record revealed that an IV of LR solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle used to start the IV and no documentation of where the IV was placed.

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A1280	Continued From page 9	A1280		

Review of the RR record revealed that the patient was medicated with Ibuprofen 800 mg PO at 12:54 PM; however, there was no physician's order for this medication.

d. Patient #4 - According to the clinical record form, Mifepristone (used to induce an abortion) 200 mg was to be given. However, the order is written incorrectly as Mifepristone is given in micrograms (mcg) NOT milligrams (mg). In addition, the order is incomplete as it does not include the route of administration.

e. Patient #5 - According to the clinical record form, no medications were given. The anesthesia record revealed that an IV of LR solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle used to start the IV and no documentation of where the IV was placed.

Review of the RR record revealed that the patient was medicated with Ibuprofen 800 mg PO at 1:45 PM; however, there was no physician's order for this medication.

f. Patient #6 - According to the clinical record form, no medications were given. However, the anesthesia record revealed that an IV of LR solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle used to start the IV and no documentation of where the IV was placed.

Review of the RR record revealed that the patient was medicated with Ibuprofen 800 mg PO at 11:55 AM; however, there was no physician's order for this medication.

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A1280	Continued From page 10	A1280		

g. Patient #7 - According to the clinical record form, Ibuprofen 800 mg PO and Oxytocin IM were given. The Ibuprofen was given at 2:13 PM; however, there was no documentation from a nurse to note when the Oxytocin was administered, the site of the IM injection or signature of the nurse who administered the medications. The order for Oxytocin is incomplete because it does not include the dosage of the medication.

h. Patient #8 - According to the clinical record, no medications were given. The anesthesia record revealed that an IV of LR solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle used to start the IV and no documentation of where the IV was placed.

Review of the RR record revealed that the patient was medicated with Ibuprofen 800 mg PO at 11:00 AM; however, there was no physician's order for this medication.

i. Patient #9 - According to the clinical record, Mifepristone 200 mg was to be given. However, the order is incomplete as it does not include the route of administration and the order is written incorrectly as Mifepristone is given in micrograms (mcg) NOT milligrams (mg). In addition, the order was incomplete as it did not include the route of administration and the nurse administering the medication did not sign her name after giving the medication.

j. Patient #10 - According to the clinical record form, no medications were given. The anesthesia record revealed that an IV of LR solution was started. There was no documentation of an order for IV fluids, no notation of the size of the needle

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A1280	Continued From page 11 used to start the IV and no documentation of where the IV was placed. 2. All medical orders, whether for IV fluids or medication, must be ordered, signed, dated and timed by a prescribing physician then signed off by a nurse. A complete order for medication must contain all of the following information: - Drug name - Dose - Route of administration - Frequency of administration - Date and time of order - Signature of physician. 3. Review of policies on 07/20-07/21/15 revealed limited policies on medication administration. Facility standards should be outlined in policy and procedures for staff uniformity of practice regarding the administration of medications. 4. Interview with Staff #5 and #14 on 07/21/15 at 3:15 PM revealed that they were under the impression that medications were being signed off by a nurse. They also were not aware that some of the medications listed on the clinical record form had been written incorrectly.	A1280		
A1510	.15 (A) .15 Physical Environment A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services. This Regulation is not met as evidenced by: Based on observations during a tour of the facility, review of policies and interview, it was determined that the facility staff did not monitor	A1510		

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A1510	Continued From page 12	A1510		

for and discard expired medications and solutions, did not properly label multi-dose medication vials (MDV) at the time of initial access, and did not secure drugs and prescription pads. Staff: #5, #6

The findings include:

1. An observational tour of the facility was initiated at 10:00 AM on 07/20/15. The findings were as follows:

A. In Procedure Room #1:
a. Laryngeal mask airway, one airway, expired 02/15;
b. 1% Lidocaine (local anesthetic) 50 ml vial, one vial, opened, some used but not dated or initialed.

B. Autoclave area:
a. Specimen collection kit, 10 kits, expired 06/30/15.

C. In the crash cart in the recovery room area:
a. Tracheal tube, size 8.0, sterile packaging discolored with yellow-brownish stains, one tube;
b. Winged Infusion set, 21 gauge (g), packaging with yellowish discoloration, four sets;
c. Vacutainer Blood Collection set, 23 g, packaging with yellowish discoloration, one set;
d. 8.4 % Sodium Bicarbonate (used to raise blood pH and reverse acidosis) 50 ml vials, two vials, expired 11/01/14.

D. Procedure Room #2 in the beige standing cabinet:
a. Sterile water 1000 ml bottle, one bottle, expired 02/14;
b. Ethicon Chromic 1 suture material, packets discolored, two packets;

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	SA000011	A. BUILDING: _____ B. WING _____	07/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
POTOMAC FAMILY PLANNING CENTER	966 HUNGERFORD DRIVE, #24 ROCKVILLE, MD 20850

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A1510	Continued From page 13	A1510		

c. Ethicon Chromic 0 suture material, packets discolored, two packets;
d. Ethicon Ethilon Black Monofilament suture material, packets discolored, two packets.

