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
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

March 26, 2013

Administrator
Associates In OB/GYN Care, LLC
6005 Landover Road
Cheverly, MD 20785

RE: NOTICE OF CURRENT VIOLATIONS, IMPOSITION OF ADMINISTRATIVE PENALTY UNDER STATE REGULATIONS

Dear

On February 20, 2013, a initial survey was conducted by the Office of Health Care Quality to determine if your facility was in compliance with State Regulations for Surgical Abortion Facilities, Code of Maryland Regulations 10.12.01.

All references to regulatory requirements contained in this letter are found in COMAR Title 10, and the State Government Article.

I. PLAN OF CORRECTION (PoC)

A PoC for the violations must be submitted within 10 days after the facility receives its Statement of Deficiencies State Form. Your Plan of Correction must be entered in the appropriate column on the right of the State Form. An authorized representative of your facility must sign and date the form in the designated space provided. Your PoC must contain the following:

- What corrective action will be accomplished for those patients found to have been affected by the violation;
- How you will identify other patients having the potential to be affected by the same violation 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 violation does not recur;
- How the corrective action(s) will be monitored to ensure the violation will not recur, i.e., what quality assurance program will be put into place;

- Specific date when the corrective action will be completed; and

- **References to staff and patients by identification number only** as noted in the Patient and Staff Roster. This applies to the PoC as well as any attachments to the PoC. It is unacceptable to include staff or patient names in these documents since the documents are released to the public.

II. Immediate Imposition of an Administrative Money Penalty Under Code of Maryland Regulations

Under the Code of Maryland Regulations (COMAR) 10.12.01.19, the Department of Health and Mental Hygiene has the authority to impose an administrative penalty of up to $1,000 for a violation of any provision of COMAR 10.12.01.

Based upon the violation(s) cited at your facility, I hereby impose an administrative penalty of $1000. The violation(s) upon which the penalty is based are enclosed with this letter on the State Form. Of particular concern were the violations cited under COMAR 10.12.01.07 B involving the facility's failure to ensure the maintenance of the automated external defibrillator and suction machines.

In determining whether to impose an administrative penalty, the Department took into consideration the following factors:

1. The number, nature, and seriousness of the violation or violations;
2. The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;
3. The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;
4. The efforts made by, and the ability of, the licensee to correct the the violation or violations in a timely manner; and
5. Such other factors as justice may require.

The facility may request a hearing on the decision to impose a penalty. Any hearing will be held in accordance with State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03. Any request for a hearing must be submitted in writing to Paul J. Ballard, Office of the Attorney General, 300 West Preston Street, Suite 302, Baltimore, Maryland 21201, no later than 30 days after receipt of this notice. The request shall include a copy of this letter. If the informal dispute resolution process referenced in elsewhere in this letter does not result in settlement of this matter, this matter will be referred to the Office of Administrative Hearings to hold a hearing and issue a proposed decision within 10 working days of the hearing. The aggrieved person may file exceptions as provided in COMAR 10.01.03.35. A final decision by the Secretary shall be issued in accordance with COMAR 10.01.03.35. If you do not request a hearing within 30 days after the receipt of this notice, the imposition of the penalty will become final at that time.

Please make your check payable to the Department of Health and Mental Hygiene and submit to the attention of Barbara Fagan, Program Manager, at the Office of Health Care Quality.

IV. ALLEGATION OF COMPLIANCE

If you believe the violations identified in Statement of Deficiencies State Form have been corrected, you may contact Barbara Fagan, Program Manager at the Office of Health Care Quality, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228 with your written credible allegation of compliance **(i.e. attached lists of attendance at provided training and/or revised statements of policies/procedures and/or staffing patterns with revisions or additions)**. If you choose and so indicate, the PoC may constitute your allegation of compliance. We may accept the written allegation of compliance and presume compliance until substantiated by a revisit or other means.

