sent via email on 8/19/19

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).**

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, 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

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
	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

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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		

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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		
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	A 600		

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A 600	Continued From page 2 practiced at the facility. These measures included 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		
A 810	.06(D)(1) .06 Personnel D. The administrator shall establish a procedure for the biennial reappointment of a physician	A 810		

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A 810	Continued From page 3 which includes: (1) An update of the information required in §B of this regulation; and This Regulation is not met as evidenced by: Based on review of 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		
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.	A1280		

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A1280	Continued From page 4 Interview of staff on July 30, 2019 at 2 pm 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.	A1280		

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A1280	Continued From page 5 Multiple use of patient single dose vials 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		
A1520	.15 (B) .15 Physical Environment B. A procedure room shall be designed and equipped to ensure that surgical abortion	A1520		

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A1520	Continued From page 6 procedures conducted can be performed in a manner that ensures the safety of all individuals 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		