



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

May 24, 2013

The Honorable Thomas McLain Middleton
Chairman
Senate Finance Committee
11 Bladen Street, 3 East
Annapolis, MD 21401

The Honorable Peter A. Hammen
Chairman
House Health and Government Operations
Committee
6 Bladen Street, Room 241
Annapolis, MD 21401

Dear Chairman Middleton and Chairman Hammen,

I am writing to provide you with an update regarding the Department of Health and Mental Hygiene's oversight of surgical abortion facilities in Maryland.

The Department has now completed initial licensure surveys of the 16 licensed surgical abortion facilities in the state. As part of this process, each facility was surveyed by the Office of Health Care Quality (OHCQ). If deficiencies were found during these surveys, a plan of correction was required to be submitted and approved by OHCQ. Through this process, to date, 12 facilities have submitted acceptable plans of correction and have been found to be in compliance with regulatory standards.

This update reviews the current status of the four facilities operated by Associates in OB/GYN Care, LLC; provides an overview of the initial licensing surveys of all 16 facilities; and summarizes the status of certain complaint investigations.

Associates in OB/GYN Care, LLC

Associates in OB/GYN Care, LLC, which operates surgical abortion facilities in Baltimore, Frederick, Cheverly, and Silver Spring, has been the subject of a series of regulatory actions in recent months. In March, as we previously communicated to you, OHCQ cited serious deficiencies at three of Associates in OB/GYN Care's four facilities, and the Department suspended the provider's licenses to operate those facilities. OHCQ lifted the suspensions after receiving acceptable plans of correction addressing the issues that were the basis of the suspension and after conducting follow-up on-site surveys.

On May 9, after receiving and investigating a complaint about patient care provided by Associates in OB/GYN Care, OHCQ identified additional serious deficiencies in the medical oversight of patient care. There were no serious adverse events associated with these deficiencies. Nonetheless, OHCQ concluded that the deficiencies posed a serious and immediate danger to patients.

Based on this conclusion, OHCQ issued an order on May 9 suspending the performance of surgical abortions at all four Associates in OB/GYN Care facilities.

Overview of Initial Licensing Surveys

Other than the issues noted above with Associates in OB/GYN Care, the initial surveys found the other licensed facilities to be free of deficiencies that presented an immediate and serious threat to the health and safety of patients. Where there were deficiencies, these were effectively addressed through plans of correction, consistent with OHCQ's regulation of other types of facilities in the state.

The three most commonly cited deficiencies in the initial licensure surveys were: (1) failure to obtain information about the professional credentials of physicians on staff from the National Practitioner Data Bank; (2) failure to maintain a sanitary environment at all times and to consistently use chemical indicator strips in sterilized equipment packaging; and (3) failure to include a discharge diagnosis in the medical record.

With respect to (1), every surgical abortion facility is required to verify a physician's credentials in the National Practitioner Data Bank. Although a number of facilities were cited for not adhering to this requirement, OHCQ did not identify in the surveys any physician lacking the educational and certification requirements to perform surgical abortions. With respect to (2) and (3), OHCQ did not find evidence that these deficiencies led to negative patient outcomes.

OHCQ has approved plans of correction for the specific deficiencies cited at all facilities other than those operated by Associates in OB/GYN Care. Consistent with oversight of other licensed health care providers, these plans include immediate and short-term actions that address the issues identified and protect the public. OHCQ may conduct unannounced inspections to assure compliance with the plans of correction.

We compared the average number of deficiencies cited by OHCQ for surgical abortion facilities with the average number cited for ambulatory surgery centers, which are subject to generally similar regulatory oversight. From November 1, 2012 to April 30, 2013, OHCQ conducted 28 regulatory surveys of ambulatory surgery centers. OHCQ identified an average of 4.3 deficiencies during inspection of ambulatory surgery centers, compared to an average of 4.2 deficiencies cited for the 16 surgical abortion facilities. OHCQ cited ambulatory surgery centers for deficiencies similar to those identified in surgical abortion facilities.

Updates on Specific Complaints

In addition to the initial surveys, OHCQ has investigated complaints directed at specific facilities.

In reviewing a complaint related to a woman's death, OHCQ reviewed medical records, examined policies and procedures, directly observed care, and interviewed staff. OHCQ also consulted with the Office of Chief Medical Examiner. OHCQ identified no deficiencies with respect to this complaint.

The Department has received complaints from members of the legislature regarding the ownership of the Associates in OB/GYN Care facilities. OHCQ and the Department's Inspector General are currently reviewing this matter.

OHCQ also investigates complaints about the performance of surgical abortion procedures in unlicensed facilities in Maryland. Under the Department's regulations, facilities that "provide surgical termination of pregnancy as a regular service" are required to obtain a surgical abortion facility license. The Department is investigating the referred complaints and intends to enforce the requirements set forth in its regulations.

Conclusion

The establishment of an effective new regulatory program for surgical abortion facilities is moving forward in Maryland. OHCQ is leading the Department's efforts – conducting surveys, taking regulatory action where appropriate, and providing education and training to covered facilities.

Through close oversight and outreach, the Department intends to use what it has learned during the first round of surveys to advance the implementation of these regulations, so that patients in Maryland have access to safe and effective health care services.

We will continue to provide periodic updates on implementation of these regulations. If you have additional questions, please contact Marie Grant, Director of the Office of Governmental Affairs, at (410) 767-6480.

Sincerely,

A handwritten signature in black ink, appearing to read "Josh M. Sharfstein". The signature is fluid and cursive, with the first name "Josh" being particularly prominent.

Joshua M. Sharfstein, M.D.
Secretary