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 25, 2013

Melissa Shachnovitz
Associates in 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 the results of those inspections, the Secretary determined that the public health, safety, or welfare imperatively required emergency action and summarily suspended the licenses held by OB/GYN Care to operate the three facilities. *See* Md. Code Ann., State Gov't § 10-226(c); COMAR 10.12.01.17. As a result of this action, OB/GYN Care immediately ceased surgical abortion procedures at these facilities.

Bases for the Secretary's Action

Among other deficiencies, the Landover 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; (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.

During its inspection of the Silver Spring facility, 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 lying on the table in the procedure room 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."

During its inspection of the Baltimore facility, 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 based these determinations on OB/GYN Care's deficient preparation for, and response to, the emergency on February 13, 2013, although neither the procedure nor OB/GYN Care's deficient response to the emergency have been found to have caused the patient's death.

Plan of Correction

OB/GYN Care submitted a written plan of correction to OHCQ that addresses the identified deficiencies. After review of this plan, OHCQ surveyors completed on-site inspections of all three facilities to determine whether the plan of correction was implemented, whether serious or life-threatening harm to patients continued to exist based on the deficiencies identified as of March 5, 2013, and whether other deficiencies at the facility imperil the health, safety, or welfare of patients. The on-site inspections included review of written material, staff interviews, and direct observation.

Your responses to the identified deficiencies include, but are not limited to, the following:

- Automated External Defibrillators: The batteries in the AED in the Baltimore facility have been fully charged. At all facilities, the AEDs have new pads and are functioning properly. All physicians, nurses, and staff at the three facilities were trained in the appropriate use of the AED.

- Tracheal suctioning: Nurses and staff at all three facilities were trained on the use of the tracheal suction. The missing A/C electrical adaptor has been located and the tracheal suction machine in Landover is working properly.

- The staff at all three facilities were trained in your policies and procedures regarding patients in a recovery and procedure room. The physician will not leave a patient who has received anesthesia until the patient has attained a sufficient level of awareness and is clinically stable.

- CPR certification: All staff now have current CPR certification.

- Emergency Preparedness: Your physicians have run drills of mock codes with the 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, hemorrhage, and 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. These drills will continue periodically to ensure that the staff remains prepared for emergencies.

Lifting of the Summary Suspension

OHCQ has determined that (a) you have submitted an appropriate plan of correction that addresses identified deficiencies, (b) you have implemented the plan of correction, and (c) there are no other deficiencies identified at the facility that are so serious that they imperil the health, safety, or welfare of patients. I have been authorized by the Secretary, based on these determinations, to lift the summary suspension at the three facilities that were the subject of the Secretary's March 5, 2013 letter.

Lifting of the summary suspension does not preclude the Department of Health and Mental Hygiene from taking further disciplinary actions related to the above-described deficiencies or other deficiencies that may be identified in survey reports arising from OHCQ's recent inspections.

Follow-Up

Please contact me if you have any questions concerning these issues.

Sincerely,

Patricia Tomsko Nay /pts

Patricia Tomsko Nay, MD, CMD,
CHCQM, FAAFP, FAIHQ, FAAHPM
Acting Executive Director and Medical Director

cc: Joshua Sharfstein, Secretary of Health and Mental Hygiene
Paul J. Ballard, Assistant Attorney General, Administrative Prosecutor
Kathleen Ellis, Deputy Counsel, DHMH