carafem

August 29, 2019

Patricia Nay, MD
Executive Director
Office of Health Care Quality

State Provider ID# MDFH

Dear Ms. Nay,

Please find the attached Provider Plans of Corrective Action in response to the standard level deficiencies as described in your letter dated August 8, 2019 and received in our office via email August 19, 2019.

Our corrective actions are attached along with completion dates and supporting documentation. You will find that the plans for correction are all complete, but that the process for continued monitoring of complain ace extends though out the calendar year or longer as potential system change seems prudent.

We appreciated the feedback and time spent with Barbara Hall and found her comments to be very helpful.

Please feel free to contact me with any questions or for any additional information as necessary.

Sincerely,

[redacted]

Chief Operations Officer
FemHealth USA/carafem

MARYLAND
Department of Health
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

August 8, 2019

Administrator
Carafem
5530 Wisconsin Avenue, Suite 1200
Chevy Chase, MD 20815

RE: NOTICE OF CURRENT DEFICIENCIES

Dear Administrator:

On July 30 and 31, 2019, 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, 7120 Samuel Morse Drive, Second Floor, Columbia, Maryland 21046-3422 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).

Ifyouchooseandsoindicate,thePoCmayconstituteyourallegationofcompliance. 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 in formal 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, 7120 Samuel Morse Drive, Second Floor, Columbia, Maryland 21046-3422. 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 410-402-8018.

Sincerely,

Patricia Nay, M.D. Executive Director

Patricia Tomoko Nay MD

Enclosures: State Form cc: License 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
	MDFH	A. BUILDING: _____ B. WING _____	07/31/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CARAFEM	5530 WISCONSIN AVENUE, SUITE 1200 CHEVY CHASE, MD 20815

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	Initial Comments A re-licensure survey was conducted at Carafem on July 30 and 31, 2019. An exit interview was conducted on July 31, 2019. The center performs surgical abortion procedures. The facility includes one procedure room. The survey included: an on-site visit; an observational tour of the physical environment; observation of one patient process; observation of cleaning of the procedure room, patient equipment and set up; observation of patient ultrasound process; observation of the registered nurse pre operative assessment; observation of medication preparation; observation of patient education process; observation of patient discharge process; observation of hand hygiene; review of the instrument cleaning/sterilization process; interview of the facility's administrator/certified nurse midwife, regional director of health services, 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. A total of six clinical records were reviewed. The surgical and medical abortion procedures that were performed between June 2018 and July 2019 were reviewed. Findings in this report are based on data present in the administrative records at the time of review. The administrator/certified nurse midwife was kept informed of the survey findings as the survey progressed. The administrator/certified nurse midwife was given the opportunity to present information relative to the findings during the	A 000		

Office of Health Care Quality

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A 000	Continued From page 1 course of the survey. A key code for patients contained herein was provided to the administrator/certified nurse midwife.	A 000		
A 410	.05 (A)(1)(d) .05 Administration (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 staff files and interview of staff, it was determined that the staff failed to provide training on the facility's policies and procedures to the staff for four of four staff files reviewed. Review of four staff files revealed that the staff have not received training on the facility's policies and procedures. Interview of staff on July 31, 2019 at 10:10 am revealed that the training acknowledgment form does not include the staff was provided training on the facility's policies and procedures.	A 410	A410 please see attached plan of correction	8/29/19
A 600	.05(C)(5) .05 Administration (5) Infection control for patients and staff; This Regulation is not met as evidenced by: Based on patient observations and interview of the staff, it was determined that the staff failed to implement infection control policies and failed to ensure that measures to prevent infection were practiced at the facility. These measures included	A 600		

