STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

March 5, 2013

OB/GYN Care, LLC

Re: Summary Suspensions of License Nos. SA 000006, 000007, and 000009 for Associates in OB/GYN Care, LLC

Dear Ms. Shachnovitz:

On February 20 and 26, 2013, the Office of Health Care Quality ("OHCQ") conducted inspections at three surgical abortion facilities owned and operated by Associates in OB/GYN Care, LLC ("OB/GYN Care") at 3506 N. Calvert St., Suite 110, Baltimore, Md. 21218 (License No. SA 000009); 9801 Georgia Ave., Suite 338, Silver Spring, Md. 20902 (License No. SA 000006); and 6005 Landover Road, Landover, Md. 20785 (License No. 000007).

Based on those inspections, I have determined that the public health, safety, or welfare imperatively requires emergency action and hereby summarily suspend the licenses held by OB/GYN Care to perform surgical abortion procedures at the three facilities. *See* Md. Code Ann., State Gov't § 10-226(c); COMAR 10.12.01.17.

Bases for the Secretary's Action

OHCQ inspected the Landover facility operated by OB/GYN Care on February 20, 2013. Among other deficiencies, the facility was in violation of COMAR 10.12.01.09 because (a) the pads of its Automatic External Defibrillator ("AED") expired in 2008; (b) the clinical nurse on site did not know how to use the AED and suction machine; and (c) the District Manager admitted to the surveyor that the nurses had not been trained on the use of the AED and suction machine; and (d) the suction machine did not work because an adapter was missing.

OHCQ inspected OB/GYN Care's Silver Spring facility on February 26, 2013. During its inspection, OHCQ staff observed an abortion procedure. After the procedure ended but while the patient was still under the influence of intravenous medications given to sedate the patient and alter her pain perception, the physician and the medical assistant left the patient alone in the

procedure room with her feet in stirrups for approximately 3 minutes. When the patient began to awaken, she was restless and at risk for falling and otherwise injuring herself with no staff in the procedure room to assist her. OHCQ determined that, among other deficiencies, the Silver Spring facility failed to adhere to the requirements set forth in COMAR 10.12.01.07A&B that "[s]urgical abortion procedures shall be performed in a safe manner by a physician" and that a surgical abortion facility "shall develop and implement policies, procedures and protocols . . . for [p]ost-anesthesia care and observation."

OHCQ inspected Associates in OB/GYN Care's Baltimore facility on February 20, 2013. During its inspection, OHCQ reviewed medical records and interviewed staff regarding a surgical abortion that was performed on February 13, 2013. After the February 13 procedure but while the patient was still very drowsy, the physician exited the procedure room, leaving the care and monitoring of the patient to an unlicensed medical assistant. Subsequently the patient experienced a cardiopulmonary arrest. The physician, who was not currently certified in CPR, was informed of the arrest and began CPR; however, no attempt was made to use the AED. The patient was transferred to the hospital, where she died. Approximately a week after the described event, OHCQ surveyors determined that the AED machine did not work and that staff had not been trained on its use. OHCQ determined that, among other deficiencies, the Baltimore facility failed to adhere to the requirements set forth in COMAR 10.12.01.07A&B that "[s]urgical abortion procedures shall be performed in a safe manner by a physician" and that a surgical abortion facility "shall develop and implement policies, procedures and protocols . . . for [p]ost-anesthesia care and observation." OHCQ bases these determinations on OB/GYN Care deficient preparation for, and response to, the emergency on February 13, 2013, despite the fact that neither the procedure nor OB/GYN Care's deficient response to the emergency have been found to have caused the patient's death.

At three facilities owned and operated by OB/GYN Care, OHCQ surveyors observed deficiencies in preparation for, or in actual response to, emergency situations. If not corrected immediately, these deficiencies could result in serious or life-threatening harm to patients. I have therefore determined that license nos. 000006, 000007, and 000009 must be summarily suspended and that surgical abortion procedures under these licenses must cease immediately.

