



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  
801 Tollhouse Road, Unit #6  
Frederick, MD 21701

**RE: NOTICE OF CURRENT DEFICIENCIES**

Dear :

On February 25, 2013, 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.

Toll Free 1-877-4MD-DHMH • TTY for Disabled – Maryland Relay Service 1-800-735-2258

Web Site: [www.dhmh.state.md.us](http://www.dhmh.state.md.us)

- References to staff or patient(s) by staff identifiers, used in the Statement of Deficiencies, 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 substantial 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 Dr. Patricia Nay, Acting 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 Joyce Janssen at 410-402-8018 or fax 410-402-8213.

Sincerely,

Barbara Fagan  
Program Manager

Enclosures: State Form

cc: License File

Office of Health Care Quality

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  SA000008	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED  02/25/2013
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NAME OF PROVIDER OR SUPPLIER  ASSOCIATES IN OB/GYN CARE, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 801 TOLLHOUSE ROAD, UNIT #6 FREDERICK, MD 21701
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(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
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A 000	Initial Comments  An initial survey of Associates In OB/GYN Care Frederick was conducted by the Office of Health Care Quality on February 25, 2013. 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. The facility includes two procedure rooms.  A total of seven clinical records were reviewed. The surgical procedures that had been performed January 2013 and February 2013 were reviewed.	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 professional credentialing files for physicians and surgeons, review of policies and procedures and interview of the administrator and the office 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 A, B and C's credentialing files revealed the file did not include information from the National Practitioner Data Bank regarding claims against physicians. Review of	A 790	NPDB was queried for all three physicians. No evidence of harm to any patients and no patients having the potential to be adversely affected. Administration will monitor all clinicians files to ensure that the NPDB has been queried.	4/15/13

OHCQ

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

TITLE

(X5) DATE

STATE FORM

6602

9PPQ11

If continuation sheet 1 of 5

*See attached addendum*

Office of Health Care Quality

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A1080	Continued From page 2  in basic life support.  Interview of the office manager (staff identifier H) on February 25, 2013 at 6 PM revealed that the manager was not aware there was no training for basic life support for this employee.	A1080		
A1170	.09(D)(1) .09 Emergency Services  D. When general anesthesia is administered, a facility shall have available in the procedure room: (1) Laryngoscopes;  This Regulation is not met as evidenced by: Based on a tour of facility and interview of the office manager, it was determined that the manager and the administrator failed to assure that all emergency equipment was functional. The findings include.  Observation of the emergency cart on February 25, 2013 at 4:20 PM revealed that the only laryngoscope (a light source used for direct visualization of the throat for placing a tube for breathing) in the facility did not have a battery for the light source.  Interview of the administrator (staff identifier - I) and the office manager (staff identifier - H) on February 25, 2013 at 6 PM revealed they were not aware that the battery was missing.	A1170	<i>We have replaced the battery and have a working laryngoscope. No patients were adversely affected by the laryngoscope. Needing a new battery</i>	3/15/13
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.	A1510		

Office of Health Care Quality

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A1510	Continued From page 4  revealed in the recovery room are two sets of window blinds. The blinds have a coating of a white dusty substance.  Interview of the administrator (I) and the office manager (H) on February 25, 2013 at 6 PM revealed they were unaware that the blinds were dusty.	A1510	<i>our blinds. Clearly, no patients were affected by our safe infection-free practice. The office manager will monitor to ensure that in addition to weekly spore testing of our autoclave and in addition to the use of sterilization indicator tape, we will also use indicator strips.</i>	<i>2/25/13</i>

**Addendum to POC submitted 4/15/13 – SA 000008**

TAG A790

Ongoing Monitoring: Physician files will be monitored annually to ensure the NPDB has been queried at least once for every Physician.

TAG A1080

Ongoing Monitoring: Personnel files will be monitored quarterly by the Compliance Officer to ensure current BLS certification.

TAG A1170

Quality Indicators: A quality indicator for the functionality of the laryngoscope would be a positive light emanating from the laryngoscope once it is turned on. The tool used to monitor the laryngoscope will be a staff member turning the laryngoscope on and assuring that the battery is working and a light emanates from the device.

Ongoing Monitoring: All laryngoscopes in the facility will be monitored by the Office Manager, District Manager, Compliance Officer and Administrator to ensure they are in proper working order.

Frequency: The laryngoscope will be checked weekly to confirm it is in proper working order.

TAG A1510

Process Changes: Internal steam sterilization indicator strips will be used in all packs of surgical instruments.

Frequency: The Office Manager and or District Manager will monitor daily to ensure all packs of surgical instruments contain a steam sterilization indicator strip.

\_\_\_\_\_  
Administrator

5-13-13  
\_\_\_\_\_  
Date