Office of Health Care Quality

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A 600	Continued From page 2 failed to follow the Centers for Disease and Control and Prevention (CDC) standards when performing hand hygiene and failed to maintain the integrity of the disinfection germicidal wipes. The findings include. Observation of patient #1's care on July 30, 2019 at 11:23 am revealed the staff member performed hand hygiene using soap and water. The staff member turned the sink faucet handle on, wet hands, applied soap, scrubbed their hands and rinsed. After the staff member completed hand hygiene the staff member then turned the handle off with their wet hands recontaminating his/her hands. The same staff member then repeated that same process at 11:24 am. Observation on July 30, 2019 at 12:10 pm revealed the staff member withdrew a cavi wipe disinfection wipe from the container to clean the patient use equipment. The staff member did not closed the lid to the disinfection wipes. As of 2 pm the lid to the wipes had not been closed allowing the wipes to dry out. At 2:15 pm a container of cavi disinfection wipes was observed in the procedure room. The lid was closed but a disinfection wipe was hanging outside of the container allowing the disinfection wipes to dry out. Interview of the staff on July 30, 2019 at 2:30 pm revealed not aware of the infection control breaches.	A 600	A600 Please see attached plan of correction	8/29/19
A 810	.06(D)(1) .06 Personnel D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes:	A 810		

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A 810	Continued From page 3 (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 credentialing files and interview of the staff, it was determined that the scope of procedures performed and medical staff privileges were not reappraised for two of two credentialing files reviewed. The findings include. Review of the facility policy and interview of the staff on July 31, 2019 at 10 am revealed the medical staff privileges and reappointment are performed biennially. The staff member thought that the peer reviews were the reappointment. Review of credentialing files revealed that two staff members privileges were not reappraised and the biennial reappointments were not performed.	A 810	A810 Please see attached plan of correction	8/29/19
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: Based on interview of the staff and observation during a tour of the facility, it was determined that the staff failed to implement procedures to discard single use medications, expired medication and failed to label multiple dose medications. The findings included. Interview of staff on July 30, 2019 at 2 pm	A1280	A1280 Please see attached plan of correction	8/29/19

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A1280	Continued From page 4 revealed that the medications are checked when someone has time, "We have a small staff and have been very busy this year." During a tour of the instrument cleaning/storage area on July 30, 2019 at 12:30 pm revealed expired medications were not discarded and single dose medications were not discarded after use. 1. One bottle of Monsels solution (controls bleeding) expired on November 14, 2018. 2. Located in a supply basket, one 50mL multiple dose vials of lidocain HCL 2% (anesthetic) was opened and some of the medication was used. 3. Located in a supply basket, two 50mL single dose vials of Sodium Chloride 0.9% was opened and some of the medication had been used. The remaining unused portion of the single dose vial was not discarded. During a tour of procedure room on July 30, 2019 at 12:55 pm revealed that that medications were not labeled. 4. Located in a cabinet, two 50mL multiple dose vials of lidocain HCL 2% (anesthetic) were opened and some of the medication was used. There was no date written on the vial to document when the vial had been opened. There were no initials of the person who opened the vial. Medication vials must be labeled with the date that they are opened. Once opened, medication vials may only be used for twenty eight days after the date they were opened or follow manufactures instructions. The use past the date opened increases the risk for patient infection. Multiple use of patient single dose vials	A1280	A1280 cont (See attached)	

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A1280	Continued From page 5 contradicts the manufacture's instructions and increases the risk of patient infection related to inadequate mediation management.	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 interview of the staff and a tour of the facility, it was determined that the staff failed to implement infection control policies and failed to ensure that measures to prevent infection were practiced at the facility. These measures included failed to ensure the hinged surgical instruments were opened when sterilized. The findings include. During a tour on July 30, 2019 2 pm revealed that seventeen peel packs (used to contain surgical instruments for sterilization) contained hinged surgical instruments. The hinged instruments were not opened when they were sterilized to assure that the sterilization include the hinged areas. Interview of the staff on July 30, 2019 at 2 pm revealed that the staff was not aware that the hinged instruments were not opened.	A1510	A1510 Please see attached plan of correction	8/29/19
A1520	.15 (B) .15 Physical Environment B. A procedure room shall be designed and equipped to ensure that surgical abortion procedures conducted can be performed in a manner that ensures the safety of all individuals	A1520	A1520 Please see attached plan of correction	8/29/19

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A1520	Continued From page 6 in the area. This Regulation is not met as evidenced by: Based on the observational tour of the facility and interview of the staff, it was determined that the staff did not identify and discard the expired surgical supplies. The findings include. During a tour of the instrument cleaning area/storage area on July 30, 2019 at 12:15 pm revealed the following surgical supplies were expired. 1. Twenty-five jars of 10% neutral buffered formalin expired January 2019. 2. One bottle of KOH 10% (test for bacteria) expired on December 4, 2018. 3. One BD vacutainer (for collection of blood) expired on December 31, 2018. Interview of the staff on July 30, 2019 at 2 pm revealed that the supplies are checked when "someone has time".	A1520	A1520 continued	

carafem

Incident Investigation Report and Corrective Action Office of Health Care Quality ID MDFH Administration- A410.05(A)(1)(d)

