IN THE MATTER OF	*	**BEFORE THE**
HAROLD O. ALEXANDER, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number D22219	*	**Case Number 2015-0019**

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FINAL DECISION AND ORDER

INTRODUCTION

On July 8, 2015, Harold Alexander, M.D., an obstetrician and gynecologist, was charged under the Maryland Medical Practice Act ("Act") with unprofessional conduct in the practice of medicine and failure to meet appropriate standards for the delivery of quality medical care. *See* MD. CODE ANN., HEALTH OCC. ("Health Occ.") § 14-404(a)(3)(ii), (22) (2014). The charges concerned Dr. Alexander's care and treatment of a woman who was between 28 and 29 weeks pregnant ("Patient A").

On September 24, 2015, the case was forwarded to the Office of Administrative Hearings ("OAH") for an evidentiary hearing and a proposed decision. A three-day hearing was held before an Administrative Law Judge ("ALJ") at OAH. At the hearing, the State presented testimony from Ishrat Rafi, M.D. ("Dr. Rafi") and Matrice Browne, M.D. ("Dr. M. Browne"), who both were qualified as experts in obstetrics and gynecology. Dr. Alexander testified on his own behalf and presented testimony from Charlie Browne, M.D. ("Dr. C. Browne"), who was qualified as an expert in obstetrics and gynecology.

On April 29, 2016, the ALJ issued a proposed decision concluding that Dr. Alexander was guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii), and failed to meet appropriate standards for the delivery of quality medical care,

in violation of Health Occ. § 14-404(a)(22).[1] The ALJ proposed that the charges be upheld and recommended the revocation of Dr. Alexander's medical license.

On June 3, 2016, Dr. Alexander filed exceptions to the ALJ's proposed decision, and the State filed a response to Dr. Alexander's exceptions. On July 27, 2016, both parties appeared before Disciplinary Panel B ("Panel B") of the Maryland State Board of Physicians ("Board") for an oral exceptions hearing.

FINDINGS OF FACT

Panel B adopts the ALJ's proposed findings of fact numbers 1-44. *See* ALJ proposed decision, attached as **Exhibit 1**. Neither party filed exceptions to any of the ALJ's factual findings, and the facts were proved by a preponderance of the evidence. These facts are incorporated by reference into the body of this document as if set forth in full.

On the evening of February 28, 2014, Patient A, a 27 year old woman from Denmark, presented to Dr. Alexander's office in Forestville, Maryland seeking to terminate her pregnancy due to significant fetal abnormalities. At the time of the office visit, the gestational age of Patient A's fetus was estimated to be between 28 and 29 weeks. Dr. Alexander intended to perform a medical induction abortion procedure due to the documented fetal abnormalities. Dr. Alexander obtained Patient A's medical history and conducted a medical examination, which included an ultrasound and auscultation.[2] Dr. Alexander did not detect a fetal heart rate through either method and documented in the medical records no fetal heart rate and dead fetus in utero.

Dr. Alexander informed Patient A that there was no fetal heart rate and that she had the option of returning to Denmark for the delivery of the stillborn fetus. Although he determined

[1] In this decision, standards for the delivery of quality medical care and standard of care are used interchangeably.

[2] Auscultation is the action of listening to sounds from the heart, lungs, or other organs, typically with a stethoscope, as a part of medical diagnosis.

that there was no fetal heart rate and the fetus was already deceased, Dr. Alexander injected digoxin[3] and lidocaine,[4] administered mifeprex,[5] and inserted laminaria[6] to cause fetal demise and induce labor. Around midnight, Dr. Alexander administered midazolam,[7] a sedative medication, to Patient A, released Patient A to her husband, and they went to a nearby hotel. About four hours later, Patient A called Dr. Alexander and told him that she was going into labor. Dr. Alexander met Patient A at his office around 5:00 a.m., on March 1, 2014, administered misoprostol,[8] and delivered the stillborn fetus at 9:00 a.m.

EXCEPTIONS

I. Standard of Care

The ALJ found Dr. Alexander violated the standard of care by performing a medically induced abortion at his private office instead of referring the patient to a higher level facility. Dr. Alexander takes exception to this finding and argues that medically induced abortions can be safely performed in outpatient settings up to 34 weeks as long as the physician has specialized training and experience. The State argues, however, that the procedure was not an abortion, but rather, the delivery of a stillborn fetus, which required labor and delivery to occur at a higher level facility, in accordance with the usual obstetric protocols.

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[3] Digoxin is used to induce fetal demise and, generally, would be used before a surgical abortion or a second trimester medical abortion.

[4] Lidocaine is a local anesthetic.

[5] Mifeprex is a medication that is taken orally and is approved for use in early non-surgical abortion procedures.

[6] Laminaria is used to dilate the cervix and induce labor and delivery.

[7] The medical records reflect that midazolam was also administered the following day, on March 1, 2014, at 5:00 a.m., 7:00 a.m., and 9:00 a.m.

[8] Misoprostol is used in conjunction with mifeprex in early non-surgical abortion procedures to induce labor and ripen the cervix prior to delivery.

The Panel is, therefore, tasked with determining whether the procedure Dr. Alexander performed was an abortion or the delivery of a stillborn fetus. The record revealed that, generally, there are two types of abortions, surgical and non-surgical.[9] The medical induction of fetal demise may be used before both surgical and non-surgical late-term abortions when the pregnancy is terminated due to significant fetal abnormalities or medical conditions affecting the mother's health. The fetus is then removed from the uterus either surgically or by inducing labor and delivering the fetus. Regardless of the method used, an abortion is performed to cause fetal death.

In this case, when Patient A presented to his office, Dr. Alexander anticipated that he would perform a medically induced abortion[10] of a 28-week fetus with significant abnormalities. He expected the fetus to have a heart rate and expected to induce fetal demise by injecting digoxin intrauterine to stop the fetal heart and terminate the pregnancy. Dr. Alexander did not expect the fetus to be already deceased prior to the induction of fetal demise. At 28 weeks, if a fetal heart rate is not detected, there is no fetal demise to induce and the procedure cannot be properly classified as an abortion. The Panel rejects Dr. Alexander's characterization of the procedure as a medically induced abortion in light of the undisputed evidence documented in the medical records that there was no fetal heart rate when Dr. Alexander examined Patient A on February 28, 2014.

Rather, in the absence of a fetal heart rate, the Panel agrees with the State's experts that the only procedure that remained was the delivery[11] of the stillborn fetus.[12] The patient could

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[9] The Panel, using its own knowledge and expertise, notes that abortions can also be spontaneous when they occur from natural causes, such as in the case of a miscarriage. A spontaneous abortion, however, by definition, can only occur prior to 20 weeks gestation.

[10] In this decision, medical abortion and induction of fetal demise are used interchangeably.

[11] Delivery includes a live birth as well as the delivery of a stillborn fetus.

have either waited to go into labor naturally or Dr. Alexander could have referred the patient to a higher level facility for the induction of labor and the delivery of the stillborn fetus. Dr. Alexander appropriately recognized the fetal demise and informed Patient A that she could return home to Denmark to give birth, but then proceeded with the procedure as if the fetus was still viable. The absence of a fetal heart rate was definitively documented in the medical record and Dr. Alexander admitted that he administered digoxin "to ensure fetal demise, even though there was demise." Without a fetal heart rate, however, there was no indication or reason to administer digoxin.[13] Dr. Alexander exercised poor clinical judgment by disregarding his own medical assessment of the patient and treating the patient he expected rather than the patient who actually presented. The Panel finds that in the absence of a fetal heart rate the intrauterine administration of digoxin for fetal demise was unnecessary and not medically indicated.

Further, at 28 weeks, the delivery of a stillborn fetus needed to occur at a higher level of care facility due to the increased risks involved. Patient A was a high risk patient due to the advanced gestation of the fetus, the documented medical abnormalities of the fetus, and the intrauterine fetal death that occurred at an unknown time during the pregnancy. All of these factors increased the risk for infection and bleeding, the potential for complications to arise with the delivery, and the possibility of requiring surgical intervention. The delivery of this 28-week stillborn fetus involved greater risks when compared to the medically induced abortion that Dr. Alexander originally intended to perform. Dr. Alexander failed to appreciate the increased risk involved in the delivery of the stillborn fetus and exhibited poor clinical judgment when he

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[12] In this decision, intrauterine fetal death, fetal death in utero, stillborn, and stillbirth are used interchangeably. Dr. Alexander testified that "fetal death in utero would be considered stillbirth[.]"

[13] Dr. Alexander testified that he administered digoxin in order to avoid an unintended live birth and comply with the Partial Birth Abortion Act. Dr. Alexander, however, did not document any doubt or question as to whether there was a fetal heart rate in the medical records or his rationale for administering digoxin when there was already fetal demise.

performed the procedure in his private office instead of referring the patient to a higher level of care facility.

