March 26, 2013

Administrator
Associates In OB/GYN Care, LLC
9801 Georgia Avenue, Suite 338
Silver Spring, MD 20902

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

Dear

On February 26, 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 provide continuous monitoring while a patient was under sedation, placing the patient at risk for falls and injury.

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

Enclosures: State Form

cc: Paul Ballard, Esq.
License File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	SA000006	A. BUILDING: _____ B. WING _____	02/26/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ASSOCIATES IN OB/GYN CARE, LLC	9801 GEORGIA AVENUE, SUITE 338 SILVER SPRING, MD 20902

(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 the facility was conducted by the Office of Health Care Quality on February 26, 2013. The facility includes one procedure room. The survey included: an on-site visit; an observational tour of the physical environment; observation of one surgical procedures; observation of the instrument cleaning/sterilization process; interview of the facility's office manager, administrator, registered nurse and physician's; review of the policy and procedure manual; review of the personnel files; review of quality assurance and review of professional credentialing. A total of six clinical records were reviewed. The surgical procedures that had been performed November 2012, January 2013 and February 2013 were reviewed.	A 000		
A 610	.05(C)(6) .05 Administration (6) Pertinent safety practices, including the control of fire and mechanical hazards; This Regulation is not met as evidenced by: Based on interview of the district manager, review of the policy and procedure manual it was determined that the administrator and the district manager failed to develop a policy and procedure for safety practices. The findings include. Review of the policy and procedure manual on February 26, 2013 revealed that the administrator and the district manager failed to develop a policy and procedure for pertinent safety practices that include the control of fire and mechanical	A 610		

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A 610	Continued From page 1 hazards. Interview of the district manager (staff K) on February 26, 2013 at 12:30 PM revealed the manager acknowledged the policies had not been developed. The failure to develop policies and procedures for control of fires and mechanical hazards place the patients at risk of injury.	A 610		
A 620	.05(C)(7) .05 Administration (7) Preventive maintenance for equipment to ensure proper operation and safety; and This Regulation is not met as evidenced by: Based on interview of the administrator and district manager, a tour of the facility and review of policy and procedures, it was determined that the administrator and district manager failed to provide preventative maintenance to emergency equipment. The findings include: Review of the policy and procedure for preventative maintenance revealed, "The facility shall have an ongoing program to monitor the safety and performance of all biomedical equipment via annual inspection performed by biomed tech." During a tour of the procedure room on February 26, 2013 at 11:05 AM revealed the automatic external defibrillator (AED), used for patient cardiac emergencies, had not had preventative maintenance performed to assure the defibrillator was functioning.	A 620		

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A 620	Continued From page 2 Interview of the administrator (staff L) and district manager (staff K) on February 26, 2013 at 5 PM revealed they were not aware that the AED had not been inspected. The failure to maintain current preventative maintenance on emergency equipment used for patient care placed the patients at risk for delayed cardiac assistance during a medical emergency.	A 620		
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 professional credentialing files for physicians and surgeons, review of policies and procedures and interview of the district manager, it was determined that three of three physician credentialing files reviewed were incomplete and did not contain National Practitioner Data Bank information. The findings include: Review of Physician's H, I and J's credentialing files revealed the file did not include information from the National Practitioner Data Bank regarding claims against physicians. Review of the policies and procedures for personnel revealed, "Credentialing of Physicians-the following is collected, reviewed, and documented on all licensed Physicians: Data provided by the National Practitioner Data Bank." Interview of the district manager (K) on February 26, 2013 at 12:30 PM revealed, the manager acknowledged that she knew the items were	A 790		

