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
3506 N Calvert Street, Suite 110
Baltimore, MD 21218

RE: NOTICE OF CURRENT DEFICIENCIES

Dear

On February 19, 20 and 21, 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.

- 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 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/LC

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:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	SA000009	A. BUILDING: _____ B. WING _____	02/21/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ASSOCIATES IN OB/GYN CARE, LLC	3506 N CALVERT STREET, SUITE 110 BALTIMORE, MD 21218

(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 survey of Associates in OB/GYN Care was conducted on February 19, 20 and 21, 2013. Survey activities included interview of the staff, an observational tour of the physical environment, observation of reprocessing of surgical equipment, review of the policy and procedure manual, review of clinical records, review of professional credentialing, review of personnel files and review of the quality assurance and infection control programs. The facility included two procedure rooms. A total of five patient clinical records were reviewed. The procedures were performed 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 professional credentialing files, review of the policy and procedure manual, and interview with the administrator, it was determined that the administrator failed to collect, review, and document data provided by the National Practitioner Data Bank (claims against the physician, dentist, or podiatrist) for three of three physicians reviewed. The findings include: Review of staff #1, 2, and 3's credentialing files on 2/19/13 at 10:00 am revealed that the files contained no evidence of documentation of data provided by the National Practitioner Data Bank. Review of the facility's policy and procedure titled	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 clinician files to ensure that the NPDB has been queried.	4/12/13

OHCQ

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Administrator — (X6) DATE: 4-15-13

See attached addendum

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A 790	Continued From page 1 "Personnel" on 2/19/13 at 10:30 am revealed that the policy stated "...1. Credentialing of Physicians- The following is collected, reviewed, and documented on all licensed Physicians... (i) Data provided by the National Practitioner Data Bank." Interview of the administrator on 2/20/13 at 10:00 am confirmed that data provided by the National Practitioner Data Bank had not been collected and documented in the physician's credentialing files.	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 policy and procedure manual, review of staff training records, observation and interview of staff, it was determined that the facility failed to implement policy and protocol that ensured that emergency services were available. The findings include: Review of the facility's policy and procedure titled "Emergency Services" on 2/21/13 at 1:30 pm revealed "...When sedation is administered, the following emergency equipment is available to the procedure room :...(c) Automated external defibrillator (AED)." An AED is used for a patient in cardiac arrest. Review of staff training records on 2/20/13 at 11:00 am revealed that Staff #4 completed an in-service training on 2/14/13 that demonstrated the task of using the defibrillator. The training was signed by Staff #4 and the administrator on 2/14/13.	A 980	All licensed staff and Managers have undgone training, in-Services and drills on the use of emgency equipment. The training on 2-14-13 does not state that staff #4 recieved training that demonstated the task of using an AED.	3.8.13

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A 980	Continued From page 2 Interview of Staff #4 on 2/21/13 at 12:55 pm revealed that she "was not trained to use the AED machine" located on the crash cart. Surveyor observed Staff #4 request assistance from the project manager and Staff #2 to use the machine. None of the staff knew how to recharge the machine.	A 980	No patients were adversely affected. No patients were potentially affected.	
A1000	.07(B)(8) .07 Surgical Abortion Services (8) Safety. This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, a tour of the facility, observation and interview of staff, it was determined that the facility staff failed to implement their policy on emergency equipment to ensure patient safety. The findings include: Review of the facility's policy and procedure titled "Quality Assurance Program" stated, "The facility shall have an ongoing program to monitor the safety and performance of all biomedical equipment via annual inspection performed by biomed technician." A tour of the facility on 2/21/13 at 12:10 pm revealed that the suction equipment used to clear patient's airway and the Automated external defibrillator (AED) used for patients in cardiac arrest did not have an inspection/maintenance sticker on them. Preventative maintenance is required on all electrical medical equipment on an annual basis to ensure the equipment is operational, calibrated and safe.	A1000	1- The AED was not functioning because the battery was not charged. 2- The battery has been fully charged and the AED is functioning properly. 3.8.13 3- The AED pads were replaced. 4- The Biomed Technician is scheduled to perform a P.M. inspection next week. 4-26-13	