Detailed Incident Description and Dates: On July 31, 2019, it was discovered upon a review of four staff files that the training acknowledgment form did not include details that the staff were trained on the policies and procedures of the health center. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted]

Why did this incident occur?
Current procedures for the onboarding and documentation of new center staff does not include a specific policy on reviewing policies. New staff onboarding does include a review of all policy and protocol with health services leadership.

Which system failed?
The policy for review of policy or protocol was not detailed to include a time frame for review of all policies nor did it contain enough assurance that all staff participated in the review of policies and a process for accountability for the review of all policies.

Why did the system fail?
The policy for review and training health center staff was not detailed and did not provide clarity for all staff.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
The policy and procedure for onboarding new or current health center staff was not clear and did not include documentation requirements after staff were trained on all health center policy and procedure.

Root Cause:
Lack of awareness and understanding of OHCQ Administrative standard A410.05(A)(1)(d) and failure to correctly interpret need for documentation and retention of the completed policy training.

Were patients affected?
No

Recommended Corrective Actions:
A revision to the current standard operating procedure for review of policies has been updated to include a policy that clarifies the need for a review of all policies during the onboarding and training of new health center staff has been completed. The policy also ensures any current staff will review any changes or updates to existing or new policy. The new procedure will be provided to the health centers immediately upon approval from the Maryland Office of Healthcare Quality. Concurrently, all health center staff have reviewed and retrained on all operating policy and procedure and documentation of the training is attached to this corrective action. Documentation will be held in the staff employee files.

Target Date to Complete Corrective Action:
Ongoing involvement from the Center Manager and VP of Clinical Operations is necessary to ensure correct documentation and process is followed for the onboarding and training of new health center staff. Staff files will be audited by the health center manager ensuring each staff member has been trained appropriately on current policy and procedure as well as any new policy and procedure that is implemented. Should any deviation from training of policy and procedure occur, the manager will report immediately to the VP for a corrective action.

Resolution:
All health center staff must be trained on all policy and procedure during the onboarding and new employee phase of employment. All current staff must be trained on any changes or additional policies. The health services manager must ensure training is provided and documented and that all documentation of training is held in the staff file. All staff and the health services manager will review this corrective action and the New Hire Policy and Procedure and immediately implement the procedures with any new staff hire. If any deviation from the training is encountered, it will be reported to the VP of Clinical Operations and a corrective action will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

Signat DocuSigned by: [redacted] C7S75D63A4624E2... Date: 8/29/2019

carafem

Incident Investigation Report and Corrective Action
Office of Health Care Quality ID MDFH Administration- A600.05(C)(5)

Detailed Incident Description and Dates: On July 30, 2019, it was observed during a review of staff hand hygiene practices that a staff member re-contaminated her hands after washing them. Also observed was a staff member not properly storing a bottle of disinfectant wipes after use causing the wipes to dry out. Another bottle of wipes was observed having the lid closed, but one wipe hanging out from under the lid. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted] VP

Why did this incident occur?
Current procedures for handwashing are posted in the health center with periodic informal review of proper techniques for hand hygiene, however staff did not follow the proper procedures to ensure contamination of clean hands after washing does not happen.

Staff did not follow the manufacturer's recommendations for the use and storage of Cavi Wipe disinfectant wipes.

Which system failed?
Staff adherence to established procedures for hand hygiene.

Staff did not follow the principles of infection control by not properly storing the bottle of wipes after use.

Why did the system fail?
Annual review of proper technique for hand hygiene was not performed. Additionally, staff did not follow previously trained techniques.

Staff failed to completely follow the manufacturer's guidelines for the use and storage of Cavi wipes. They did not read the label on the bottle of wipes to understand how the lid should be closed.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
Principles of infection prevention were not followed when a staff member was observed performing hand hygiene, however failed to use a paper towel to turn off the water after cleaning her hands. This caused recontamination of her hands breaching infection control.