Dr. Alexander delivered Patient A's stillborn fetus at 28 weeks gestation in his private office without the assistance of any licensed medical staff and without the surgical equipment needed to perform surgery if any complications arose. The office was not a licensed surgical abortion facility, Dr. Alexander did not have hospital privileges, the closest hospital was approximately ten minutes away, and there was no transfer agreement in place with any hospital in the case of an emergency. According to the State's experts, Dr. Alexander violated the standard of care by inducing labor and delivering a 28-week stillborn fetus at his private office when the appropriate obstetric protocols required the induction of labor and delivery to occur at a higher level facility. The Panel agrees.

Dr. Alexander submitted several articles regarding late-term abortions and terminations of pregnancy in outpatient office settings in support of his position that he did not violate the standard of care. The articles were admitted into evidence by the ALJ, but the ALJ found that "[t]here were four articles that specifically discussed abortions in an outpatient setting" and that based on the age of the fetus, "only one is directly applicable, addressing fetal anomalies and fetal death." The Panel, however, finds that none of the articles submitted by Dr. Alexander are relevant to the facts of this case because the articles pertained specifically to abortions, pregnancy terminations, and induction of fetal demise, and not to the delivery of a stillborn fetus, which is a higher risk procedure.

The procedure that Dr. Alexander performed was unnecessary, not medically indicated, and had the potential to cause serious harm to the patient when performed in Dr. Alexander's private office setting. Based on the totality of the evidence presented, the Panel finds that Dr.

Alexander violated the appropriate standards for the delivery of quality medical care. Dr. Alexander's exception is denied.[14]

II. Unprofessional Conduct

Dr. Alexander takes exception to the ALJ's finding that he committed unprofessional conduct in the practice of medicine. There is no dispute that Dr. Alexander's conduct was in the practice of medicine, but he argues that his actions did not rise to the level of unprofessional. Unprofessional conduct has been defined as that "which breaches the rules or ethical code of a profession, or conduct which is unbecoming a member in good standing of a profession." *Finucan v. Maryland Bd. of Physician Quality Assurance*, 380 Md. 577, 593 (2004).

Dr. Alexander argues that the ALJ impermissibly found that he committed unprofessional conduct because he violated the standard of care. He contends that a violation of the standard of care does not necessarily mean that the conduct was unprofessional. The Panel agrees that a standard of care violation may not automatically constitute unprofessional conduct, but the Board has previously determined that certain violations of the standard of care may be "so egregious as to amount to unprofessional conduct in themselves." *Geier v. Maryland State Bd. of Physicians*, 223 Md. App. 404, 437 (2015).

The facts and evidence presented in this case demonstrate that the standard of care violations were so egregious and so unsound as to amount to unprofessional conduct in themselves. Dr. Alexander performed an unnecessary procedure that was not medically indicated. In his testimony, Dr. Alexander readily acknowledged that "generally speaking stillbirths can be managed conservatively and in most instances patients will go into labor and

[14] Dr. Alexander also takes exception to the ALJ's finding that he violated the standard of care with regard to his record-keeping and his failure to immediately produce Patient A's medical records when requested by the Board's investigators. The Panel, however, need not reach these issues, and declines to do so, in light of the other standard of care violations, which are discussed herein. The Panel does not find that Dr. Alexander violated the standard of care or committed unprofessional conduct in the practice of medicine with regard to the storage of his records.

will deliver the fetus at any gestational age." Dr. Alexander, however, did not manage Patient A's stillbirth conservatively. Instead, he ignored the fact that the fetus was deceased and went through the steps of performing a medically induced abortion, as if the fetus was still viable. In doing so, he administered digoxin without any documented medical indication and did not follow the usual obstetric protocols which required the induction of labor and delivery to occur at a higher level of care facility.

In light of the fact that Patient A was at an advanced stage of gestation and had an intrauterine fetal death at an unknown point in time during her pregnancy, there was an increased risk to the patient for infection and bleeding. The potential for harm was great and his office, which lacked the safeguards and resources that are available at a higher level facility, was not the proper setting to induce labor and deliver Patient A's stillborn fetus.

The totality of Dr. Alexander's conduct was unbecoming of a member in good standing in the profession and is commonly understood as unprofessional within the medical community. Based on the evidence presented, the Panel finds that Dr. Alexander is guilty of unprofessional conduct in the practice of medicine. Dr. Alexander's exception is denied.

III. Notice

Dr. Alexander argues that it would be unjust to find violations of the standard of care for administering sedative medications without proper monitoring, failing to document the precise time the fetus and placenta were delivered, and failing to produce medical records upon request because these allegations were not specifically included in the charging document. Dr. Alexander's exception is moot, however, because the Panel does not find a standard of care violation on any of these bases. The Panel's findings are consistent with the allegations set out in the charging document. *See Regan v. State Bd. of Chiropractic Examiners, 355 Md. 397, 417-*

18 (1999) (Notice is sufficient to satisfy due process concerns when "the gist of the charges . . . and the gist of the Board's findings" against the individual are consistent).

IV. Expert Witnesses

Dr. Alexander argues that the ALJ impermissibly gave greater weight to the testimony of the State's experts and contends that the Panel should give greater deference to Dr. C. Browne's testimony because of his specialized experience in the subspecialty of mid to late term medically induced abortions.[15] As discussed above, the Panel rejects Dr. Alexander's characterization of the procedure in this case as a medically induced abortion in light of the undisputed evidence that the fetus was deceased prior to the procedure being performed. Dr. C. Browne's testimony and conclusions were premised on the fact that the procedure was a medically induced abortion, which it was not.

The management of a stillbirth is a basic obstetric procedure and, according to the March, 2009 American College of Obstetricians and Gynecologists ("ACOG") practice bulletin, after 28 weeks gestation, induction of labor for a stillbirth should be managed according to the usual obstetric protocols. Dr. Rafi and Dr. M. Browne are Board-certified in obstetrics and gynecology and had the requisite skill, knowledge, and expertise to testify on the standard of care for the delivery of a stillborn fetus. Dr. Alexander does not dispute that Dr. Rafi and Dr. M. Browne had the requisite knowledge and skill to be qualified as experts in obstetrics and gynecology. The Panel agrees that all three doctors were properly qualified as experts in obstetrics and gynecology and were sufficiently qualified to testify as experts on the topics at issue in this case. The ALJ found that the testimony of the State's experts outweighed the

[15] Dr. Alexander argues that the ALJ committed legal error by qualifying Dr. Rafi and Dr. M. Browne as experts in mid to late term medically induced abortions. The Panel extensively reviewed the ALJ's decision and the hearing transcript and found no evidence to support that the ALJ qualified any of the witnesses as experts in mid to late term medical abortions. Rather, the record demonstrates that the ALJ qualified Dr. Rafi, Dr. M. Browne, and Dr. C. Browne all as experts in obstetrics and gynecology.

problematic testimony of Dr. C. Browne, which was based on the incorrect assumption that the procedure in question was a medically induced abortion.

"When two experts offer conflicting opinions, the trier of fact must evaluate the testimony of both experts and decide which opinion, if either, to accept." *Blaker v. State Board of Chiropractic Examiners*, 123 Md. App. 243, 259 (1998). In considering the testimony of all three experts, the Panel rejects Dr. C. Browne's conclusions regarding the standard of care and accepts the testimony of Dr. Rafi and Dr. M. Browne. Dr. C. Browne's opinions were not sufficiently founded on the specific facts of this case and, therefore, his conclusion that Dr. Alexander did not violate the Act was unjustified. In contrast, Dr. Rafi's and Dr. M. Browne's conclusions were founded on the specific facts of this case and supported by the ACOG practice bulletin. Dr. Alexander's exception is denied.

CONCLUSIONS OF LAW

Based on the foregoing factual findings, Panel B concludes that Dr. Alexander failed to meet the appropriate standards as determined by peer review for the delivery of quality medical care, in violation of Health Occ. § 14-404(a)(22). The Panel also concludes that Dr. Alexander is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii).

SANCTION

Pursuant to Health Occ. § 14-404(a), a disciplinary panel is authorized to sanction a licensee for violating any of the disciplinary grounds, including: (3)(ii) is guilty of unprofessional conduct in the practice of medicine; and (22) fails to meet the appropriate standards for the delivery of quality medical care. The sanctioning guidelines in this case range from a reprimand to revocation. COMAR 10.32.02.10B. A disciplinary panel has broad

discretion in sanctioning licensees and the ALJ's proposed sanction of revocation is within the sanctioning guidelines in this case.