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A1000	Continued From page 3 Observation of the AED machine on 2/21/13 at 12:15 pm revealed that the electrode pads were soiled and stuck to each other. Further observation revealed that the AED unit read "do not use" on the machine, and would not operate when the "on" button was pressed. Interview of the project manager on 2/21/13 at 12:50 pm revealed that she acknowledged that the suction equipment and AED were not maintained as required. Interview of Staff 4 revealed that additional electrode pads were not available and had to be ordered. Review of the facility's preventative maintenance test results on 2/21/13 at 1:10 pm revealed the facility's medical equipment was tested on 11/30/12. However, the suction machine and the AED machine were not tested at this time.	A1000	No Patients have been adversely affected by this deficiency.	
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 for three of four licensed staff reviewed. The findings include: Review of the policy and procedure manual revealed, "All licensed personnel employed by the	A1080	Staff 1-3 have all had BLS training previously. Though their Certifications may have lapsed. All licensed staff are currently BLS certified	3-7-13

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A1080	Continued From page 4 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 revealed that staff #1, 2, and 3 did not have current certification in basic life support.	A1080	6) The expired medications have been discarded.	2-20-13
A1280	.11 (B)(1) .11 Pharmaceutical Services B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice. This Regulation is not met as evidenced by: Based on an observational tour of the facility and interview of Staff #4, it was determined that the agency staff failed to identify and discard expired medications. The findings include: During a tour of the facility on 2/19/13 at 2:00 pm, the following expired medication was observed in the emergency cart: a. Sodium bicarbonate (used for cardiopulmonary resuscitation), 2 vials, expired 2/1/13. The following expired medication was located in the refrigerator: a. Methergine (used to control excessive bleeding following childbirth and spontaneous or elective abortion), 1 box, expired 1/13. Interview of Staff #4 on 2/19/13 at 2:00 pm revealed that the staff failed to identify and discard the expired medications.	A1280	Please note the sodium bicarbonate had been expired by only 2 weeks. The methgine had been expired by just a few weeks. The expired Medications have been replaced w current Medications	2-27-13

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A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis. This Regulation is not met as evidenced by: Based on patient medical record review and interview of the administrator, it was determined that the administrator failed to ensure that the patient's medical records included a discharge diagnosis for five of five patient records reviewed. The findings include: Review of Patients A, B, C, D and E's medical records revealed there was no evidence that a discharge diagnosis was documented in the medical records. Interview of the administrator on 2/20/13 at 10:00 am confirmed that a discharge diagnosis was not documented in the patient medical records.	A1430	The discharge diagnosis of all five patients was stable. Status-post termination of pregnancy procedure. This diagnosis could be inferred from the medical record, since it was clear that the patient had a T.O.P. procedure. The physician signed off that she was stable prior to discharge. Nonetheless, we have added a line to the medical record to document explicitly the discharge diagnosis. See attachment #1	4-16-13
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. This Regulation is not met as evidenced by: Based on observation of surgical instrument reprocessing and interview of Staff #4, it was determined that the administrator failed to ensure adequate surgical instrument reprocessing in order to maintain a sanitary environment for the provision of surgical services. The findings include: 1. Observation of surgical instrument reprocessing on 2/19/13 at 2:00 pm revealed that surgical instruments were placed in small and	A1510		

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A1510	Continued From page 6 medium sized peel packs (packaging used to sterilize pieces of surgical equipment) and towel wraps in preparation to be placed in the autoclave machine (machine used for sterilization). Interview of Staff #4 on 2/19/13 at 2:00 pm revealed that steam indicator strips were not placed inside the small or medium sized peel packs, or inside the towel wrapped surgical instruments when the surgical instruments were sterilized in the autoclave machine. It is essential to put a steam indicator strip inside each peel pack towel wrap to ensure adequate sterilization of the surgical instruments. 2. Observation of surgical instrument reprocessing on 2/19/13 at 2:00 pm revealed that surgical instruments were soaking in a bin located in procedure room 2. The bin contained Cidex Plus 28 day Solution (a detergent used for high level disinfection of surgical instruments). Review of the manufacturer's instructions for Cidex Plus 28 day Solution revealed, "Solution can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in Directions for Use within this insert. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by the CIDEX PLUS Solution Test Strips to determine that the solution is above the minimum effective concentration (MEC) of 2.1% glutaraldehyde1...Test the solution prior to each use to assure that the glutaraldehyde1 concentration is above its MEC. CIDEX PLUS Solution Test Strips must be used for this purpose." Interview of Staff #4 on 2/19/13 at 2:00 pm revealed that the Cidex Plus 28 day Solution is not tested with CIDEX PLUS Solution Test Strips	A1510	Although we maintain that we have carefully maintained a sanitary environment & successfully prevented infections, as proven by our perfect track-record of infection free medical practice, nonetheless, 1- We now insert steam indicator strips inside each CSR wrap or pouch, In addition to the steam sterilization indicators type that we have always used. 2- Additionally we perform weekly spore testing	2-25-13 4-16-13