A staff member removed a Cavi Wipe from the bottle to disinfect a piece of equipment after client use. The staff member did not ensure the lid to the Cavi Wipe bottle was completely closed which can cause the wipes to dry out. The staff member also did not ensure that on closed bottles of Cavi Wipes there were no wipes hanging out the side of the closed lid. This error caused a breach in the principles of infection control by allowing the wipes to be exposed to air and dry out.

Root Cause:
Lack of awareness and understanding of OHCQ Administrative standard A600.05(C)(5) and failure to correctly understand the principles of infection control as it pertains to hand hygiene and the use and storage of disinfectant wipes.

Were patients affected?
No

Recommended Corrective Actions:
Health center staff have attended an infection prevention training. This online learning module is made available by the National Abortion Federation. The training includes the principles and proper technique for hand hygiene which included the necessity of preventing recontamination of hands by using a paper towel to turn of the water. Staff also reviewed the manufacturer's recommended use and storage for Cavi Wipes. Staff were trained on the importance of ensuring the lid is tightly sealed and no wipes are hanging out of the lid. All health center staff have reviewed and retrained on these infection control procedures and documentation of the training is attached to this corrective action. Documentation will be held in the staff employee files. The monthly OSHA audit will be updated to include this criteria and will be reported forward at quarterly quality and risk management meetings.

Target Date to Complete Corrective Action:
Ongoing involvement from the Health Services Manager is required to monitor hand hygiene technique. The manager will periodically observe staff to ensure proper technique is used. The Manager will also monitor all bottles of Cavi Wipes in use in the center to ensure they are properly closed and stored. Should any deviation from either of these procedures occur, the manager will report immediately to the VP for a corrective action.

Resolution:
All health center staff have been trained on the principles of infection control. All current staff will adhere to the guidelines for hand hygiene and proper use and storage of disinfectant wipes. All health center staff and the health services manager will review this corrective action and immediately implement and sustain principles of infection control. If any deviation from the

training is encountered, it will be reported to the VP of Clinical Operations and a corrective action will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

DocuSigned by:

Signat [redacted] **Date:** 8/29/2019

carafem

Incident Investigation Report and Corrective Action Office of Health Care Quality ID MDFH Administration- A810.06(D)(1)

Detailed Incident Description and Dates: On July 31, 2019, it was discovered upon a review of two physician credentialing files that a biennial medical staff reappointment letter was not on file. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted] VP

Why did this incident occur?
Current procedures for the reappointment of medical staff includes a biennial physician-to-physician peer review of skills with documentation of the skills observation. These reviews are retained in the physician credentialing files; however, these reviews were erroneously interpreted as the reappointment of privileges documentation.

Which system failed?
Carafem leadership's review and interpretation of the Personnel Standards of the Maryland Comar and required documentation for physicians who are privileged to provide abortion services.

Why did the system fail?
The system for review failed due to leadership interpretation which was not confirmed with an officer of the OHCQ.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
The Maryland Comar Standard for granting and maintaining physician privileging to provide abortion care was not interpreted correctly. The standard includes specific language around re-appointing privileges biennially including a letter of reappointment, not a peer skills review. Specific documentation reappointing the two physicians were not maintained by the health center.

Root Cause:

Lack of awareness and understanding of OHCQ Administrative standard A810.06(D)(1) and failure to correctly interpret need for the reappointment of physician privileges to provide abortion care biennially.

Were patients affected?
No

Recommended Corrective Actions:
In addition to a biennial peer review, a formal reappointment of privileges for physicians has been implemented along with a physician job description which outlines all duties per provider end encompasses the entirety of each staff physician responsibilities. These will be held in the physician credentialing files (see attached example). The new documentation for reappointment and privileging has been approved by the Medical Director and will be provided to the health center manager immediately upon approval from the Maryland Office of Healthcare Quality. Both physicians on staff have been reappointed and documentation of the reappointment is attached to this corrective action. Documentation will be held in the physician credentialing files and audited by administration annually.

Target Date to Complete Corrective Action:
Immediate completion of physician credentialing and reappointment has occurred. Ongoing physician file reviews by the Manager and VP of Clinical Operations is necessary to ensure physicians are not only observed by the medical director or his designee for skills evaluation, but that physicians are reappointed and granted privileges to perform abortion services at carafem. Physician files will be audited annually by by administration ensuring each physician is appropriately appointed. Should any deviation from this corrective action occur, the manager will report immediately to the VP for additional action.