In determining an appropriate sanction, the Panel has considered Dr. Alexander's conduct and poor judgment in this case, which had potential to cause serious patient harm. The Panel has also considered Dr. Alexander's extensive prior disciplinary history with the Board dating back to May of 2012 and that the Board's previous attempts at rehabilitation have been unsuccessful.

In 2012, the Board found that Dr. Alexander was guilty of unprofessional conduct in the practice of medicine, failed to meet the appropriate standards for the delivery of quality medical care, and failed to keep adequate medical records. The Board suspended Dr. Alexander's license for a minimum of three months and imposed a period of probation for a minimum of two years with terms and conditions including evaluation by the Professional Rehabilitation Program and one-on-one tutorials in medical ethics and record-keeping.

Shortly thereafter the Board received a complaint from the Office of Health Care Quality (OHCQ) regarding an inspection conducted at Dr. Alexander's office. The inspection revealed, in part, that Dr. Alexander was performing surgical abortions at an unlicensed office facility without licensed and properly trained medical staff. Based on the serious deficiencies noted in the OHCQ inspection report, the Board issued a Cease and Desist order prohibiting Dr. Alexander from performing surgical abortions, which was later modified to prohibit Dr. Alexander from performing surgical abortions at unlicensed facilities. The Board also found that Dr. Alexander was guilty of unprofessional conduct in the practice of medicine, in part, for performing surgical abortions at an unlicensed facility. Dr. Alexander remains on probation and he is prohibited from performing surgical abortions, which includes the use of any surgical equipment, at his unlicensed office facility.

It is evident from the current complaint and peer review reports that the Board's previous attempts at rehabilitating Dr. Alexander have been unsuccessful. Dr. Alexander has repeatedly demonstrated his poor judgment and inattentiveness to patients during complicated procedures. The Board has a duty to protect the public and the Panel does not have confidence in Dr. Alexander's ability to safely practice medicine.

The Panel concludes that the ALJ's proposed sanction of revocation is appropriate.

ORDER

On an affirmative vote of a majority of a quorum of Disciplinary Panel B, it is hereby

ORDERED that Dr. Alexander's license to practice medicine in Maryland (License Number D22219) is **REVOKED**; and it is further

ORDERED that the revocation goes into effect **ten business days**[16] from the date of this Order; and it is further

ORDERED that this is a public document pursuant to Md. Code Ann., Gen. Prov. § 4–101 *et seq.*

10/25/2016
Date

Christine A. Farrelly
Christine A. Farrelly, Executive Director
Maryland State Board of Physicians

[16] The revocation will go into effect 10 business days from the date of this order so proper arrangements can be made for the appropriate transfer of Dr. Alexander's patients.

NOTICE OF RIGHT TO PETITION FOR JUDICIAL REVIEW

Pursuant to Md. Code Ann., Health Occ. § 14-408, Dr. Alexander has the right to seek judicial review of this Final Decision and Order. Any petition for judicial review shall be filed within thirty (30) days from the date of mailing of this Final Decision and Order. The cover letter accompanying this Final Decision and Order indicates the date the decision is mailed. Any petition for judicial review shall be made as provided for in the Administrative Procedure Act, Md. Code Ann., State Gov't § 10-222 and Title 7, Chapter 200 of the Maryland Rules of Procedure.

If Dr. Alexander files a Petition for Judicial Review, the Board is a party and should be served with the court's process at the following address:

Christine A. Farrelly, Executive Director
Maryland State Board of Physicians
4201 Patterson Avenue
Baltimore, Maryland 21215

Notice of any Petition for Judicial Review should also be sent to the Board's counsel at the following address:

Stacey M. Darin, Assistant Attorney General
Office of the Attorney General
Department of Health and Mental Hygiene
300 West Preston Street, Suite 302
Baltimore, Maryland 21201

MARYLAND STATE BOARD	*	**BEFORE LORRAINE E. FRASER,**
OF PHYSICIANS	*	**AN ADMINISTRATIVE LAW JUDGE**
V.	*	**OF THE MARYLAND OFFICE**
HAROLD ALEXANDER, M.D.,	*	**OF ADMINISTRATIVE HEARINGS**
RESPONDENT	*	**OAH CASE NO.: DHMH-MBP-71-15-32239**
LICENSE NO. D22219	*	**MBP CASE NO.: 2015-0019A**

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PROPOSED DECISION

STATEMENT OF THE CASE
ISSUES
SUMMARY OF THE EVIDENCE
FINDINGS OF FACT
DISCUSSION
CONCLUSIONS OF LAW
PROPOSED DISPOSITION
NOTICE OF RIGHT TO FILE EXCEPTIONS

STATEMENT OF THE CASE

On July 8, 2015, the State Board of Physicians (Board) charged Harold O. Alexander, M.D., (Respondent) with violating section 14-404(a)(3)(ii) and (a)(22) of the Maryland Medical Practice Act. Specifically, the charges alleged that the Respondent was guilty of unprofessional conduct in the practice of medicine and that he failed to meet appropriate standards for the delivery of quality medical care[1] in connection with his treatment of a patient on February 28, 2014 and March 1, 2014.

On September 24, 2015, the Board transmitted this matter to the Office of Administrative Hearings (OAH) with a delegation to issue proposed findings of fact, proposed conclusions of law, and a proposed disposition.

[1] In this decision I use the terms standard of care and standard of quality care interchangeably.

On October 19, 2015, I conducted a scheduling conference and on November 23, 2015, I conducted a prehearing conference.

On January 12 and 13, 2016, and February 1, 2016, I conducted a hearing at the OAH. Md. Code Ann., Health Occ. § 14-405(a) (2014). Dawn L. Rubin, Assistant Attorney General, Administrative Prosecutor, Health Occupations Prosecution and Litigation Division, represented the State. William Sinclair, of Silverman, Thompson, Slutkin & White, LLC, represented the Respondent, who was present throughout the hearing.

The contested-case provisions of the Administrative Procedure Act, the Board's Rules of Procedure, and the OAH Rules of Procedure govern procedure in this matter. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2014); Code of Maryland Regulations (COMAR) 10.32.02; COMAR 28.02.01.

ISSUES

(1) Is the Respondent guilty of unprofessional conduct in the practice of medicine?

(2) Did the Respondent fail to meet appropriate standards for the delivery of quality medical and surgical care?

(3) If so, what sanction should be imposed on the Respondent's license to practice medicine?

SUMMARY OF THE EVIDENCE

Exhibits

The State offered the following exhibits, which were admitted as evidence:

State 1 Charges under the Maryland Medical Practice Act, 7/8/15

State 2 Identification of individuals by name

State 3 Initial application for licensure, Board of Medical Examiners of Maryland, 5/24/78, licensed 7/21/78

State 4 Maryland Board of Physicians License Renewal, 9/3/14

State 5 Complaint with attachments from Cigna, 7/14/14

State 6 Letter to the Respondent from the Board, with subpoenas, 10/7/14

State 7 Letter to the Board from the Respondent, 10/14/14

State 8 Subpoena ad testificandum for the Respondent, 10/9/14

State 9 Transcript of interview with the Respondent, 10/16/14

State 10 Transcript of interview with the Respondent, 11/24/14

State 11 Subpoena duces tecum to the Respondent, 12/8/14; with response from the Respondent, 12/23/14

State 12 Email between Dana Mullen and Angelica Branon, Cigna, 9/23/14-9/24/14

State 13 Email between Ms. Mullen and Patient A,[2] 9/30/14-10/6/14

State 14 Email to Patient A from Ms. Mullen, 10/10/14

State 15 Email to Ms. Mullen from Patient A, 10/16/14

State 16 Transcript of interview with Javaka Moore, M.D., 10/28/14

State 17 Emails forwarded to Ms. Rubin from Cigna, 9/24/15

State 18 Memorandum of Unannounced Office Visit, 10/7/14

State 19 Memorandum of Unannounced Office Visit, 10/28/14

State 20 Photographs taken during unannounced office visit, 10/28/14

State 21 The Respondent's handwritten patient log for February – April 2014

State 22 The Respondent's typewritten patient log for 2/1/14 – 9/30/14, 11/20/14

State 23 Medical record for Patient A provided by the Respondent

State 24 Subpoena duces tecum to the Respondent, 12/8/14; with response from the Respondent, 12/9/14

State 25 Certification of Medical Records for Patient A from the Respondent, 1/6/15

State 26 Peer Review by Ishrat Rafi, M.D., M.P.H.,[3] 2/10/15

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[2] The patient is identified as Patient A to protect her confidentiality.
[3] Masters of Public Health

State 27 Curriculum Vitae for Ishrat Zia Rafi, M.D., M.P.H.

State 28 Peer Review by Matrice W. Browne, M.D., 2/10/15

State 29 Curriculum Vitae for Matrice Washington Browne, M.D.