This summary suspension does not preclude the Department of Health and Mental Hygiene from taking further disciplinary actions related to the above-described deficient practices or other deficiencies that may be identified in survey reports arising from OHCQ's recent inspections. However, I will lift the summary suspension of each facility for which this letter provides upon a determination by OHCQ that (a) the facility has submitted an appropriate

plan of correction addressing identified deficiencies, (b) the facility has fully implemented that plan of correction, and (c) any other deficiencies identified at the facility are not so serious as to imperil the health, safety or welfare of patients.

Hearing Rights

Pursuant to section 10-226(c)(2) of the State Government Article, OB/GYN Care has the right to be heard regarding the propriety of these summary suspensions. I have designated Tricia Nay, M.D., Acting Executive Director and Medical Director of OHCQ, to conduct a show cause hearing on March 14, 2013, at 1:00 p.m., at the offices of OHCQ, Bryant Bland Building, 55 Wade Avenue, Baltimore, MD 21228. At that hearing, OB/GYN Care will have the opportunity to argue that the Secretary should rescind the summary suspensions.

At the show cause hearing, Paul Ballard, Assistant Attorney General, will be requesting that the Secretary's designee continue the summary suspension. Please contact him at 410-767-6918 if you wish to discuss the show cause hearing.

In addition to the right to the show cause hearing described above, OB/GYN Care has the right to request an evidentiary hearing within thirty days of receipt of this letter. The request shall be made to the Office of Administrative Hearings, 11101 Gilroy Road, Hunt Valley, MD 21031 and attach a copy of this letter. At that hearing, OB/GYN Care has the right to be represented by counsel, to call witnesses, to cross-examine the Department's witnesses, to present documentary evidence, and to present argument. A request for a hearing will not stay the issuance of the summary suspension pending such a hearing.

Sincerely,

Joshua M. Sharfstein, M.D.
Secretary

cc: Patricia Tomsko Nay, M.D., Acting Director and Medical Director, OHCQ
Paul J. Ballard, Assistant Attorney General, Administrative Prosecutor
Kathleen Ellis, Deputy Counsel, DHMH

Associates in Ob/Gyn Care

March 8, 2013

Joshua M. Sharfstein, M.D.
Secretary of Health
Maryland Department of Health
201 West Preston Street
Baltimore, Maryland, 21201

Re: Implementation of Plan of Correction

Dear Dr. Sharfstein,

I am writing in reply to your letter which was received by Associates in Ob/Gyn Care, LLC three days ago concerning deficiencies noted by the Department of Health inspectors. In your letter you informed us that you were summarily suspending our license to perform surgical procedures and that you would lift the summary suspension upon a determination that we had submitted an appropriate Plan of Correction and fully implemented that Plan of Correction.

I want to personally thank you for bringing these deficiencies to our attention. We are committed to providing safe medical care to our patients and we are not happy if we fall short of our goals. Furthermore, we are in agreement with you that surgical services should not be provided unless patient safety can be appropriately protected. I also want to thank you for offering to lift the summary suspension of our licenses once we have submitted a satisfactory Plan of Correction and fully implemented that Plan of Correction. The purpose of this letter is to submit to you our Plan of Correction addressing all of the deficiencies identified in your letter. We have already implemented this Plan of Correction. Accordingly, we are hereby requesting that the temporary suspension of our licenses be lifted. We hope that this Plan of Correction and its implementation are acceptable to the Department, and that you will agree to lift the suspension of our licenses.

We understand from your letter that we have a right to a show cause hearing and to an evidentiary hearing. While we do not want to waive any of our legal rights, nevertheless, as I discussed via telephone with Dr. Nay, our preference would be to work informally with the Department to resolve this matter. Hopefully the Plan of Correction in this letter and its implementation will be acceptable to the Department and the summary suspensions can be lifted without any hearings. This would save both us and the Department time and expense. We believe that the Department's requests are reasonable, and rather than engaging in adversarial legal proceedings, we would prefer to move forward, correct any identified problems, and to work together with the Department toward our mutual goal of protecting patients.

Our Plan of Correction in this letter will address each specific deficiency identified in your letter, and offer a corresponding correction. The deficiencies you identified fell into a few categories:

Deficiency #1: The Automated External Defibrillator in our Baltimore facility did not adequately work because the batteries needed charging. Likewise, while the AED in Cheverly worked properly and normally, however the expiration date on its pads had passed.

Correction #1: The batteries on the AED in Baltimore have been charged and it is now working properly. Brand new pads have been purchased, and delivered, for the AED in Cheverly, which always worked properly.

Deficiency #2: Nurses and Staff in Cheverly and Baltimore needed training on the use of the AED and tracheal suction.

Correction #2: The Nurses and Staff in Cheverly and Baltimore have been trained by our physicians in the operation and use of the AED and tracheal suction.

In addition, we have gone beyond simply correcting the deficiencies the Department cited. We have taken extra steps in emergency preparedness. Our physicians have run drills of mock codes with our staff in order to ensure that nurses and staff are appropriately trained to respond to emergencies. These drills included responding to emergencies involving respiratory depression, respiratory distress or arrest, cardiac arrest, and hemorrhage. We have also run drills with our staff in how to respond to complications such as uterine perforation. These drills included the use and operation of AED and suction machines, as well as a review of the crash cart and the drugs within it, including reversal agents for the anesthetics used. It also included review of monitoring of patients using pulse oximetry and vital sign measurement during procedures, in recovery, and during codes.

Deficiency #3: It was noted that during an inspection in Silver Spring, the staff briefly left a sedated patient unattended while cooperating with the inspection. The Department also noted that the facility shall develop and implement policies and procedures for post-anesthesia care and observation.

Correction #3 All staff in Silver Spring have been reminded of Associates in Ob/Gyn Care's existing policies and procedures to never leave a patient unattended in recovery or in the procedure room. Staff have been warned that failure to properly attend to patients is grounds for disciplinary action, up to and including termination of employment. Associates in Ob/ Gyn Care believes that our existing policies and protocols already in place currently proscribe against this behavior. We merely need to be more vigorous in enforcing these policies with our staff in Silver Spring. No staff members in any other facility were observed leaving a patient unattended; nevertheless, they have also been reminded of this policy.

Deficiency #4: The tracheal suction machine in Cheverly temporarily could not be plugged into a wall outlet because the A/C electrical adaptor could not be immediately located.

Correction #4: The missing A/C electrical adaptor has been located and the suction machine in Cheverly is working properly.

As you requested, we have now submitted a Plan of Correction for each deficiency identified in your letter, and that Plan of Correction has been fully implemented. Accordingly, I hereby respectfully request that the summary suspensions for our three facilities be lifted. We believe that we have corrected all of the deficiencies identified in your letter which form the basis for the suspension.

We understand that the inspectors may have found other deficiencies which were not identified in your letter. If that is the case, then we will also work with the Department to correct any other deficiencies that have not yet been provided to us. In addition, I invite the Department to communicate informally with us toward our mutual goal of improving patient safety.

Lastly, because we were informed that your letter and our reply may possibly be released by the Department to become a matter of public record, we realize that the content in our letters could be publicized by persons who wish to harm our reputation because they are religiously or philosophically opposed to a woman's right to freedom of choice. As a result, we feel that it is necessary to defend our reputation against false impressions. For that reason, we wish to offer the following response to the comments about the woman who died in the hospital several days after visiting our facility:

The information that forms that basis for these comments comes from observations of the patient by our physician and CPR-certified registered nurse, and from comments that the physicians in the hospital made to our physician. Some of this information is second-hand and cannot be verified by us; however, this is the most accurate information that we have about this patient to date:

1. This patient immigrated to the U.S. from a remote region in a third-world country and allegedly had not seen a physician in many years. As a result, she was not aware that she suffered from cardiomyopathy, which is a fatal heart condition. In addition, the patient may have had defective heart valves and was probably in compensated right heart failure.

2. The patient requested and underwent a routine first-trimester surgical termination of pregnancy procedure. The patient was sedated but conscious throughout the surgical procedure. The procedure was successfully accomplished and was uneventful. There were no complications of any kind during the course of the eight-minute procedure. Specifically, during the surgical procedure there were no perforations, no hemorrhage, no excessive bleeding, and no discomfort on the part of the patient. Her medical condition and vital signs remained within normal limits at all times during the procedure. It was a simple, routine, uncomplicated, uneventful, first-trimester vacuum aspiration procedure which was carried out properly and successfully.

