MARYLAND
Department of Health

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

Office of Health Care Quality, 55 Wade Avenue, Catonsville, Maryland 21228

October 12, 2018

Administrator
Abortionclinics Org, Inc
10401 Old Georgetown Road, Suite 104
Bethesda, MD 20814

RE: NOTICE OF CURRENT DEFICIENCIES

Dear Administrator:

On August 13, 14, 15 and 16, 2018, 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.

III. 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, Spring Grove Center, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228 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.

IV. 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, 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.

If you have any questions concerning the instructions contained in this letter, please contact me at 410-402-8055.

Sincerely,

Patricia Nay, MD

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
	SA00020	A. BUILDING: _____ B. WING _____	C 08/16/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ABORTIONCLINICS ORG, INC	10401 OLD GEORGETOWN ROAD, SUITE 104 BETHESDA, MD 20814

(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 complaint investigation was conducted at AbortionClinics.Org in Bethesda, Maryland on 0/8/13-08/16/18. The complaint was anonymous. Complaint reference number: #MD00129648 The survey included an unannounced on-site visit; an observational tour of the physical environment; observation of one surgical procedure; observation of cleaning of the procedure room, patient equipment and set up; observation of the pre operative assessment; observation of medication preparation; observation of patient education process; observation of patient discharge process; observation of hand hygiene; observation of instrument cleaning/sterilization process; interviews of the facility's medical director, administrator and clinical staff; review of the policy and procedure manuals; review of the personnel files; review of quality assurance and infection control programs; and review of professional credentialing. The complaint was unsubstantiated; however, the investigative process identified other areas of deficient practice, resulting in the following citations.	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 policies, review of personnel files and interview, it was determined that	A 410		

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A 410	Continued From page 1 administration failed to ensure all staff had been trained in the facility's policies and procedures. This was evident for 5 of 7 staff. The findings include: Review of personnel files on 08/13/18, starting at 10:55 AM, revealed that 5 of 7 staff failed to have documentation of training on the facility's policies and procedures. Review of policies revealed that the facility has a form specific to staff training; however, this form was not present in each employee's personnel file.	A 410		
A 420	.05 (A)(1)(e)(i) .05 Administration (e) Ensuring that all personnel: (i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices; This Regulation is not met as evidenced by: Based on review of policies, review of personnel files and interview, it was determined that administration failed to ensure all staff received orientation and competency assessments prior to performing patient care tasks. This was evident for 7 of 7 staff. The findings include: Review of personnel files on 08/13/18, starting at 10:55 AM, revealed that 7 of 7 staff failed to have documentation of orientation to the facility. Review revealed that 5 of 7 staff failed to have documentation of competency/skills assessment.	A 420		
A 560	.05(C)(2)(b) .05 Administration	A 560		

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A 560	Continued From page 2 (b) Job descriptions on file for all personnel: and This Regulation is not met as evidenced by: Based on a review of the facility's policy manual and review of personnel files, the administration failed to have a signed job description on file for each staff member. This was evident for 7 of 7 staff. The findings include: Review of personnel files on 08/14/18, starting at 10:55 AM, revealed that 7 of 7 personnel files failed to contain a signed job description.	A 560		
A 570	.05(C)(2)(c) .05 Administration (c) Procedures to ensure personnel are free from communicable diseases; This Regulation is not met as evidenced by: Based on review of policies and review of personnel files, it was determined that administration failed to ensure all staff were screened to ensure that they were free from communicable diseases. This was evident for 2 of 7 staff. The findings include: Review of personnel files on 08/13/18, starting at 10:55 AM, revealed that 2 of 7 staff failed to have documentation of Hepatitis B vaccination series or declination. Review of personnel files revealed that 1 of 7 staff failed to have documentation of tuberculin skin testing.	A 570		

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A 600	Continued From page 3	A 600		
A 600	.05(C)(5) .05 Administration (5) Infection control for patients and staff; This Regulation is not met as evidenced by: Based on observations, it was determined the administration failed to ensure all measures to prevent infection were practiced at the facility. These measures include the failure to ensure use of full personal protective equipment (PPE) and the failure to monitor for and discard expired medical supplies. The findings include: 1. Observations of the process of precleaning surgical equipment on 08/14/18 at 1:40 PM revealed the staff member was not wearing full PPE. Staff wore a gown, gloves and his/her own eyeglasses while cleaning contaminated instruments. Staff failed to wear a facemask and protective eye goggles for full protection against accidental spills or splashes. 2. Observations on 08/14/18, starting at 3:30 PM, revealed the following expired items: a. Red top vacutainer, 10 ml; 1; expired 02/18; b. Yellow top vacutainer, 5 ml; 3; expired 02/28/18; 3. Observations on 08/15/18 at 9:45 AM and revealed the following expired items: a. Yellow top vacutainer, 5 ml; 1; expired 06/20/18; b. Blue top vacutainer; 12; expired 06/30/18.	A 600		
A 620	.05(C)(7) .05 Administration (7) Preventive maintenance for equipment to ensure proper operation and safety; and	A 620		