State 30 Letter to the Respondent from the Board providing him with the peer review reports and requesting his supplemental response, 2/13/15

State 31 The Respondent's supplemental response, 3/13/15, with three attachments: Warren M. Hern, Outpatient Abortion for Fetal Anomaly and Fetal Death from 15-34 Menstrual Weeks' Gestation: Techniques and Clinical Management, 81:2 Obstetrics & Gynecology 301-306 (Feb. 1993); Warren M. Hern, Laminaria, Induced Fetal Demise and Misoprostol in Late Abortion, 75 Int'l Journal of Gynecology & Obstetrics 279-286 (2001); Dan Morse, Death After Late-Term Abortion at Germantown Clinic Resulted from Natural Causes, The Washington Post, 5/29/13

State 32 ACOG[4] Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists, Management of Stillbirth, No. 102 (Mar. 2009)

State 33 Society of Family Planning, Clinical Guidelines, Induction of Fetal Demise Before Abortion (Jan. 2010)

State 34 Consent Order, 8/22/12

State 35 Order Terminating Suspension and Imposing Probation, 4/4/13

State 36 Cease and Desist Order, 10/25/13

State 37 Letter modifying the October 25, 2013 Cease and Desist Order, 12/19/13

State 38 Consent Order, 4/16/14

State 39 Order Staying Suspension and Imposing Probation, 7/21/14

State 40 Maryland Board of Physicians Report of Investigation, 5/20/15

The Respondent offered the following exhibits, which were admitted as evidence:[5]

Resp. 12 Warren M. Hern, Selective Termination for Fetal Anomaly/Genetic Disorder in Twin Pregnancy at 32+ Menstrual Weeks, 19 Fetal Diagnosis and Therapy 292-295 (2004)

Resp. 16 Warren M. Hern, Laminaria, Induced Fetal Demise and Misoprostol in Late Abortion, 75 Int'l Journal of Gynecology & Obstetrics 279-286 (2001)

[4] American College of Obstetricians and Gynecologists

[5] The Respondent's exhibits were premarked. Only those exhibits listed here were admitted into evidence; however, the original numbering was used during the hearing to avoid confusion.

Resp. 17 Dan Morse, Death After Late-Term Abortion at Germantown Clinic Resulted from Natural Causes, The Washington Post, 5/29/13

Resp. 21 Michael Molaei, Heidi E. Jones, Tara Weiselberg, Meghan McManama, Jay Bassell, & Carolyn L. Westhoff, Effectiveness and Safety of Digoxin to Induce Fetal Demise Prior to Second-Trimester Abortion, 77 Contraception 223-225 (2008)

Resp. 23 Amos Grunebaum & Frank A. Chervenak, Fetal Demise and Stillbirth: Maternal Care, 2015 UpToDate

Resp. 26 Anna K. Sfakianaki & Joshua Copel, Induced Fetal Demise, 2015 UpToDate

Resp. 28 B. Shakya, P. Chaudhary, M. Tumbahangphe, & M. Jha, Intra-Amniotic Digoxin for Fetal Anomaly in Second and Early Third Trimester, 9:1 NJOG 17 (Jan. – Jun. 2014)

Resp. 30 Cassing Hammond, Recent Advances in Second-Trimester Abortion: An Evidence-Based Review, American Journal of Obstetrics & Gynecology (Apr. 2009)

Resp. 32 Cassing Hammond, Second Trimester Pregnancy Termination: Induction (Medication) Termination, 2015 UpToDate

Resp. 73 Curriculum Vitae for Charlie Browne, M.D., F.A.C.O.G.

Resp. 74 Exhibit C to [the Respondent's] Prehearing Conference Statement, 11/16/15

Resp. 75 Guidelines for Women's Health Care 4th Ed. 2014, pp. ii-xii, 142-145, 717-723, 870-883

Testimony

The following witnesses testified for the State: Ishrat Zia Rafi, M.D., M.P.H., who was accepted as an expert in obstetrics and gynecology; Matrice Washington Browne, M.D., who was accepted as an expert in obstetrics and gynecology; Dana Mullen, Compliance Analyst for the Board; and Elizabeth Ward, Senior Fraud Specialist, Cigna Special Investigations Unit.

The Respondent testified on his own behalf. He also presented testimony from the following witness: Charlie Browne, M.D., F.A.C.O.G., who was accepted as an expert in obstetrics and gynecology.

FINDINGS OF FACT

I find the following facts by a preponderance of the evidence:

1. The Respondent has been licensed to practice medicine in Maryland since 1978 under license number D22219.

2. At all times relevant to this case, the Respondent practiced medicine at Practice A[6] in Maryland. The Respondent performed medical abortions and gynecologic services in his practice. The Respondent did not hold hospital privileges.

3. The Respondent's Practice A was located in an office maintained by Dr. Moore, an obstetrician-gynecologist. Dr. Moore's clinical practice was separate from the Respondent's. The Respondent's office hours were part-time in the evenings and on Saturdays.

Disciplinary History

4. On August 22, 2012, the Respondent entered into a Consent Order with the Board to resolve May 14, 2012 charges that he was guilty of unprofessional conduct in the practice of medicine, failed to meet appropriate standards for the delivery of quality care, and failed to keep adequate medical records. Specifically, the Respondent could not produce medical records for patients; he inappropriately shredded medical records; his medical documentation for patients was inadequate; he failed to properly evaluate and follow-up with patients after performing surgical procedures; he kissed, hugged, and made inappropriate sexual comments to patients; and he prescribed medication to family members, friends, and himself without maintaining medical records. The Board imposed a minimum three months suspension and two years of probation with conditions.

5. On April 4, 2013, the Board terminated the suspension of the Respondent's license and imposed a minimum of two years of probation with conditions.

[6] The facility is identified as Practice A to protect patient confidentiality.

6. On October 25, 2013, the Board issued to the Respondent a cease and desist order requiring him to stop performing surgical abortions and administering any controlled dangerous substances (CDS).

7. On December 19, 2013, the Board modified the cease and desist order. The Board required the Respondent to stop performing surgical abortions in any unlicensed surgical facility and to adhere to an October 28, 2013 Drug Enforcement Administration agreement regarding prescribing and administering CDS.

8. On April 16, 2014, the Respondent entered into a Consent Order with the Board to resolve January 13, 2014 charges that he was guilty of unprofessional conduct in the practice of medicine and violated the regulations regarding surgical abortion facilities.[7] Specifically, the Respondent performed surgical abortions in an unlicensed facility; performed surgical abortions without the presence of a registered nurse; directed two unlicensed employees who did not have medical backgrounds to administer CDS narcotics and intravenous sedation; did not properly maintain, store, and record the administration of CDS; failed to document post-operative vital signs, bleeding, and ambulation of patients, and could not produce medical records for two patients. The Board imposed a minimum three months suspension and three years of probation with conditions.

9. On July 21, 2014, the Board terminated the suspension of the Respondent's license and imposed a minimum of three years of probation with conditions.

Patient A

10. On February 28, 2014, after 7:00 pm, Patient A appeared in the Respondent's office requesting an abortion because of a fetal defect.

[7] COMAR 10.12.01.

11. The gestational age of Patient A's fetus was twenty-eight weeks and six days, as calculated by the date of her last menstrual period on August 10, 2013.[8]

12. Patient A provided to the Respondent the results of her prior ultrasounds, copies of which he included in his records for her.

13. The most recent ultrasound had been performed on February 22, 2014 and diagnosed the fetus with bilateral vetriculomegaly, spina bifida meningomyelocele, and a right club foot.

14. Patient A filled out forms regarding her medical history and signed consent forms for an abortion, including the use of Mifeprex and Misoprostol, and the operative risks for abortion by vacuum. The consent forms were witnessed by the Respondent and a staff person whose signature is illegible on February 28, 2014. Patient A signed the "Mifeprex/Misoprostol Abortion Consent & Information" form but did not date her signature. Patient A signed the "Operative Risks, Complications and Consent" form and dated her signature March 1, 2014. That date is crossed out and February 28, 2014 is written in its place.

15. The "Mifeprex/Misoprostol Abortion Consent & Information" form was inapplicable, at least in part, to Patient A's situation, in that it states at the top: "I acknowledge that I am fewer than 9 weeks (63 days) pregnant and I have decided to have an abortion with the medications Mifeprex and Misoprostol. Mifeprex blocks the action of progesterone; a hormone needed to continue pregnancy." State 23.

16. The "Operative Risks, Complications and Consent" form was inapplicable, at least in part, to Patient A's situation, in that it states at the top: "As with any kind of procedure, complications can occur during and after an abortion, however, early abortion by vacuum aspiration is very safe." State 23. The form discusses the risks of an early abortion by vacuum

[8] Two medical records identify the date of Patient A's last menstrual period as August 10, 2013, and one record identifies it as August 9, 2013. On the Respondent's record, Patient A identified it as August 14, 2013.

including perforation of the uterine wall by an instrument. The Respondent did not plan to perform Patient A's abortion by vacuum or any other surgical procedure and was prohibited from performing surgical abortions by the Board's 2013 consent order.

