



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

May 9, 2013

Via U.S. Mail & Email

OB/GYN Care, LLC

Re: Summary Suspensions of License Nos. SA 000006, 000007, 000008 and 000009 for Associates in OB/GYN Care, LLC

Dear

On May 7, 2013, the Office of Health Care Quality ("OHCQ") received an anonymous complaint about the treatment of a patient at Associates in OB/GYN Care ("OB/GYN Care") at 3506 N. Calvert St., Suite 110, Baltimore, MD 21218. On Thursday, May 9, 2013, OHCQ completed an investigation of the complaint. Based on the results of that investigation, I concluded that the public health, safety or welfare imperatively required emergency action, and the Secretary of Health and Mental Hygiene authorized me to issue summary suspensions of the four licenses held by OB/GYN Care to operate surgical abortion facilities in the State of Maryland.

Bases for the Summary Suspensions

On May 4, 2013, a woman presented to OB/GYN Care at 3506 N. Calvert St., Suite 110, Baltimore, for a scheduled appointment for an abortion. No physician was on site. An employee asked the patient to complete the initial paperwork. The same employee, who holds no health care license or certification, then performed an ultrasound on the patient that revealed multiple gestations. There is no evidence that this employee had any training in or demonstrated competency in performing ultrasounds. This employee asked the patient to sign a form giving consent for a surgical abortion and for the administration of Misoprostol, a medication used to induce abortions. This employee understood the purpose and effects of giving Misoprostol. She administered it to the patient when no physician was present in the facility and before any physician or licensed health care professional had any contact with the patient.

When the physician arrived, the physician determined that the patient, due to the multiple gestations, had a 22-week sized uterus. The physician declined to complete a surgical abortion, stating that "this facility is not equipped to do this procedure safely." The doctor orally offered the patient three options: (1) The patient could travel in two days to OB/GYN Care's Frederick facility for the administration of laminara, a type of seaweed that is used to dilate the cervix, and additional Misoprostol,

with follow-up the following day in OB/GYN Care's Baltimore facility for a D & C and follow-up the day after that in OB/GYN Care's Cheverly or Silver Spring facility for a second D & C, if needed. The facility staff would provide transportation from the patient's home to these locations. (2) An OB/GYN Care employee could transport the patient to a site in New Jersey where a surgical abortion could be performed with the patient under general anesthesia. (3) The physician could attempt to identify a local hospital that could complete a surgical abortion procedure.

The patient reportedly chose the first option and left the facility. Facility staff provided no written discharge instructions. The patient's medical record did not accurately describe what occurred and what was discussed with the patient during the encounter. Later that day, the patient presented to another facility where the staff safely and appropriately completed a surgical abortion procedure with no complications.

In interviews conducted by OHCQ surveyors, four OB/GYN Care employees -- two unlicensed, one certified, and one licensed -- reported that it is a standard protocol at OB/GYN Care to administer Misoprostol to all patients at 11 weeks gestation or beyond, even if the patient has not been evaluated by a physician, and even if no physician is available on site. According to an interview with an OB/GYN Care physician, all four OB/GYN Care facilities follow this standard protocol.

OB/GYN Care initiated a surgical abortion in a facility that was not equipped to complete the procedure safely. In addition, OB/GYN Care failed to implement a safe discharge plan for the patient. These deficiencies, which violate COMAR 10.12.01.07A and 10.12.01.10A, could have resulted in serious or life-threatening harm or death to the patient.

On May 8, 2013, surveyors from the OHCQ went to the OB/GYN Care site at 3506 N. Calvert St., Suite 110, Baltimore, MD, 21218, during the facility's reported hours of operation to investigate the complaint described above. The office was closed at that time in violation of COMAR 10.12.01.04A(2).

OHCQ previously inspected the four surgical abortion facilities operated by OB/GYN Care. As a result of those inspections, the Secretary summarily suspended the licenses of three of the four facilities for violations of the regulations that threatened the public health and safety. OB/GYN Care's 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; 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. At both its Silver Spring and Baltimore facilities, OB/GYN Care violated COMAR 10.12.01.07A & B by failing to perform surgical abortion services in a safe manner and failing to develop appropriate post-anesthesia procedures and protocols. OB/GYN Care submitted and implemented acceptable plans of correction, and the summary suspensions were lifted.

As a result of the initial licensure surveys and complaint investigations, OHCQ also cited the four OB/GYN Care sites for other violations of the regulations governing their operation. To date, OB/GYN Care has not provided acceptable plans of correction for all of the deficiencies at each site. In addition, OB/GYN Care has failed to respond to repeated phone calls and emails from OHCQ. Thus, as of today,

OB/GYN Care is not in compliance with the regulations for surgical abortion facilities in the State of Maryland.

For all of these reasons, the Secretary has authorized me to suspend summarily the licenses of all four OB/GYN Care sites, license nos. 000006, 000007, 000008, and 000009 effective immediately. Thus, surgical abortion procedures under these licenses must cease immediately.

The summary suspensions do 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.

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 will conduct a show cause hearing on May 16, 2013, at 2 PM, at the offices of OHCQ, Spring Grove Center, Bryant Bland Building, 55 Wade Avenue, Baltimore, MD 21228. At that hearing, OB/GYN Care will have the opportunity to argue that I should rescind the summary suspensions.

At the show cause hearing, Paul Ballard, Assistant Attorney General, will be requesting that I 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 a copy of this letter must be attached. 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 summary suspension pending such a hearing.

Sincerely,



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

cc: Joshua M. Sharfstein, M.D., Secretary
Paul J. Ballard, Assistant Attorney General, Administrative Prosecutor
Kathleen A. Ellis, Deputy Counsel, DHMH