Resolution:
All physicians must be evaluated and reappointed biennially in order to provide abortion care. The health services manager must ensure both a skills assessment and a letter of privileging reappointment is maintained biennially in the physician credentialing files. The physicians and health services manager will review this corrective action and will immediately implement and sustain the practice of biennial privilege reappointment. If any deviation from the action is encountered, it will be reported to the VP of Clinical Operations and additional actions will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

DocuSigned by:
Signatur [redacted] **Date:** 8/29/2019

carafem

Incident Investigation Report and Corrective Action
Office of Health Care Quality ID MDFH
Administration- A1280.11(B)(1)

Detailed Incident Description and Dates: On July 30, 2019, it was discovered upon observation during a tour of the facility that medical staff did not discard single use medications or expired medications and failed to discard expired medications. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted] VP

Why did this incident occur?
Staff failed to adhere to procedures for managing the storage and use of medications including proper labeling techniques of opened medications. Staff failed to perform expiration checks for medications stored in all cabinets, drawers and supply baskets.

Which system failed?
The procedures for inventory and medication management was not followed.

Why did the system fail?
Staff did not properly ensure all storage areas of the clinic were routinely inspected. Staff did not follow operating procedures for the use of single and multiple dose vial medications.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
The Maryland Comar Standard for pharmaceutical services was not followed. The standard includes instruction for the use and discard of single dose vials of medications, instructions for labeling multi-dose vials of medication with the initials of the staff member opening the medication and an expiry date of 28 days from the open date and instructions for the disposal of expired medications.

Root Cause:
Lack of awareness and understanding of OHCQ Administrative standard A1280.11(B)(1) and failure to correctly manage medication inventories and disposal of medications.

Were patients affected?
No

Recommended Corrective Actions:
A review to the current procedure for the inventory of all medications and supplies has been completed. Staff have attended a training for the proper handling, use and disposal of multi-dose and single dose vial medications. Additionally, staff viewed an online learning module from the National Abortion Federation entitled "Clinic Inventory Management". The Health Services Manager will perform a monthly audit of all single and multi-dose vials of medication to ensure no single dose vials have been retained after opening and all multi-dose vials are labeled appropriately with staff initials and the expiry date. This audit of medications will occur in addition to the routine monthly supply inventory being performed.

Target Date to Complete Corrective Action:
Immediate completion of all medication inventory has occurred. Ongoing audits of medication inventories will occur monthly and will occur continuously with no end date. Should any deviation from this corrective action occur, the manager will report immediately to the VP for additional action.

Resolution:
All medications in the health center must be handled, used and disposed of according the Maryland Comar Standard. The health services manager and health center staff will review this corrective action and will immediately implement and sustain the practice of monthly audits of all medication inventory in addition to the regular inventory management process. If any deviation from the action is encountered, it will be reported to the VP of Clinical Operations and additional actions will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

DocuSigned by:
Signatu [redacted] **Date:** 8/29/2019

carafem

Incident Investigation Report and Corrective Action Office of Health Care Quality ID MDFH Administration- A1520.15(B)

Detailed Incident Description and Dates: On July 30, 2019, it was discovered upon observation during a tour of the health center that medical staff did not discard expired lab/surgical supplies. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted] VP

Why did this incident occur?
Staff failed to adhere to procedures for managing the storage and use of all supplies. Staff failed to perform expiration checks for supplies stored in all cabinets, drawers and supply baskets.

Which system failed?
The procedures for inventory and medication management was not followed.

Why did the system fail?
Staff did not properly ensure all storage areas of the clinic were routinely inspected. Staff did not follow operating procedures for the storage and discarding of expired supplies.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
The Maryland Comar Standard for Physical Environment was not followed. The standard includes instruction for the storage, handling and discarding of expired supplies.

Root Cause:
Lack of awareness and understanding of OHCQ Administrative standard A1520.15(B) and failure to correctly follow inventory management procedures.