V. INFORMAL DISPUTE RESOLUTION

You have one opportunity to question cited violations through an informal dispute resolution process. To be given such an opportunity, you are required to send your written request, along with the specific violation(s) being disputed, and an explanation of why you are disputing those violations, to Dr. Patricia Nay, Acting Executive Director, Office of Health Care Quality, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228, or by fax at 410-402-8234. This request must be sent during the same 10 days you have for submitting a PoC for the cited violations. An incomplete informal dispute resolution process will not delay the effective date of any enforcement action.

VI. LICENSURE ACTION

In the event a revisit determines that compliance has not been achieved, appropriate administrative action may be taken against your State license.

If you have any questions concerning the instructions contained in this letter, please contact Joyce Janssen, Acting Chief Nurse at 410-402- 8018.

Sincerely yours,

Patricia Nay /ds

Patricia Nay, M.D.
Acting Executive Director
Office of Health Care Quality

Enclosures: State Form

cc: Paul Ballard, Esq.
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
	SA000007	A. BUILDING: _____ B. WING _____	02/20/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ASSOCIATES IN OB/GYN CARE, LLC	6005 LANDOVER ROAD CHEVERLY, MD 20785

(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 An initial survey of Associates in OB/GYN was conducted on February 20, 2013 by the Office of Health Care Quality. Survey activities included the following: interview of the clinical staff; observational tour of the facility's physical environment; observation of the facility's sterilization equipment reprocessing; policy and procedure review; review of the facility's patient clinical records; review of the physicians credentialing; review of employee personnel files; review of the facility's Quality Assurance program and review of the facility's infection control program. The facility has two procedure rooms. A total of five patient clinical records were reviewed. The clinical patient records reviewed had procedures done between November 2012 and February 2013.	A 000		
A 790	.06(B)(9) .06 Personnel (9) Data provided by the National Practitioner Data Bank. This Regulation is not met as evidenced by: Based on review of the physician credentialing files, interview with the facility district manager and review of the facility's policy and procedure manual, it was determined that the administrator failed to collect, review and document data provided by the National Practitioners Data Bank, (this is a database for physicians in connection with medical liability settlements or judgments as well as adverse peer review actions against licenses, clinical privileges) for three of three physicians reviewed. The findings include: 1. Review of facility's policy and procedure	A 790		

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A 790	Continued From page 1 manual on 2/20/13 at 11:00 am revealed policy "Personnel" stated that Credentialing of Physicians- The following is collected, reviewed and documented on all licensed Physicians:(i) Data provided by the National Practitioner Data Bank. 2. Review of the Physicians Credentialing on 2/20/13 at 11:00 am revealed that Physicians 1, 2 and 3 contented no evidence to support that data provided by the National Practitioners Data Bank was collected, documented or review. 3. Interview of the District manager on 2/20/13 at 11:30 am, confirmed that no data had been collected, reviewed or documented from the National Practitioners data Bank any of the Physicians.	A 790		
A 980	.07(B)(6) .07 Surgical Abortion Services (6) Emergency services; This Regulation is not met as evidenced by: Based on review of the clinical policy and procedures, review of staff personnel files and interview of facility staff,it was determined that the facility failed to ensure that implemented policies and procedures are followed to ensure proper training of emergency equipment. The findings include: 1. Review on 2/20/13 at 2:00 pm of clinical policy " Emergency services" revealed when sedation is administered, the following emergency equipment is available: automated external defibrillator (AED) use to restart the heart in the event of a cardiac arrest and suction machine (used to keep a patients airway clear).	A 980		

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A 980	Continued From page 2 2. Review of personnel files on 2/20/13 at 10 am revealed that none of the license staff 1, 2, or 3 had been trained or in-serviced on the use of the emergency equipment. 3. On 2/20/13 at 1:00 pm the surveyor asked staff member #3 to demonstrate how to use the AED and the suction machine. The Registered nurse (RN) stated that she was unable to do either. The district manager was also observing the RN and stated that the equipment was non- functional and the suction machine needed an adaptor, which needed to be ordered before the machine would work.	A 980		
A1000	.07(B)(8) .07 Surgical Abortion Services (8) Safety. This Regulation is not met as evidenced by: Based on observational tour, interview and observation of staff, and review of the clinical policy and procedure manual, it was determined that the facility's Medical Director failed to ensure policies and procedures were implemented on emergency equipment maintenance ensuring patient safety. The findings include: 1. An observational tour on 2/20/13 at 1:00 pm revealed that the only facility suction machine (used to keep a patients airway clear) and automated external defibrillator (AED) (use to restart the heart in the event of a cardiac arrest) did not have a preventative maintenance/inspection sticker on them. Preventative Maintenance is an equipment inspection that is done on a yearly basis to	A1000		