17. The Respondent's medical records for Patient A do not contain a consent form describing the risks of a late term medical abortion in an office setting (one performed via medicine only, without surgical procedures) or the risks of delivering a stillborn fetus in an office setting.

18. The only mention of a late term abortion is the following: "For patients undergoing second trimester (2-3 day) procedures, I understand that I am required to remain within a 10 minute radius of the office during the entire process." State 23.

19. The records contain a consent form for the use of anesthetics; however, it is not signed by Patient A. The Respondent signed and dated the form February 28, 2014.

20. The Respondent examined Patient A. He documented that he could not detect a fetal heart rate by auscultation or during an ultrasound.

21. According to the Respondent, on February 28, 2014, around 8:00 or 9:00 pm, he administered the following to Patient A: digoxin, lidocaine, saline, Mifeprex, and laminaria. Around midnight, the Respondent administered Versed (midazolam) to Patient A. The Respondent then released Patient A to her husband and they went to a hotel.

22. The Respondent's medical record for Patient A shows that the following were administered: digoxin "1.5 mg", "5 cc 1%" lidocaine, Mifeprex "200 p.o.", and laminaria "x 9."[9] However, the record does not state who administered the medications and laminaria or what time any of the medications or laminaria were administered. Also, it is unclear whether the medications and laminaria were administered on February 28 or March 1. The record does not

[9] The Respondent appears to have administered I.V. midazolam to Patient A at midnight on March 1, 2014. See finding of fact 26.

mention saline being administered. The Respondent noted, "Will administer Dig & lidocaine despite absence of FHR."[10] State 23. The Respondent did not note in the record whether Patient A was released to a responsible individual after being given sedating medication (midazolam).

23. According to the Respondent, shortly before 5:00 am on March 1, 2014, Patient A called the Respondent and stated that she was in labor. Patient A met the Respondent at his office around 5:00 am.

24. The Respondent's medical record for Patient A shows that Misoprostol "800 sl"[11] was administered at 5:00 am on March 1, 2014, but does not state who administered the medication. State 23.

25. The medical record states that Nubain 20 mg I.V. was administered to Patient A at 9:00 am. No date is identified; presumably it was administered on March 1, 2014. It does not state who administered the medication.

26. The medical record also states that I.V. midazolam was administered to Patient A "x 4 5 A, 7, 9 A, 12." State 23. The record does not identify the dosage given and it does not state who administered the medication. No date is identified; presumably it was administered on March 1, 2014, at 12:00 am (midnight), 5:00 am, 7:00 am, and 9:00 am; however, the way the times are listed - 5 A, 7, 9 A, 12 - is confusing and could mean 12:00 pm (noon). It does not state who administered the medication.

27. According to the Respondent, Patient A's fetus was delivered at 9:00 am.

28. The Respondent's medical record for Patient A states: "NSVD[12] non viable fetus & placenta intact 3/1/14 Time In 5 AM Time Out 9 AM." State 23.

29. Under the heading Tissue Examination, the medical record states tissue volume was moderate and the embryo/fetus was seen. There is no estimated blood loss given nor is there

[10] Fetal heart rate.
[11] It is unclear what sl is an abbreviation for.
[12] Normal spontaneous vaginal delivery.

a description of any fetal abnormalities. In addition, there is no statement whether the Respondent offered Patient A a pathologic evaluation of the abnormal fetus.

30. Under the heading Post Procedure/Discharge Orders, the medical record states that Patient A was given "Percocet 5/325 #15 Rx" and "Pitocin IM 2 cc." State 23. The record does not state the date, time, or who administered the Pitocin; presumably it was administered on March 1, 2014.

31. The Respondent wrote in the medical record that his discharge diagnosis was: "28 wk IUP,[13] Multiple Anomalies, Medical Abortion." State 23. He also wrote that Patient A was stable for discharge and had minimal bleeding. Patient A's signature appears underneath, as does the Respondent's.

32. The medical record contains Patient A's vital signs taken by the Respondent after the procedure on March 1, 2014 at 9:15, 9:30, and 9:45 (presumably am, the record does not say) and "No Complaints" is circled. Her vital signs were normal and she was experiencing light bleeding and medium cramping. The Respondent noted Patient A would follow up with her private physician. Patient A did not sign this form although there is a space for her to sign agreeing that she is being discharged without complaint, has received post-operative medications and instructions, has the clinic's emergency number, and has had all her questions answered. The Respondent did not note in the record whether Patient A was released to a responsible individual because she had been given sedating medication (Nubain and midazolam).

33. Sometime shortly after 9:45 am on March 1, 2014, Patient A left the Respondent's office with her husband and returned to her hotel. She did not return to the Respondent's office for any follow up care.

[13] Intrauterine pregnancy.

34. On March 7, 2014, the Respondent wrote on a prescription form the following: "Patient had a spontaneous loss of pregnancy and was delivered of a non viable pregnancy 3/1/14 (Dead Fetus in Utero)." State Ex. 23. This form was provided to Patient A.

35. Sometime later, Patient A wrote $9,500.00 on the bottom of the prescription form and submitted it to her health insurer, Cigna, for reimbursement.

36. Cigna conducted an investigation of Patient A's claim and forwarded that information to the Board, which prompted the Board's investigation in this case.

37. The Board attempted to interview Patient A, but she declined to be interviewed. Patient A explained in an October 16, 2014 email to the Board that she was pregnant again and that she and her husband were "trying to move on" and "get away from the past." State 15.

The Board's Request for Records

38. On October 7, 2014, Dana Mullen and Nancy Louthan, Board Compliance Analysts, and Shelly Moore, Nurse Surveyor, Office of Health Care Quality, went to the Respondent's medical office unannounced to hand deliver an Initial Contact Letter and subpoenas for patient appointment logs and medical records. Office staff told Ms. Mullen, Ms. Louthan, and Ms. Moore that the Respondent was not there, that they did not work for him; however, they gave a contact number for him. Ms. Mullen, Ms. Louthan, and Ms. Moore called the Respondent and he said he was in Virginia and would meet them in forty minutes. He arrived thirty minutes later.

39. When asked to produce his patient appointment logs and medical records, the Respondent stated that some of his records were locked in a file cabinet at the end of the hall, but he did not have a key. He said that Angelica had the key, but she was in Virginia and too far away to get there timely. He stated that his other records were located at the Oasis Foundation, who was helping him manage his records. He said that he would locate the records and fax them

to the Board by 5:30 pm that day. He did not provide the patient appointment logs or medical records to Ms. Mullen, Ms. Louthan or the Board that day.

40. On October 16, 2014, the Respondent provided handwritten patient appointment logs for the months of February, March, and April 2014 to the Board in response to its subpoena. The Patients were identified by initials only.

41. On October 28, 2014, Ms. Mullen and Ms. Louthan went to the Respondent's medical office unannounced to deliver a target letter to Dr. Moore and subpoenas to interview Dr. Moore and for his appointment logs for February 28, 2014 and March 1, 2014.

42. Gina Thomas gave Ms. Mullen and Ms. Louthan a tour of the office and they took photographs.

43. On November 20, 2014, the Respondent provided typewritten patient appointment logs to the Board for the months of February, March, and April 2014 that included the patients' full names.

44. On January 6, 2015, the Respondent provided Patient A's medical record to the Board.

Standard of Care

45. The standard of care for a patient twenty-eight weeks pregnant with an intrauterine fetal death is to refer that patient to a facility with a higher level of care, such a surgical facility or a hospital, because the patient faces a higher risk of infection, excessive bleeding, uterine rupture, and other complications, and the potential need for surgical intervention if there were difficulty delivering the fetus.

46. The Respondent violated the standard of care by performing a medically induced abortion on Patient A in his medical office instead of referring her to a higher level of care facility.

47. The standard of care requires that the date, time and provider of examinations, vital signs, and the administration of medication be documented clearly in a patient's medical record.

48. The Respondent violated the standard of care because his record for Patient A does not clearly document the date, time and provider for her examination, vital signs, and each medication administered to her.

49. The standard of care requires that a patient be continually observed and her vital signs monitored and documented when given sedative medication.

50. The Respondent violated the standard of care by administering sedative medications, Nubain and midazolam, as well as digoxin, Mifeprex, and laminarias to Patient A without continuing to observe her or monitor her vital signs. The medical records do not show that the Respondent checked her vital signs each time he administered a dose of sedatives. Further, the Respondent released Patient A to her husband to go to a hotel overnight sometime late February 28 or early March 1 to await the beginning of labor.