Were patients affected?
No

Recommended Corrective Actions:
All 25 vials of buffered formalin were discarded as collection of cervical smears for pap testing was not a service rendered. The bottle of KOH and the single vacutainer for the transport of urine were both discarded. A review of the current procedure for the inventory of all medications and supplies has been completed. Staff completed an online learning module from the National Abortion Federation entitled "Clinic Inventory Management". The Health Services Manager has created a central supply system of storage for all laboratory supplies and has removed all supplies from storage cabinets outside of the lab. As recommended by the online learning module and per the existing policy and procedure, the manager will perform monthly inventory of all laboratory supplies. Additional, the manager will mark any supply with an expiry date of 60 days or less to identify expiring supplies to be used or discarded prior to the expiration. Additionally, the manager will perform a quarterly supply audit of all cabinets, drawers and baskets to identify any supplies that may be in use to confirm they have not expired. This quarterly audit will be reported forward to the quality and risk management team. All expired supplies will be discarded according to the manufacturer's recommended practices.

Target Date to Complete Corrective Action:
Review of all supply inventories has occurred. Ongoing monthly inventories of all supplies will continue and the quarterly audit of supplies will begin immediately and will quarterly for two consecutive quarters. Should any deviation from this corrective action occur, the manager will report immediately to the VP for additional action.

Resolution:
All supplies in the health center must be handled, used and disposed of according the Maryland Comar Standard. The health services manager and health center staff will review this corrective action and will immediately implement the updated procedures and will begin expanded inventory audits. If any deviation from the action is encountered, it will be reported to the VP of Clinical Operations and additional actions will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

DocuSigned by:
Signat[redacted] Date: 8/29/2019

carafem

Incident Investigation Report and Corrective Action Office of Health Care Quality ID MDFH Administration- A1510.15(A)

Detailed Incident Description and Dates: On July 30, 2019, it was discovered upon observation during a tour of the health center that medical staff failed to ensure that hinged instruments were open when sterilized. This was confirmed by the Maryland office of Health Care Quality via OHCQ State Form on August 8, 2019.

Location of Incident: carafem, Friendship Heights- 5530 Wisconsin Ave, Ste 1200, Chevy Chase, MD 20815
Persons Affected: No affected persons
Documented by: [redacted] Compliance Officer and [redacted] VP of Clinical Operations
Director Notified: 7/31/19

Person Appointed to Perform Investigation: [redacted] VP

Why did this incident occur?
Staff failed to adhere to procedures for infection control and prevention. Staff failed to properly open all hinged instruments during the sterilization process.

Which system failed?
The procedures for infection prevention was not followed.

Why did the system fail?
Staff did not follow operating policy and procedures for the prevention and control of infection during sterilization sessions.

Were patient specimens tested while this problem existed?
Yes, however there is no indication of error in procedure or performance of patient testing.

Conclusion:
The Maryland Comar Standard for Physical Environment was not followed. The standard includes infection control policies for the prevention of infection.

Root Cause:
Lack of awareness and understanding of OHCQ Administrative standard A1510.15(A) and failure to correctly follow infection prevention practices.

Were patients affected?
No

Recommended Corrective Actions:
A review of the current procedure for the sterilization of surgical instruments has been completed. Staff have an online learning module from the National Abortion Federation entitled "Infection Prevention 2- Instrument Processing". All instrument packs containing hinged instruments have been sterilized with the hinges open to maximize the sterilization process. The manager will inspect all sterilized packs to ensure all hinges are open during processing for the next 90 days. If no other infractions are documented, the manager will then perform spot checks of sterilized packs. The spot check of sterilized instrument is added to the monthly laboratory audit and results will be reported forward to the quality and risk management team.

Target Date to Complete Corrective Action:
Proper sterilization of all hinged instruments has occurred. Inspection of all sterilized packs will begin immediately and will occur weekly for the next 90 days. Should any deviation from this corrective action occur, the manager will report immediately to the VP for additional action.

Resolution:
All hinged instruments sterilized for use in the health center must be processed according the Maryland Comar Standard. The health services manager and health center staff will review this corrective action and will immediately implement and sustain the practice of infection prevention as it pertains to sterilizing instruments and will audit all sterilized packs monthly to ensure hinges are open during the process. If any deviation from the action is encountered, it will be reported to the VP of Clinical Operations and additional actions will be completed for review by the Quality and Risk Management team.

Verification of resolution if patient testing was stopped: Not applicable

Medical Director's Review and Approval:

DocuSigned by:

Signatu [redacted] **Date:** 8/29/2019