E. Procedure Room #2 on top of anesthesia cart:
a. 1% Lidocaine 50 ml vial, one vial, opened, some used but not dated or initialed.

F. Procedure Room #2 in the anesthesia cart:
a. Endotracheal tube 7.0 size, two tubes, expired 02/15;
b. Endotracheal tube 7.5 size, one tube, expired 04/15;
c. Nipro 18 g needle, one needle, expired 10/08;
d. BD Nexiva Closed IV System 20 g, two systems, expired 09/14;
e. BD Nexiva Closed IV System 20 g, one system, expired 11/14;
f. Furosemide (a diuretic) 4 ml vial, one vial, expired 06/01/15;
g. Phenylephrine (used to increase blood pressure) 1 ml vial, one vial, expired 05/15;
h. Succinylcholine (a paralytic drug used to induce muscle relaxation and short term paralysis; generally used to make endotracheal intubation possible) 10 ml vial, two vials, expired 07/01/15;
i. Succinylcholine 10 ml vial, one vial opened, some used dated 02/25/15.

G. Procedure Room #2, metal stand, in drawer:
a. 1% Lidocaine 50 ml vial, two vials, opened, some used but not dated or initialed.

The above noted expired items were reviewed with facility staff after discovery.

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A1510	Continued From page 14 2. During the observational tour, three vials of succinylcholine were found in the anesthesia cart. Succinylcholine is a known triggering agent for an inherited life threatening syndrome called Malignant Hyperthermia (MH). In susceptible individuals, succinylcholine can induce a drastic and uncontrolled increase in the body's skeletal muscle metabolism. As a result, the body cannot supply oxygen, remove carbon dioxide or regulate the body's temperature which leads to a circulatory collapse and death if not treated immediately. Observations revealed that the facility did not have a specific MH emergency cart set up to deal with an MH crisis with specialized medications and equipment. In case of an MH crisis, it is imperative that a facility utilizing triggering agents is equipped to manage an MH crisis as every minute counts in an emergency situation. As soon as MH is suspected, medical professionals must act rapidly to treat the condition and prevent complications as an episode can be life threatening. Interview with Staff #5 on 07/21/15 at 3:15 PM confirmed that the facility did not have an MH cart available with the recommended medication and equipment for use if an MH crisis occurred. 3. Multidose vials (MDV) of medication must be labeled with the date of opening and with the initials of the person opening the vial. Once opened, medication vials may only be used for 28 days after the date they were initially accessed. The practice of using medication past the 28 days increases the risk for patient infection. 4. Solutions of sterile water must be marked with the date and time of opening. Once opened,	A1510		

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A1510	Continued From page 15 bottles of sterile water are only good for 24 hours. 5. Review of policies on 07/20-07/21/15 revealed limited policies on medication administration. A policy entitled 'Emergency Medications' stated, in part, "Emergency medications will be kept in the emergency cart in the recovery room. The medications will be checked monthly to ensure adequate supplies and that medications are within expiration dates. When emergency medications are expired and unavailable it should be noted. Any medication which is expired will be replaced immediately. The staff nurse will perform the monthly check and be responsible for replacement of medications." Facility standards should be outlined in policy and procedures for staff uniformity of practice regarding the use of and administration of medications and solutions, the use of and administration of medication in single-dose and multi-dose vials, and IV fluids. All items used for patient care must be monitored for expiration dates. By failing to discard expired items, the facility cannot ensure the viability of medication and solutions or the sterility of equipment. 6. Evidence of stains or discoloration on packages identified as "sterile" compromise the integrity of the contents and should not be used for patient care. There were no facility policies to address this finding. 7. During the observational tour on 07/20/15, the crash cart, drawers in Procedure Room #2, on top of the anesthesia care in Procedure Room #2, and drawers in the anesthesia cart in Procedure Room #2 were all noted to contain	A1510		

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A1510	Continued From page 16 vials of medication. During the tour, a blank prescription pad was found in an unlockable drawer of a desk in the RR. During a tour of the counselors office at 10:40 AM revealed an unlocked drawer with a blank prescription pad. During a tour of the instrument cleaning room at 11:05 AM revealed an unlocked draw with a blank prescription pad. Interview with Staff #6 on 07/20/15 at 2:05 PM revealed that prescription pads are to be locked in the safe. Access to medication and prescription pads must be limited to authorized personnel only and must be locked when not in use in order to prevent unauthorized use and theft.	A1510		
A9999	Final Comments An exit conference was conducted on 07/21/15 and the survey findings were reviewed. The administrator was directed to submit a written plan of correction in response to the State of Maryland 2567 form within ten calendar days. Failure to submit an acceptable plan of correction may result in revocation of the license from the Department of Health and Mental Hygiene Surgical Abortion Facilities program.	A9999		