3. After the procedure was over, while the patient recovered, she was monitored via pulse oximetry, vital sign measurement, and visual observation by a certified medical assistant, consistent with Department of Health regulations. The patient was still sedated, but conscious, oriented, and able to talk.

4. Suddenly, while being recovered, the patient experienced extreme difficulty in breathing. The physician was sitting at a desk in the adjacent room, just 10 feet from the patient. She was immediately notified and she ran to the patient and began mouth-to-mouth resuscitation, which was correctly and properly performed. EMS was immediately called and arrived very quickly. EMS rapidly transported the patient to the hospital, which was located directly across the street from our facility.

5. The patient never had a cardiac arrest in our facility. Throughout the event, the patient maintained a spontaneous, regular pulse with a heart rate in the range of 60 beats per minute. Accordingly, defibrillation or cardioversion would not be helpful to this patient. In fact, attempting to defibrillate or cardiovert a patient with a regular pulse of normal rate might even have been dangerous as such an action could possibly have precipitated a cardiac arrhythmia. For this reason, the patient was not harmed, and may theoretically have been helped by the fact that "no attempt was made to use" our defibrillator. While certainly unacceptable to us, the fact that the batteries on the AED weren't charged played no role whatsoever in the outcome of this patient.

6. It is now known that the patient presented to the ER with pulmonary edema and it is believed that the patient may have had a pulmonary embolism or some other respiratory insult, possibly caused by a blood clot from her defective heart valves or elsewhere. Such a blood clot would not originate from the uterus or the abortion procedure.

7. The patient's hospital course lasted for several days. At some point after admission to the hospital, the patient developed a new problem which was increased intracranial pressure. This subsequently caused brain stem herniation, which led to the patient's death in the hospital. Again, this increased intracranial pressure and brain stem herniation did not occur in our facility, and it did not emanate from the patient's uterus or from the abortion procedure.

8. There is no direct evidence that the patient's blood clot, brain herniation, or death were caused by, or even related to, the abortion procedure. Consequently, it is not even certain that this tragic event was a "complication" of the abortion procedure. It is entirely possible that because of the patient's underlying fatal heart condition, that it was <u>inevitable</u> that this patient would have released a blood clot at some point in time. The mere fact that it occurred while she was sitting in our facility recovering after an abortion procedure may possibly have been simply a coincidence. Because of her underlying heart condition, the release of her blood clot and her death could easily have happened while she was just sitting at home watching television.

9. Our Ob/Gyn physician's quick reflexes and fast response may have temporarily saved this patient's life. Our doctor did not hesitate. She did not delay. She immediately instituted mouth-to-mouth resuscitation which she performed properly. She immediately ordered EMS called. She kept the patient alive until EMS arrived and transported the patient to the hospital. And this transfer of care was appropriately and properly carried out by our Board-Certified Ob/Gyn physician. All of this proves that

our physician can, and did, respond appropriately to an emergency situation.

10. We agree with the Department of Health's determination "that neither the (abortion) procedure" nor our response to the emergency "have been found to have caused the patient's death".

These comments about this patient are being provided in order to set the record straight and to prevent any misunderstandings about what transpired with this patient.

I wish to thank you for your time and attention in reviewing this letter and this Plan of Correction. I hope that you will find our Plan of Correction acceptable, and since it has already been implemented, I hope that you will agree to lift the summary suspension without the need for more formal proceedings. Please do not hesitate to contact me if you have any questions or concerns, or if you would like more information or documentation. Thank you.

Respectfully submitted,

Administrator
Associates in Ob/Gyn Care, LLC
(215) 651-6993

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 _____	R 03/13/2013

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 A follow up survey was conducted on 3/13/13 for the initial survey that was completed on 2/20/13. On 3/5/13 an emergency suspension was imposed due to having emergency equipment in non-working condition and licensed staff was not trained on how to operate the equipment. 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.	{A 000}		

OHCQ

TITLE (X6) DATE

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