MARYLAND
Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Office of Health Care Quality
Patricia Nay M.D., Executive Director
7120 Samuel Morse Drive, Second Floor
Columbia, MD 21046- 3422

January 6, 2020

Administrator
Hillcrest Clinic, Inc
5602 Baltimore National Pike, Suite 600
Baltimore, MD 21228

RE: NOTICE OF CURRENT DEFICIENCIES

Dear Administrator:

On November 4, 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, MD

Patricia Nay, M.D.
Executive Director

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
	SACHCMD	A. BUILDING: _____ B. WING _____	11/05/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HILLCREST CLINIC, INC	5602 BALTIMORE NATIONAL PIKE, SUITE 600 BALTIMORE, MD 21228

(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 Maryland state licensure survey of Hillcrest Clinic, Inc. was conducted on November 4 and 5, 2019. The survey included: interview of the staff; an observational tour of the physical environment; observation of a surgical procedure; 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 operating rooms. A total of six patient clinical records were reviewed. The procedures were performed between February 2019 and November 2019. A key code for the staff and patients 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 380	.05 (A)(1)(a) .05 Administration (a) Consulting with the staff to develop and implement the facility ' s policies and procedures in accordance with §C of this regulation; This Regulation is not met as evidenced by: Based on interview of staff, review of the policy	A 380	A380 1. No patients were affected. 2. Staff will hold a fire drill on a quarterly basis.	1/10/2020

OHCQ

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

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A 380	Continued From page 1 and procedure manual and review of fire drill documentation, the administrator failed to ensure that fire drills were conducted on quarterly basis, according to policy. The findings include: Interview of staff on 11/5/19 at 1:30 pm revealed that fire drills with staff were to be conducted on a quarterly basis. Review of the policy and procedure manual revealed that the policy did not include the frequency fire drills were to be conducted at the facility, and the components of fire drill documentation. The components of fire drill documentation must include: date of the drill, start and stop times, scenario of fire, critique of the drill and a sign in sheet for the staff who participated in the drill. Review of fire drill documentation from November 2017 to the survey date revealed lack of documentation that the fire drills were not conducted on a quarterly basis and in accordance with the policy.	A 380	A380 Continued. 3. Quarterly staff fire drills with include: - scenario, start and stop times, sign in sheet for staff, a critique and review of the drill. 4. The administrator will be responsible for insuring fire drills are done quarterly and they will be mandatory for all staff.	
A 900	.06(E)(1)(b) .06 Personnel (b) The administrator shall approve the delineation of services to be provided by the health professional. This Regulation is not met as evidenced by: Based on review of staff credentialing files and interview of staff, the administrator failed to ensure the delineation of services were approved for two of three anesthesia providers reviewed. The findings include:	A 900	A900 1. No patients were affected. 2. N/A 3. All employee files will be reviewed monthly to ensure all necessary paperwork if filled out correctly and signed but the appropriate employee. 4. The administrator will review employee files.	1/10/2020

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A 900	Continued From page 2 Review of two anesthesia providers credentialing files revealed that the "Application for Medical Staff Privileges" was signed by one of the providers on 6/21/18. The other anesthesia provider signed the form on 8/16/19. However, the Chair of the Governing Body failed to sign both forms to approve the delineation of services.	A 900		
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 a tour of the facility, interview of staff and observation of a patient procedure, the staff failed to maintain and prepare medications in a secure and safe manner. The findings include: 1. A tour of the facility revealed there was an anesthesia machine located in operating room #2. The operating room was unoccupied by staff, and was not in use that day. The drawers on the anesthesia machine were unlocked, and one of the drawers contained medications. Medications must be stored in a secure, locked location to prevent unwanted access and misuse. 2. During a tour of the facility, the following expired medication was observed in a locked cabinet in the supply room: Naloxone (medication used to block effects of opioid medication), 3 vials, expired 5/1/19. Interview of staff on 11/5/19 at 9:00 am revealed that she/he acknowledged that the staff failed to	A1280	A1280 1. (1,2,3) No patients were affected. 2. (1) All medications will be kept in a locked cabinet in a monitored and secure area. (2) All expired medication will be properly disposed of. A monthly expiration date check will be conducted. (3) All pre-drawn medication will be labeled at the time they are drawn up. 3. (1) Medications will be kept in locked cabinet that will be opened at the beginning of each day and returned to that cabinet to be locked at the end of each day. When the medications are taken out the are given directly to the anesthesia provider and never left unmonitored. (2) A monthly expiration date of all medication will be conducted. (3) Labels for each medication will be provided and kept with each medication. 4. (1)The administrator will be responsible for getting the medications out of the locked cabinet and putting them back, making sure the cabinet is locked. While medications are in use the anesthesia provider will be responsible for medications. (2) The RN will check all medications.	1/10/2020