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A 620	Continued From page 4 This Regulation is not met as evidenced by: Based on observations, it was determined that the administration failed to ensure annual bio-medical maintenance of equipment used for patient care. The findings include: 1. Observations on 08/14/18, starting at 3:30 PM, revealed the following: a. Pulse Ox machines; 2; last tested 02/17, due for retest 02/18. 2. Observations continued on 08/15/18 at 9:45 AM and revealed the following: a. Automatic External Defibrillator (AED) without an inspection sticker; b. Ritter-M11 Ultra Care Automatic Sterilizer without an inspection sticker.	A 620		
A1250	.10 (B)(5) .10 Hospitalization (5) Appropriate training for staff in the facility 's written protocols and procedures. This Regulation is not met as evidenced by: Based on a review of policies and review of personnel records, it was determined that administration failed to have all staff trained in the protocol for emergency transfer from the clinic to a hospital. This was evident for 3 of 7 staff members. The findings include: Review of personnel records on 08/14/18, starting at 10:55 AM, revealed that 3 of 7 staff members did not have documentation of emergency transfer training.	A1250		

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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 observations and review of the daily narcotic count log, it was determined the administration failed to monitor for and discard expired medications, and failed to account for and dispose of narcotic medication according to standards of practice. The findings include: 1. Observations on 08/14/18, starting at 3:30 PM, revealed the following expired items: a. Bacteriostatic Water, 30 ml multi-dose vial (MDV); 1; expired 07/01/18; b. Misoprostol (used to start labor) bottle of 200 mcg tablets; 1 bottle; opened, used, not dated at the time of initial access; c. 10 ml syringe, labeled as containing Pitocin (used to cause the uterus to contract); 1; predrawn on 08/13/18 at 9:04 AM; label states "Discard in 24 hrs"; d. 10 ml syringe, labeled as containing Bupivacaine 0.25 % with Epinephrine 1:500,000 (used as an anesthetic); 3; predrawn on 08/14/18 at 9:30 AM; label states "Discard in 24 hrs". e. 10 ml syringe, labeled as containing KCl (potassium); 1; predrawn on 08/13/18 at 11:19 AM; label states "Discard in 24 hrs". 2. Observations on 08/15/18 at 9:45 AM revealed findings are as follows: a. Hydroxyzine Pomoate (used to treat allergy symptoms or with other medication to induce sleep before surgery) capsules 50 mg, bottle of 500 caps; 2 bottles; opened, some used, not	A1270		

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A1270	Continued From page 6 dated or initialed at the time of initial access; b. Ibuprofen (pain reliever) tablets 800 mg, bottle of 500 tabs; 1 bottle; opened, some used, not dated or initialed at the time of initial access; c. Ciprofloxacin (antibiotic) tablets 500 mg, bottle of 500 tabs; 1; opened, some used, not dated or initialed at the time of initial access; d. Diphenhydramine HCl (used to treat allergy symptoms) capsules 25 mg, bottle of 1000 caps; 1; opened, some used, not dated or initialed at the time of initial access; e. Azithromycin (antibiotic) tablets 500 mg, bottle of 30 tabs; 1; opened, some used, not dated or initialed at the time of initial access. 3. Review of the "Daily Narcotics Count Log" from January 2018 to 08/15/18 revealed there is only one licensed personnel signing off for the AM/ PM count of narcotics. Further review revealed that unlicensed staff were conducting AM/PM narcotic counts. 4. Review of the "Daily Narcotics Used and Wasted Log" on 08/15/18 at 10:30 AM revealed that narcotics are not being wasted and witnessed by 2 licensed personnel.	A1270		
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 review of facility documentation and interview, it was determined that the administration failed to conduct fire and disaster drills. The findings include:	A1510		

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A1510	Continued From page 7 Review of facility documentation failed to reveal documentation of fire and disaster drills. During an interview with the administrator on 08/13/18 at 1:35 PM, it was revealed fire and disaster drills have not been performed as their policy states.	A1510		
A1550	.16 (A)(1) .16 Quality Assurance Program A. The administrator shall ensure that the facility develops and maintains a quality assurance program which includes: (1) Monitoring and evaluation of the quality of patient care; and This Regulation is not met as evidenced by: Based on review of policies, review of facility documentation and interview, it was determined that administration failed to perform on-going Quality Assurance activities. The findings include: Interview with the administrator on 08/13/18 at 1:35 PM confirmed that quarterly Quality Assurance meetings are not being held.	A1550		