51. The standard of care requires a physician to document the precise time the fetus and placenta are delivered, as well as the details of the delivery, including estimated blood loss, a description of fetal anomalies and Apgar scores.

52. The Respondent violated the standard of care by failing to document the precise times the fetus and placenta were delivered. In addition, the Respondent violated the standard of care by failing to document Patient A's estimated blood loss, the fetal Apgar scores, and failing to describe any fetal anomalies.

53. The standard of care requires that there be an indication for medication to be administered to a patient.

54. The Respondent violated the standard of care when he administered digoxin and lidocaine to Patient A to induce fetal death after he had determined the absence of a fetal heart rate.

55. The standard of care requires that a physician have medical records readily accessible.

56. The Respondent violated the standard of care by failing to produce medical records when requested to do so by Ms. Mullen and Ms. Louthan on October 7, 2014.

DISCUSSION

The Board alleged that the Respondent failed to meet appropriate standards as determined by peer review for the delivery of quality medical care and that his conduct was unprofessional in connection with his treatment of Patient A on February 28, 2014 and March 1, 2014. Md. Code Ann., Health Occ. § 14-404(a) (3)(ii), (22) (Supp. 2015).

The State argued that the Respondent failed to meet the quality standard of care and was unprofessional when he delivered a twenty-eight to twenty-nine week old stillborn fetus in an outpatient office without the assistance of any licensed staff or the ability to perform surgery if needed. The State asserted that the standard of quality care required that the Respondent refer Patient A to a higher level of care facility, such as a labor and delivery unit at a hospital or an ambulatory surgical care center. The State maintained that the advanced fetal age meant the fetus was larger and would be more difficult to deliver and there would be a higher risk of infection and excessive bleeding. The State contended that the articles relied upon by the Respondent described outpatient facilities with special surgical instruments, specially trained staff, and a community hospital located across the street from the facility. In contrast, the State noted the Respondent testified that his medical office was approximately ten minutes from the closest hospitals, he did not have hospital privileges, and his emergency plan was to call 911.

The State alleged that the Respondent also violated the standard of care when he injected digoxin and lidocaine intra-amniotically after finding there was no fetal heart rate via ultrasound and auscultation.

The State maintained there were material omissions in the Respondent's medical record, including the clear time and date medications were administered, the specific times the fetus and placenta were delivered, Patient A's estimated blood loss, a description of the fetal anomalies, Apgar Scores, fetal weight, and specific counseling provided to Patient A. The State asserted the Respondent failed to document that Patient A was released to a responsible person and went to a hotel after receiving intravenous sedation the night before and the morning of the procedure. The State maintained that the Respondent failed to document any monitoring of Patient A after giving her intravenous sedation the night before the procedure and only documented three sets of vital signs over forty-five minutes postpartum. The State argued that another provider reading Patient A's record would not be aware of her care history. The State contended that poor and inadequate documentation constitutes substandard care. The State maintained that the Respondent has been on notice since July 2012 that he needed to improve his record keeping.

The Respondent argued that it was not a violation of the standard of care to perform the procedure on Patient A in his medical office. The Respondent asserted that there is no standard of care regarding the use of digoxin in the absence of a fetal heart rate and its use did not pose an undue risk to Patient A. The Respondent contended that digoxin is used to ensure compliance with the Partial-Birth Abortion Act (to ensure a live birth does not occur), and for cervical priming and softening fetal tissue. The Respondent acknowledged he had issues with his medical record keeping but maintained that his records met basic requirements. The Respondent claimed that he had not yet completed the record keeping course with Dr. Steinberg in March of 2014 but that the Board was aware he had not completed it. The Respondent asserted that it was

unfair to charge him with a record keeping violation before he had completed the course. The Respondent argued that the Board should have charged him with violating subsection (a)(40) if it were pursing charges against him regarding how he stored his medical records. He argued further that it was also unfair to charge him regarding how he stored his records when he had not completed the record keeping course. The Respondent asserted that his conduct was not so egregious as to rise to the level of unprofessional conduct.

Standard of Care

On the evening of February 28, 2014, Patient A presented to the Respondent requesting an abortion because of fetal defects. She was twenty-eight weeks pregnant. Patient A gave the Respondent her prior ultrasound records, the most recent of which showed severe fetal anomalies. The Respondent gave Patient A several consent forms to sign; she signed most of them but did not sign the one for anesthesia. The Respondent examined Patient A, performed an ultrasound and found there was no fetal heart rate. He also auscultated and did not hear a fetal heart rate. The Respondent described the events that evening as follows. Around 8:00 or 9:00 pm on February 28, 2014, he administered the following to Patient A: digoxin, lidocaine, saline, Mifeprex, and laminaria. Around midnight, he administered Versed (midazolam) to Patient A. He then released Patient A to her husband and they went to a hotel. Shortly before 5:00 am on March 1, 2014, Patient A called him and stated that she was in labor. Patient A met him at his office around 5:00 am and he delivered her fetus at 9:00 am. He administered Pitocin to Patient A and gave her a prescription for Percocet. He took Patient A's vital signs after the procedure at 9:15, 9:30, and 9:45 am and discharged her. Patient A left his office with her husband and returned to her hotel. She did not return to his office for any follow up care.

Doctors Rafi and M. Browne (the State's experts) testified that the Respondent's treatment of Patient A violated the standard of care. Dr. Rafi testified that the Respondent

performed an appropriate history and physical and determined that Patient A had an intrauterine fetal death at twenty-eight weeks. Dr. Rafi stated that the standard of care required the Respondent to refer Patient A to a higher level of care facility and keep her under observation. Dr. Rafi explained that a higher level of care was required because the advanced gestational age of the fetus put Patient A at higher risk of infection and bleeding. In addition, Dr. Rafi stated that the fetal abnormalities placed Patient A at higher risk of infection and bleeding. Further, Dr. Rafi stated the fact that the fetus was dead for an unknown period of time placed Patient A at a higher risk of bleeding. Dr. Rafi testified that possible complications during the delivery were another reason a higher level of care was required. Dr. Rafi explained that complications, such as the fetus becoming entrapped and only partially delivered, would require certain instruments to facilitate the delivery, that is, surgical intervention. Dr. Rafi testified that the Respondent administered Mifeprex, laminaria, digoxin, and lidocaine the evening of February 28, 2014 and then released Patient A to a hotel, which violated the standard of care. Dr. Rafi described the Respondent's delivery of Patient A's fetus in his office as dangerous and opined that he breached the standard of care.

Dr. M. Browne testified that the standard of care for a patient with fetal demise at twenty-eight weeks required a higher level of care, such as labor and delivery or the operating room in a hospital, a surgical suite, a birthing center, or an ambulatory care center with surgical capabilities. Dr. M. Browne opined that the Respondent's medical office without any specialized surgical equipment or staff did not meet the standard of care. Dr. M. Browne explained that the higher level of care was necessary for the safety of the mother. Dr. M. Browne stated that complications could arise, such as excessive blood loss or uterine rupture, which would require specialty care.

Dr. Rafi and Dr. M. Browne both noted that the Respondent determined fetal death via ultrasound and auscultation and both questioned why the Respondent administered digoxin, which induces fetal death, when fetal death had already occurred. Both Dr. Rafi and Dr. M. Browne testified the Respondent's administration of digoxin after fetal demise violated the standard of care because there was no indication for the use of the medicine.

Dr. Rafi and Dr. M. Browne testified that they had difficulty understanding the Respondent's medical record for Patient A. Both doctors described missing information, disorganized recording of information in the record, and questions they could not answer from the record. In addition, they had to rely on statements the Respondent made to the Board, *i.e.,* information outside the medical record, to gain a better understanding of what occurred.

Dr. Rafi explained that medical records should contain a timeline of what occurred and that one should be able to follow the record and know what occurred and when, what time medications were administered, and the status of the patient. The Respondent's medical record shows that he performed a vaginal exam, which he stated was negative, but does not give the date or time of the exam. Dr. Rafi stated that she did not know what the Respondent meant by negative. The record has vital signs recorded at the top of the page but does not state the date and time they were taken. The record shows that laminaria, digoxin, and lidocaine were administered but does not state the date or time or who administered them. The record does not show the Respondent administered saline. Further, the record does not state that the Respondent released Patient A to a hotel overnight with directions to return when she felt pain. The record shows Mifeprex was administered but does not state the date or time or who administered it. The record shows Nubain (I.V. sedation) was administered at 9:00 am but does not state the date or who administered it. The record shows midazolam (I.V. sedation) was administered "x 4 5 A, 7, 9 A, 12." State 23. The record does not state the dosage given, the date(s) given, or who

administered it. Moreover, it is unclear whether "12" means 12:00 am or pm. Written sequentially after 9:00 am implies 12:00 pm (noon); however, the Respondent testified it was 12:00 am (midnight), before the procedure. Further, there are no vital signs recorded with each administration of I.V. sedation.