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A1510	Continued From page 7 prior to each use.	A1510	3 - We now test the Cidex Solution the day prior to use. This testing is done w Cidex plus test Strips.	2-23-13

Addendum to POC submitted 4/15/13 – SA 000009

TAG A980
Scope of deficiency: After evaluation the management team determined that the scope of the deficiency was limited. All staff and been trained on the location of the AED and what it was used for, but some staff had not actually been trained on how to use it.

Process Changes: All employees will participate in annual training on the use of emergency equipment. All new employees will have training on the use of emergency equipment upon hire.

Quality Indicators: Training records will be monitored by Compliance Office, Office Manager, District Manager and the Administrator to ensure continued participation in training on the use of emergency equipment.

TAG A1000
Scope of deficiency: After evaluation the management team determined that the scope of the deficiency was limited. Although almost all of the medical equipment was properly inspected by a biomedical technician and in good working order, the tracheal suction machine was not inspected, and the AED battery had lost charge. The AED battery is reported by the manufacturer to last for two years. Nevertheless, the AED battery lost charge in only two months and would not recharge.

Process Changes: The Compliance Officer, Office Manager, District Manager and the Administrator along with staff RN's will monitor the AED. When a low battery indicator light is lit, a new battery will be ordered. The Office Manager, District Manager and the Administrator will assure that the AED and tracheal suction machine are annually inspected by a biomed technician.

Quality Indicators: The battery indicator light on the AED will provide a quality indicator as to whether the battery is properly charged. The biomedical technician will provide an inspection sticker to be placed directly on the machine to serve as a quality indicator that the equipment has been inspected and certified to be in proper working order.

TAG A1080
Scope of Deficiency: After evaluation the management team determined that the scope of the deficiency was limited. All licensed staff did have proper basic life support certification and training. However, three licensed staff members certifications were past their expiration date.

Quality Indicators: Current, valid, non-expired certifications will serve as the quality indicator for each licensed staff member that they possess proper, valid certification in basic life support.

TAG A1280
Scope of Deficiency: After evaluation the management team determined that the scope of the deficiency was limited to only two instances of expired medications and both instances were very recent. The two instances include: two vials of sodium bicarbonate were 18 days past their expiration date, and one box of methergine was 37 days past its expiration date.

Quality Indicators: The expiration date put on the medication by the manufacturer will serve as a quality indicator for the medication that the medication has not expired. It is the responsibility of the Office Manager to routinely check the expiration dates of all medications in the facility.

TAG A1430
Quality Indicator: The recovery room record form shall contain a documented discharge diagnosis. The approval of the DHMH of the preprinted forms containing a discharge diagnosis shall serve as a quality indicator that these forms are acceptable to DHMH, and that the corrective taken was sufficient and acceptable. The Office Manager will be responsible for ensuring that these approved forms are properly utilized.

TAG A1510
Quality Indicator: The color of the steam indicator test strips placed in the autoclaved instruments shall serve as a colorimetric quality indicator that the autoclave is properly sterilizing instruments. These steam indicator strips are in addition to the steam sterilization indicator tape which we also use and which changes color upon sterilization and can also serve as a second colorimetric quality indicator that the instruments are properly sterilized.

The color of the cidex plus solution test strips shall serve as a colorimetric quality indicator that the efficacy of the cidex plus solution is verified.

The Office Manager and nurses shall be responsible for checking the color of the steam indicator test strips and cidex plus solution test strips upon each use to confirm that the instruments are sterile and that the cidex plus cold sterilization is effective.

Administrator

5-2-11
Date

STATE OF MARYLAND
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Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
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May 7, 2013

Associates in OB/GYN Care, LLC
3506 N. Calvert Street, Suite 110
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RE: ACCEPTABLE PLAN OF CORRECTION

Dear

We have reviewed and accepted the Plan of Correction submitted as a result of an initial survey completed at your facility on February 21, 2013.

Please be advised that an unannounced follow-up visit may occur prior to the standard survey to ensure continual compliance.

If there are any questions concerning this notice, please contact this Office at 410-402-8040.

Sincerely,

Barbara Fagan

Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality