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

Melissa Shachnovitz
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