



STATE OF MARYLAND

**DHMH**

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**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

3506 N Calvert Street, Suite 110

Baltimore, MD 21218

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

Dear

On February 19, 20 and 21, 2013, a complaint 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.

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 PoC 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

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Web Site: [www.dhmh.maryland.gov](http://www.dhmh.maryland.gov)

- **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 \$1,000. 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 (4) involving Patient #G.

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

Office of Health Care Quality

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>SA000009</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>C</b> <b>02/21/2013</b>
NAME OF PROVIDER OR SUPPLIER  <b>ASSOCIATES IN OB/GYN CARE, LLC</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>3506 N CALVERT STREET, SUITE 110 BALTIMORE, MD 21218</b>		
(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	<i>Initial Comments</i>  <i>On February 19, 20 and 21, 2013, an investigation of complaint #00075700, was conducted at Associates in OB/GYN Care by the Office of Health Care Quality. The survey included: interview of the staff, review of the patient's medical record, review of the policy and procedure manual, review of professional credentialing, review of personnel files and an observational tour of the facility. The facility included two procedure rooms.</i>  <i>The complaint was substantiated, and deficiencies were issued as stated in this report.</i>	A 000			
A 960	<i>.07(B)(4) .07 Surgical Abortion Services</i>  <i>(4) Post-anesthesia care and observation;</i>  <i>This Regulation is not met as evidenced by: Based on interview of staff and patient record review, it was determined that the administrator failed to ensure provision of post-anesthesia care and observation.</i> <i>The findings include:</i>  <i>Interview of Staff #3 on 2/20/13 at 12:00 PM revealed that Patient G was not alert and oriented to person, place or time prior to Staff #3 leaving the procedure room after the patient's surgical abortion procedure on 2/13/13. Staff #3 was in another room writing orders and not in the procedure room with Patient G when she was called to help with Patient G. Review of Patient G's medical record on 2/20/13 at 2:00 PM revealed that Patient G had a surgical abortion procedure performed by Staff #3 at the facility on 2/13/13. Patient G was 12.5 weeks pregnant, and</i>	A 960			

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TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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A 960	<p><i>Continued From page 1</i></p> <p><i>I.V. (intravenous) sedation medication (Ketamine, Versed and Fentanyl) was used for anesthesia during the procedure. Staff #3's progress note dated 2/13/13 stated, "Patient, like many do, slept throughout. While writing orders, called by nurse that patient could not sit-up and had poor color...Patient (G) not breathing and pulse faint I immediately began CPR...911 requested as soon as I began CPR."</i></p> <p><i>Interview of Staff #4 on 2/20/13 at 12:15 PM revealed that she was not involved in Patient G's surgical procedure until the patient was observed not breathing. Staff #4 stated that she was completing the facility's narcotic log and did not assist with Patient G until she was told to bring ammonia inhalant (used to awaken) from the crash cart. During the code, Staff #4 completed three pulse checks on Patient G (58, 60, and 59 beats per minute). Review of the facility's record revealed that full vital signs were not documented during or after the procedure.</i></p> <p><i>Interview of Staff #6 on 2/20/13 at 12:40 PM revealed that she was left alone in the procedure room with Patient G after the patient's procedure to dress the patient and transfer her to the recovery room. Review of the facility's record on 2/20/13 at 2:15 PM revealed an incident report written on 2/13/13 at 1:00 PM by Staff #6 stated, "...After the surgery I took the pulse ox (imetry) off and then I took the jars apart and handed them to (Staff #7)...As I was handing her (Staff #7) the jars and asked her (Staff #7) to help me get her (Patient G) dressed. When I turned around (Patient G) looked a little pale."</i></p> <p><i>Interview of Staff #7 on 2/20/13 at 12:55 PM revealed that she was assigned to sterilize</i></p>	A 960			

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A 960	Continued From page 2  surgical instruments on the day of Patient G's procedure. Review of the facility's record on 2/20/13 at 2:20 PM revealed an incident report written on 2/13/13 at 12:45 PM by Staff #7 stated, "Staff #3 said that the patient would probably need to be carried into the recovery room, so I went to help Staff #6 move the Patient (G). I asked why she was so pale and said it didn't look like she (Patient G) was breathing. We (Staff #7 and Staff #6) got Staff #3 and she (Staff #3) sat the Patient (G) up and tried a sternum rub."  Review of Patient G's hospital medical record on 2/25/13 at 12:00 PM revealed that EMS continued CPR on Patient G from transport from the surgical abortion facility to the hospital admission on 2/13/13. Review of Patient G's Certificate of Death on 2/25/13 at 12:20 PM revealed, " the patient died on 2/15/13 at 10:05 PM due to Severe Pulmonary Edema, Acute Respiratory Distress Syndrome, and Hypoxic Brain 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 the policy and procedure manual, review of staff credentialing and personnel files and interview of the administrator, it was determined that the administrator failed to ensure that all licensed staff were certified in basic life support, this was evident for three of four licensed staff reviewed. The findings include:	A1080		

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A1080	Continued From page 3  Review of the policy and procedure manual revealed, "All licensed personnel employed by the facility shall have a certification in basic life support." Review of staff #1, 2, and 3's credentialing files revealed no documented evidence that they had current certification in basic life support.  Interview of the administrator on 2/20/13 at 10:00 am confirmed that staff #1, 2, and 3 did not have current certification in basic life support.	A1080		
A1130	.09(C)(3) .09 Emergency Services  (3) Automated external defibrillator (AED);  This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, an observational tour of the facility, review of the patient's medical record and interview of staff, it was determined that the staff failed to use the Automated external defibrillator (AED) used to diagnose and treat cardiac arrest during a cardiac medical emergency. The findings include:  Review of the policy and procedure manual revealed, "When sedation is administered, the following emergency equipment is available to the procedure room...Automated external defibrillator (AED)." An observational tour of facility on 2/19/13 at 2:00 PM revealed there was an AED located on the emergency cart in the area outside of the procedure rooms. Review of Patient G's facility medical record on	A1130		

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A1130	Continued From page 4  2/20/13 at 2:00 PM revealed that Patient G had a surgical abortion procedure performed by Staff #3 at the facility on 2/13/13. Patient G was 12.5 weeks pregnant, and I.V. (intravenous) sedation medication (Ketamine, Versed and Fentanyl) was used for anesthesia during the procedure. Staff #3's progress note dated 2/13/13 stated, "Patient, like many do, slept throughout. While writing orders, called by nurse that patient could not sit-up and had poor color...Patient (G) not breathing and pulse faint I immediately began CPR...911 requested as soon as I began CPR." Interview of Staff #3 on 2/20/13 at 12:00 PM, Interview of Staff #4 on 2/20/13 at 12:15 PM, Interview of Staff #6 on 2/20/13 at 12:40 PM and Interview of Staff #7 on 2/20/13 at 12:55 PM revealed that staff failed to retrieve and use the AED during Patient G's cardiopulmonary medical emergency.	A1130		



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{A 000}	<p>Initial Comments</p> <p>A follow up survey was conducted on 3/13/13 for complaint investigation that was completed on 2/21/13. On 3/5/13 an emergency suspension was imposed due to leaving a patient alone with an unlicensed staff, the patient than began to experience cardiopulmonary arrest, the physician returned and began CPR, however, the physician's CPR was not current and no attempt was made to use the AED. It was later discovered that the AED did not work. The facility staff submitted a plan of correction on 3/8/13 and it was approved. The emergency suspension was lifted on 3/25/13.</p>	{A 000}		
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