Dr. Rafi testified that the standard of care required that Patient A's vital signs be taken and recorded each time she was given I.V. sedation. There is a space on the document to record estimated blood loss, but it is blank. Dr. Rafi testified that the standard of care required estimated blood loss to be documented. The record states the tissue volume was moderate and the fetus was seen. The record also states "NSVD nonviable fetus and placenta intact." State 23. The record identifies the discharge diagnosis as "28 wk IUP, Multiple Anomalies, Medical Abortion." State 23. However, the record does not state the times the fetus and placenta were delivered, a description of the fetal anomalies, fetal Apgar scores, or fetal weight. Dr. Rafi testified the standard of care required that the delivery times, a description of the fetal anomalies, fetal Apgar scores, and fetal weight be recorded. She explained that this information would be useful to a patient who wishes to become pregnant again in the future. For example, according to the ultrasound Patient A's fetus had spina bifida; Dr. Rafi stated there are medications Patient A could take in the future to decrease the chances of a future neural tube defect. Dr. Rafi also stated that a death certificate should have been written because this was a stillbirth.

Dr. M. Browne testified that she could not identify the time of delivery from the record. The Respondent made a notation "Time Out 9 am." State 23. Dr. M. Browne stated that the Respondent's notation did not meet the standard of care. She explained, "where is she [Patient A] out of? Is she out of the office, is she out of delivery, is the baby out, is the placenta out? What is out? I don't know. I can't answer." Tr. p. 159. Dr. M. Browne testified that the standard of care requires that the time the placenta was delivered be documented. She testified

further that the standard of care required documentation of the time of delivery and the condition of the fetus, including fetal weight and any anomalies. She questioned the Respondent's notation that the fetus was nonviable because nonviability means the fetus could not sustain life if it had been born alive. However, in this case, the Respondent had ascertained fetal death in utero. Dr. M. Browne stated the standard for nonviability is the delivery of a fetus before twenty-four weeks gestation. She explained that spina bifida does not deem a fetus nonviable. She explained further that the fetal anomalies should be documented for the mother's benefit regarding possible future pregnancies. Dr. M. Browne testified that the Respondent should have documented how the fetus was disposed and should have produced a death certificate.

The record shows Pitocin was administered post procedure but it does not state the date, time, or who administered it. The record does not state what time Patient A was discharged from the Respondent's care. The Respondent appears to have recorded the entire procedure from the administration of laminaria and medications presumably on the evening of February 28th to the delivery presumably on the morning of March 1st on one sheet because there are references to both dates but the entries are not in chronological order and it is not clear from the document itself what occurred when. Both Dr. Rafi and Dr. M. Browne testified that they were unable to ascertain from the record itself the course of Patient A's care. Further, Dr. Rafi and Dr. M. Browne stated that the record did not show that Patient A's vital signs were monitored when she was given Nubain and midazolam, which are sedating medications. Dr. Rafi and Dr. M. Browne opined that the Respondent's medical record did not meet the standard of care.

Dr. Rafi testified that she was confused about the consent form ("Mifeprex/Misoprostol Abortion Consent & Information") that the Respondent used with Patient A that had her acknowledge she was less than nine weeks pregnant when she was in fact twenty-eight weeks pregnant. Dr. Rafi noted that Patient A did not date her signature on that consent form. Dr. Rafi

observed that Patient A did not sign the discharge instructions, and that the standard of care required that she sign it. Dr. Rafi noted that Patient A was under the effects of I.V. sedation and that she believed Patient A's partner was there with her; however, there was no signature for that person, nor was that person identified anywhere in the record. Dr. Rafi testified that the standard of care required that Patient A be released to a responsible individual who must sign the discharge instructions. Dr. M. Browne also testified that the standard of care required that Patient A sign the discharge form and that the responsible individual to whom she was released be identified in the record.

Dr. Rafi testified that the standard of care requires that a physician be able to access his/her medical records. She opined that the Respondent violated the standard of care when he could not access his medical records immediately when asked to do so by the compliance analyst.

Dr. C. Browne (the Respondent's expert) opined that the Respondent did not violate the standard of care when he performed Patient A's procedure in an outpatient setting. He opined further that the Respondent's administration of digoxin and lidocaine did not pose an undue risk to Patient A.

I found a number of fundamental problems with Dr. C. Browne's testimony. First and foremost, Dr. C Browne's testimony treated the procedure the Respondent performed on Patient A as a termination of an unwanted pregnancy. His testimony addressed the safety of late term abortions in outpatient settings. From his testimony, it is not clear to me whether Dr. C. Browne was aware of all the facts in this case. However, the record is clear that Patient A sought an abortion from the Respondent on February 28, 2014, only six days after she learned that her fetus had severe anomalies on February 22, 2014. Until that point, Patient A appears to have been receiving pre-natal care, as evidenced by the medical records she provided to the Respondent.

Thus, it is more likely than not that Patient A and her husband desired her pregnancy, a conclusion which is further supported by the fact that she was pregnant again seven months later. More importantly, when Patient A presented to the Respondent on February 28, 2014, he determined that there was no fetal heart rate. It is unclear to me why, at that point, the Respondent continued to treat Patient A as if he were terminating an unwanted pregnancy and needed to ensure fetal demise. Dr. C. Browne did not offer an explanation as to how providing a medically induced, non-surgical abortion to a patient with a dead twenty-eight week old fetus met the standard of care. Dr. C. Browne did not explain why it was necessary to administer digoxin and lidocaine to induce fetal demise in a fetus that was already dead. When asked if digoxin caused cervical priming, Dr. C. Browne responded "we do not know."[14] When asked if he were aware of any studies showing lidocaine facilitated delivery, he stated he was not. Dr. C. Browne did not address the increased risk of complications posed by the fact that Patient A's fetus was dead for an unknown period of time; complications that may have required immediate surgical intervention. It is not clear to me that Dr. C. Browne was even aware that the Respondent was prohibited by the Board from providing surgical abortions. Dr. C. Browne's testimony that it was not necessary "in this setting"[15] to confirm and document the fetal anomalies ignored Patient A's desire for this pregnancy and future pregnancies. A description of the fetal anomalies is information that would be useful to a woman for any future pregnancies.

On cross examination, Dr. C. Browne admitted that the medical record did not state the precise times the fetus and placenta were delivered. He presumed the fetus was delivered somewhere before or at 9:00 am based on the notes and comments. He testified that in an outpatient setting the only times that mattered were when the procedure began and ended, but did not explain why the times of delivery did not matter in an outpatient setting. Dr. C. Browne

[14] Tr. p. 492.
[15] Tr. p. 485.

testified that the record stated that midazolam was administered to Patient A at 5:00 am, 7:00, 9:00 am, and 12:00. When asked how Patient A received midazolam at 12:00 when she was discharged at 10:00 am, Dr. C. Browne acknowledged the uncertainty as to whether 12:00 referred to 12:00 midnight or 12:00 noon, that the record may have been out of sequence, and that the standard of care required that the date and time medications were administered be clearly documented. Dr. C. Browne also acknowledged that the standard of care required Patient A be monitored after being given I.V. sedation (Nubain and midazolam) and that the record did not show that Patient A was monitored except at 9:15 am, 9:30 am, and 9:45 am. Dr. C. Browne further acknowledged that the standard of care required that Patient A's estimated blood loss be documented but was not. Dr. C. Browne agreed that it was prudent to discharge a patient who had received I.V. sedation to a responsible individual; however, he did not agree that it was required. Dr. C. Browne also agreed that it would have been prudent to document that Patient A was discharged to a hotel the night before the procedure after she had received Mifeprex and lamineria, although he was not sure whether that was required.

I note that Dr. C. Browne did not produce a written report that was admitted into evidence. The only document I have signed by Dr. C. Browne is a series of conclusory proffers written by the Respondent's counsel. This document is not helpful in explaining the basis of Dr. C. Browne's opinions.

In sum, Dr. C. Browne's testimony was contradictory regarding whether the Respondent's medical record met the standard of care. Further, Dr. C. Browne's testimony failed to acknowledge important facts and failed to adequately explain his reasons for concluding that the Respondent met the standard of care. I find Dr. Rafi's and Dr. M. Browne's detailed testimony far outweighs Dr. C. Browne's problematic testimony.

The Respondent submitted to the Board and introduced into evidence a number of articles regarding late term abortions, including those in outpatient settings. All of the articles discussed both medical and surgical abortions, and the possibility that surgical interventions may be necessary if complications arose. There were four articles that specifically discussed abortions in an outpatient setting. Three were written by Dr. Warren Hern, one of which discussed selective termination of a twin for fetal anomaly or genetic disorder at thirty-two weeks gestation and greater. The fourth discussed patients at the Parkmed Women's Center that were seventeen to twenty-four weeks pregnant. Thus, only two of Dr. Hern's articles appear applicable to this case based on the age of the fetus and only one is directly applicable, addressing fetal anomalies and fetal death.