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A1280	Continued From page 3 identify and discard the expired medication. 3. Observation of a patient procedure revealed that prior to the start of the procedure, the staff pre-drew ten syringes of Propofol (anesthesia medication) to be given to several patients throughout that morning. However, the staff failed to label the syringes of Propofol to be used throughout that morning. All pre-filled syringes of medication must be labeled with the following information: name of the medication, strength of the medication, and date and time the medication was drawn into the syringe. Interview of staff on 11/5/19 at 1:00 pm revealed that she/he acknowledged that the pre-filled syringes of Propofol should have been appropriately labeled.	A1280	A1280 Continued 4. (3) The anesthesia provider will be responsible for drawing up medications and labeling each one at the time they are drawn up.	
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, observation of surgical instrument reprocessing and observation of a patient procedure, the administrator failed to ensure that a safe and sanitary environment was maintained for the provision of surgical services. The findings include: 1. A tour of the facility revealed that there were two portable oxygen tanks freestanding on the floor in the patient recovery area. They were not secured in stands, or with chains against the wall.	A1510	A1510 1. (1,2,3,4) No patients were affected. 2. (1) Oxygens tanks will be kept in a secure location. (2) The correct ratio of solution to water will be measured each time according to the manufacturers recommendations. (3) All equipment will wiped down and disinfected between patients. (4) [A,B,C,D] Correct Hand hygiene practices will be implemented in all areas of the clinic. 3. (1) Free standing oxygen tanks will be secured to a wall if they are not secured in a stand. (2) Measuring tools are in kept in CSR with the instructions posted on how to mix the solution and water to ensure it is done correctly every time.	1/10/2020

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A1510	Continued From page 4 Interview of staff on 11/5/19 at 9:00 am revealed she/he acknowledged that the unsecured oxygen tanks were a safety hazard. 2. Observation of surgical instrument reprocessing revealed the staff used an enzymatic cleaner to pre-clean dirty surgical instruments. The manufacturer's instructions on the bottle of enzymatic cleaner stated "1/2 to 1 ounce of solution to one gallon of water." The staff poured an undetermined amount of water into a basin, then mixed an undetermined amount of enzymatic solution into the water. The staff failed to measure the amount of enzymatic solution and water in order to make the appropriate mixture, according to manufacturer's instructions. It is essential to follow the manufacturer's instructions to ensure the dirty surgical instruments are adequately cleaned in order to minimize the risk of patient infections. The facility used two autoclave machines to sterilize surgical instruments. Review of the spore testing log from January 2019 to the date of this survey revealed that the autoclave machines were not spore tested on a weekly basis. Centers for Disease Control recommend weekly use of spore testing to ensure the efficacy of an autoclave machine in the sterilization process. Interview of staff on 11/5/19 at 12:00 pm revealed that the enzymatic cleaner was not prepared according to manufacturer's instructions, and that spore testing on the autoclave machines was not performed on a weekly basis. 3. Observation of a patient procedure revealed the following breach in infection control regarding	A1510	A1510 Continued 3. (3) Sani wipes will be kept in each room of the clinic to ensure all equipment coming in contact with a patients is wiped down and disinfected between uses. (4) A quarterly hand hygiene in-service will be held in the clinic to assess and re-ensure staff is following the correct hand hygiene protocol. Attendance in mandatory and staff will need to sign in showing they attended. 4. (1) The administrator will be responsible for ensure oxygen tanks are secure. (2) The medical assistant setting up CSR for that day will be responsible for ensuring the enzymatic solution is mixed properly. (3) Each medical assistant will be responsible for disinfecting the equipment in the room that he/she is working in that day. (4) The RN will give the hand hygiene seminar on a quarterly basis.	