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A 790	Continued From page 3 missing from the credentialing files. The failure to collect, review and maintain documentation of current information from the National Practitioner Data Bank concerning the physicians placed the patients at risk of injury by receiving surgery and treatment from a physician with a possible history of malpractice.	A 790		
A 960	.07(B)(4) .07 Surgical Abortion Services (4) Post-anesthesia care and observation; This Regulation is not met as evidenced by: Based on observation of a surgical abortion procedure and interview of the medical assistant it was determined that the physician and the medical assistant failed to protect the patient by leaving the patient unattended, after the abortion procedure, in the procedure room. The findings include. Observation of a surgical abortion procedure on February 26, 2013 at 3 PM revealed the patient was lying on her back with her feet up in stirrups. Doctor (staff identifier - H) administered twilight sedation, two milligrams of versed/midazolam (used for sedation, causes relaxation, sleepiness and partial or complete loss of memory) and twenty-five micrograms of ketamine (an anesthetic, causes impaired motor function, relaxation, and a feeling of being detached from the body) intravenously. This type of anesthetic requires monitored anesthesia care (a process that monitors the patient's blood pressure, pulse and respiration). After the abortion procedure was completed Doctor (H) left the procedure room. The medical	A 960		

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A 960	Continued From page 4 assistant (staff identifier- B) retrieved a basin with body fluid and left the room for ninety seconds. The medical assistant returned to the room and retrieved surgical instruments and left the room again for ninety seconds. The patient was groggy with periods of awareness. The patient was left unattended by the physician and the medical assistant at the same time for three minutes. There were no other employees of the abortion center in the room to monitor and assist the patient. There were no side rails on the surgical bed or any method of protecting the patient from falling. Interview of the medical assistant (B) at 3:40 PM revealed "sometimes there is someone who can come in and help watch the patient and sometimes not". The failure to continuously monitor the patient placed the patient at risk for falls and injury.	A 960		
A1080	.09(A) .09 Emergency Services A. Basic Life Support. Licensed personnel employed by the facility shall have certification in basic life support. A licensed staff individual trained in basic life support shall be on duty whenever there is a patient in the facility. This Regulation is not met as evidenced by: Based on review of personnel files, review of policies and procedures and interview of the district manager, it was determined that the administrator and the manager failed to assure two of four licensed personnel received certification in basic life support. The findings include. Review of policy and procedure for emergency	A1080		

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A1080	Continued From page 5 services revealed, "All licensed personnel employed by the facility shall have a certification in basic life support." Review of the policy and procedure for personnel files revealed, "Personnel files contain the following documentation: documentation of initial and ongoing training." Based on review of the personal file for the registered nurses (staff identifier D,& F) revealed there is no current certification in basic life support. Interview of the district manager on February 26, 2013 at 12:30 PM revealed that the manager acknowledged there was no training for basic life support for this employee. The failure of the administrator and the district manager to ensure that all licensed staff had current certification in basic life support placed the patient at risk for injury or death related to a cardiopulmonary emergency.	A1080		
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 interview of the district manager and review of personnel files, it was determined that the administrator and district manager failed to provide emergency training for patient transfers to the hospital for seven of seven employees. Staff: A, B, C, D, E, F, G and K	A1250		

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A1250	Continued From page 6 The findings include. Review of personnel files for seven staff members (staff identifiers: A, B, C, D, E, F and G) revealed that there is no documentary evidence that the members received training for emergency patient transfer's to the hospital. Interview of the district manager (K) on February 26, 2013 at 12:30 PM revealed the manager acknowledged that no training had been provided.	A1250		
A1500	.14 (B) .14 Patients' Rights and Responsibilities B. Confidentiality of medical records and the right to approve or refuse release of records to any individual outside the facility, except as provided by federal or State law. This Regulation is not met as evidenced by: Based on interview of the district manager, review of the policy and procedure manual it was determined that the administrator and the district manager failed to develop a policy and procedure for confidentiality of medical records. The findings include. Review of the policy and procedure manual on February 26, 2013 revealed that the administrator and the district manager failed to develop a policy and procedure for confidentiality of the medical records that include the patient's right to approve or refuse the release of their records to any one individual outside the facility, except as provided by federal or state law. Interview of the district manager (K) on February	A1500		

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A1500	Continued From page 7 26, 2013 at 12:30 PM revealed the manager acknowledged the policies had not been developed. The failure to maintain the patient's right to be released and confidentiality of the medical records placed the patient's confidential medical information at risk for loss and misuse.	A1500		