In his articles Outpatient Abortion for Fetal Anomaly and Fetal Death from 15-34 Menstrual Weeks' Gestation: Techniques and Clinical Management and Laminaria, Induced Fetal Demise and Misoprostol in Late Abortion, Dr. Hern described his practice setting as a single private office located across the street from a community hospital. Dr. Hern noted that his facility had been "specially equipped and staffed to provide assistance for women seeking late abortion." State 31 p. 301, Resp. 16 p. 280. Dr. Hern wrote: "Patients receive individual counseling and support throughout their experience at the clinic." *Id.* He discussed the use of Dilation and Evacuation (D & E) if expulsion of the fetus did not occur. He noted the importance of draining amniotic fluid as completely as possible before inducing labor to reduce the risk of amniotic fluid embolism. He described his method for measuring blood loss. He explained that procedure time was measured from the beginning of delivery of the fetus or entering the uterine cavity with instruments "until completion of the procedure by final curettage and vacuum aspiration." State 31 p. 302, Resp. 16 p. 281. He described post-operative tissue examination as follows: "weighing the fetus and placenta separately and carefully measuring fetal parts, including foot length, biparietal diameter,

crown-rump length, rump-shoulder length, abdominal diameter, and chest diameter." Resp. 16 p. 281; see also State 31 p. 302. He stated that patients were observed in the recovery room for one to two hours or more.

The Respondent's treatment of Patient A contrasted sharply with Dr. Hern's practice. The Respondent testified that his office was ten minutes from two hospitals. Given the address of his office and the addresses of the two closest hospitals, I believe it would take more than ten minutes to travel from his office to the closest hospital; however, for the purposes of this decision I will accept the Respondent's ten minute estimate. The Respondent testified that if an emergency arose he would call 911 for an ambulance and he would call the emergency room and speak to the obstetrician and gynecologist on call to give that doctor a summary of the patient. He stated that he did not have a patient transfer agreement in place. Thus, the time it takes for an ambulance to respond to the Respondent's office must be added to the time it takes to travel from the Respondent's office to the hospital. The location of Dr. Hern's office across the street from a hospital provides a much quicker response time in the event of an emergency than the Respondent's situation.

The Respondent's practice did not have any specialized equipment or staff. The Respondent was barred by the Board from performing any surgical abortion procedures. He testified that he sold all of his instruments to Dr. Moore, although he said he could use the instruments if he needed to. On the evening of February 28, 2014 it appears there was a staff person present assisting the Respondent; an illegible signature appears on one of the consent forms in addition to Patient A's and the Respondent's signatures. The Respondent testified that he occasionally has assistance from Angelica (last name not identified), Keiko Friday and his daughter; however, none of these women are registered nurses or licensed by any health occupation board in Maryland. In addition, there is no evidence showing anyone was assisting

the Respondent on the morning of March 1, 2014. There is no evidence showing the Respondent provided any counseling to Patient A; there is no documentation of any counseling in the medical record. The Respondent did not document in the medical record that Patient A's amniotic fluid was drained. The Respondent did not document the amount of Patient A's blood loss. The Respondent did not document the specific times the fetus and placenta were delivered or the exact time the procedure ended. The Respondent did not document any post-operative tissue examination or description of the fetal anomalies. Finally, the Respondent documented that he observed Patient A for forty-five minutes post procedure, which is less than the one hour minimum Dr. Hern used.

In sum, the articles submitted by the Respondent do not support his position that his treatment of Patient A met the standard of care.

Unprofessional Conduct

Dr. Rafi opined that the Respondent's delivery of Patient A's fetus in his office was unprofessional because his conduct could have harmed Patient A. Dr. M. Browne stated that when a provider provides care that does not meet the standard, that provider's conduct is unprofessional. Dr. M. Browne opined that the Respondent's delivery of Patient A's fetus in his office was unprofessional because he should have known that the fetus should have been delivered in a higher level of care facility.

Dr. C. Browne opined that the Respondent's care of Patient A did not constitute unprofessional conduct. In addition, he opined that the Respondent's record keeping did not constitute unprofessional conduct, although he acknowledged the Respondent's records could have been more complete and clearly delineated.

The testimony and documents in this case convincingly demonstrated that the Respondent's treatment of Patient A and his documentation in her medical record violated the

standard of care. I agree with Dr. Rafi and Dr. M. Browne that conduct that does not meet the standard of care is unprofessional conduct.

In addition, I find the Respondent's inability to produce medical records requested by the Board on October 7, 2014 constituted unprofessional conduct. As the State noted, the Respondent has been on notice since July 2012 that he needed to improve his record keeping. At a minimum, the Respondent should have been aware that he needed to be able to access his medical records promptly. The Respondent gave the Board a handwritten appointment log that contained only patient initials on October 16, 2014. He did not provide an appointment log with patient names until November 20, 2014. Finally, he did not provide Patient A's medical record to the Board until January 6, 2015. The Respondent's delay in producing those records was inexcusable and unprofessional. Therefore, I find the evidence shows that the Respondent's actions constituted unprofessional conduct.

Sanction

The State argued that the aggravating factors in this case include the Respondent's extensive disciplinary history. The State asserted the Respondent has been disciplined by the Board for unprofessional conduct, violations of the standard of quality care, and for inadequate recordkeeping. The State contended that the Respondent's actions were deliberate, had the potential for harm, and were part of a pattern of detrimental conduct. The State alleged Patient A was vulnerable, from another country,[16] and sought a late term abortion for a fetus with abnormalities; she was not aware that the fetus had died when she presented to the Respondent. The State maintained that the Board had made previous attempts to rehabilitate the Respondent and has been unsuccessful. The State argued that there were no mitigating factors. The State recommended revocation of the Respondent's medical license.

[16] Patient A is from Denmark.

The Respondent argued that he did not violate the standard of care and did not engage in unprofessional conduct. He did not address the sanction or the aggravating factors directly; however, I infer that his position is that no sanction is warranted.

I agree with the State that revocation of the Respondent's medical license is warranted. The Respondent's treatment of Patient A could have caused her great harm if complications had arisen. The Respondent should have referred Patient A to a higher level of care facility to manage the delivery of her dead fetus. At a minimum, the Respondent should have referred Patient A to a facility that had the ability to perform surgical abortions if necessary to complete Patient A's medically induced labor. The Respondent's emergency plan of calling 911 was simply insufficient to ensure Patient A's well being. The Respondent's confusing and incomplete record of Patient A's procedure also placed her at risk if she needed additional immediate care; a subsequent physician would not be aware of her course of care. The Respondent's assertion that he had not completed his record keeping course is disingenuous. The Respondent has known since July 2012 that he needed to improve his record keeping and the Board directed him to complete a record keeping course within six months. The Respondent is responsible for his delay in completing the course. Moreover, he remained under an obligation to improve his record keeping in the meantime. I agree with the State that the Respondent's actions were deliberate and had the potential for harm. I also agree that Patient A was vulnerable; she was from a foreign country and had recently learned her fetus had severe abnormalities. The Respondent's disciplinary history, detailed in the findings of fact above, further supports revocation of his license. On January 13, 2014, the Board filed charges against the Respondent that included failing to document post-operative vital signs, bleeding, and ambulation of patients, and failing to produce medical records for patients. Thus, in February of

2014, the Respondent was well aware of specific improvements that he needed to make to his record keeping but he failed to do so.

For all the above reasons, I find that the Respondent violated the standard of care and engaged in unprofessional conduct.

CONCLUSIONS OF LAW

Based on the above Findings of Fact and Discussion, I conclude that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical care, in violation of section 14-404(a)(22). Md. Code Ann., Health Occ. § 14-404(a)(22) (Supp. 2015).

I further conclude that the Respondent is guilty of unprofessional conduct in the practice of medicine, in violation of section 14-404(a)(3)(ii). Md. Code Ann., Health Occ. § 14-04(a)(3)(ii) (Supp. 2015).

I further conclude that, as a result, the Board may discipline the Respondent by revoking his license to practice medicine. Md. Code Ann., Health Occ. § 14-404(a) (Supp. 2015).

PROPOSED DISPOSITION

I **PROPOSE** that the charges filed by the Board against the Respondent for violation of section 14-404(a)(3)(ii) and (a)(22) be **UPHELD.** I further **PROPOSE** that the Board revoke the Respondent's license to practice medicine.

April 29, 2016
Date Report Mailed

Lorraine E. Fraser/RAB
Lorraine E. Fraser
Administrative Law Judge

LEF/sm
#160917