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A1510	Continued From page 5 the use of medical equipment for patient care: At the start of the patient's procedure, staff placed a clip device around the patient's forearm to monitor cardiac function. The inside of the clip, which goes against the patient's skin was not cleaned between patients. In order to prevent infection from cross contamination, medical equipment that comes in contact with patients must be cleaned with an EPA approved produce between every patient use. 4. Observation of a patient procedure revealed the following breaches in infection control regarding hand hygiene: a. Staff put on non-sterile gloves, handled the patient's container of a urine sample, then removed the non-sterile gloves. The staff failed to wash her/his hands with hand gel or soap and water prior to putting the non-sterile gloves on, and after taking the gloves off. b. Staff put on non-sterile gloves, then performed the patient's ultrasound test. After performing the test, the staff removed the non-sterile gloves and failed to wash her/his hands with hand gel or soap and water. c. Staff used hand gel, answered his/her cell phone, then put on non-sterile gloves. The staff failed to use hand gel after touching the phone, prior to putting on non-sterile gloves. d. After removing non-sterile gloves, staff washed his/her hands with soap and water in the sink. The staff turned the water off to the sink with wet hands, then dried his/her with a paper towel. Staff must wash hands with soap and water or	A1510		

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A1510	Continued From page 6 hand gel immediately before putting gloves on, and immediately after taking gloves off. Additionally, after washing hands with soap and water, staff must first dry hands with a paper towel. Then, turn off the water to the sink with the paper towel touching the sink handles.	A1510		
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 in the area. This Regulation is not met as evidenced by: Based on a tour of the facility and interview of staff, the staff failed to identify and discard the expired surgical supplies. The findings include: A tour of the facility revealed the following expired supplies were located in the supply room: a. Four boxes of catheters, expired 7/19. b. Ten 7mm curettes, expired 9/19. c. Fifty 7mm curettes, expired 7/19. d. Four 6mm curettes, expired 2/17. e. Four 6mm curettes, expired 4/17. f. Two 6mm curettes, expired 1/18. g. Three 6mm curettes, expired 3/18. h. Two 6mm curettes, expired 7/18. i. Forty 11mm curettes, expired 8/18. j. Four 11mm curettes, expired 1/18. k. Three 11mm curettes, expired 5/18. l. One 9mm currette, expired 11/18. m. Ten 10mm curettes, expired 6/19. n. One 12mm curette, expired 7/17. o. Three 12mm curettes, expired 6/19. p. Three 12mm curettes, expired 10/19.	A1520	A1520 1. No patients were affected. 2. All expired supplies will be properly discarded prior to the expiration date. 3. A monthly expiration date check on all supplies in the clinic will be preformed. Any expired supplies will be noted and disposed of. 4. All medical assistants will coordinate to ensure all expired supplies are thrown out.	1/10/2020

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A1520	Continued From page 7 The following expired supplies were located in the surgical instrument reprocessing room: a. One bottle of Envirocide (cleaning product), expired 10/16. b. One bottle of Revital - Ox Resert (high level disinfectant), expired 1/19. Interview of staff on 11/4/19 at 12:00 pm revealed that she/he acknowledged that the staff failed to identify and discard the expired supplies.	A1520		