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A1000	Continued From page 3 ensure that equipment is properly functioning and safe. Further observation of the AED machine revealed two sets of AED pads expired in February 2008. The facility only had the two expired sets of pads to use with the AED machine. Another observation was that the suction machine was non-functional. 2. Review of the Facility policy on 2/20/13 at 2:00 pm revealed that "Quality Assurance Program" policy states that "The facility shall have an ongoing program to monitor the safety and performance of all bio-medical equipment via annual inspection performed by biomed technician." 3. Interview of the District Manager on 2/20/13 at 1:30 pm revealed that the suction machine needed an adaptor to function and that staff had not checked the AED or the suction to see if both machines were functional.	A1000		
A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis. This Regulation is not met as evidenced by: Based on patient clinical records and interview with the district manager, it was determined that the facility administrator failed to ensure that the patient medical records were complete and included a discharge diagnosis for five of five patients records reviewed. The findings include: Review on 2/20/13 at 10 am of patient clinical records revealed, that patients #1, 2, 3, 4, and 5 medical records did not content any evidence that	A1430		

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A1430	Continued From page 4 a discharge diagnosis was documented. Interview on 2/20/13 at 10:30 am of the district manager confirmed that there is not a discharge diagnosis done on the patients before they are discharged to home.	A1430		
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 observation of instrument reprocessing sterilization, interview of clinical staff and policy review, it was determined that the facility failed to ensure the policies and procedures were implemented and followed, to ensure instrument reprocessing was conducted in a sanitary environment. The findings include: 1. Observation on 2/20/13 at 12 noon of the instrument reprocessing room revealed a basin with a bluish substance. The basin contained instruments with a cylinder with traces of blood on top of the instruments, and in front of the basin, on the counter was a bloody soiled chux containing contaminated instrument that had been used in a procedure. Further observation revealed a dish drainer with instrument lying in the drainer next to the basin and soiled chux containing instruments. 2. Interview of Staff #3 on 2/20/13 at 12 noon during observation of cleaning of instruments, revealed that she did not know what was mixed in the basin with the instruments because she did	A1510		

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A1510	Continued From page 5 not prepare the solution. She stated that the instruments in the basin were cleaned and ready to be wrapped for the autoclave. The staff was unable to measure out the correct amount of Maxizyme dual enzymatic because she lacked a measurement container. Staff also did not know that 1oz of Maxizyme should be used for every gallon of water. Further interview of staff #3 revealed that because the reprocessing space is so small it is hard to not contaminate things and keep clean things clean and dirty things from mixing. 3. Interview of Staff #3 on 2/20/13 at 12:15 pm revealed that when asked staff did not know how to use the Cidex (used for high disinfection of surgical instruments) Staff stated that instruments are only soaked for 3 minutes when manufacturer's instructions state that instruments should be soaked for at least 20 minutes. Staff was unaware of how long Cidex could be kept (solution can be reused for 28 days but must be verified daily for effectiveness with Cidex Plus solution test strips). She further stated that she did not use any strips to test Cidex. 4. Review of High Level disinfectant policy on 2/20/13 at 12:30 pm revealed that "All high level disinfectants will be used in a safe effective manner and in accordance to the product manufacturer's recommendations. Further review of policy "Instrument Sterilization" All non-disposable instruments are stream sterilized after being thoroughly washed in enzymatic detergent. After every procedure, the used instruments are brought to the clean-up area. Disposable items are discarded and the instruments are submerged into enzymatic detergent and water solution per manufacturer	A1510		

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A1510	Continued From page 6 instructions.	A1510		