

THE COMMONWEALTH OF MASSACHUSETTS

Suffolk, ss.

Division of Administrative Law Appeals

Board of Registration in Medicine,
Petitioner

v.

Docket No. RM-14-810

Mark Hughes, M.D.
Respondent

Appearance for Petitioner:

James Paikos, Esquire
Complaint Counsel
Board of Registration in Medicine
200 Harvard Mill Square, Suite 330
Wakefield, MA 01880

Appearance for Respondent:

Paul R. Cirel, Esquire
Collora, LLP
100 High Street, 20th Floor
Boston, MA 02210-2321

Thomas S. Crane, Esquire
Mintz, Levin, Cohn, Ferris,
Glovsky & Popeo, PC
One Financial Center
Boston, MA 02110

Administrative Magistrate:

Judithann Burke

CASE SUMMARY

The Board of Registration in Medicine has not met its burden of proving that the Respondent's treatment of Patients A and B violated the standard of care for ophthalmologists who are retinal specialists.

RECOMMENDED DECISION

Pursuant to G.L. c. 112 §§ 5 and 61-62 and 243 CMR 1.03(5) (a) (3), 103.5(a)17, and 103(5)(a)18, the Petitioner, Board of Registration in Medicine (BRM), issued on December 18, 2014 an Order to Show Cause why the Respondent, Mark Hughes, M.D., should not be disciplined. Originally, the BRM issued allegations pertaining to eleven (11) patients (Patients A-K) in its Statement of Allegations. In or about May 2015, the BRM indicated that it was proceeding with the allegations pertaining to only 2 of the 11 patients, Patients A and B. The BRM made an oral motion on the record at the commencement of the hearing on July 20, 2015 to amend the Statement of Allegations and dismiss those allegations pertaining to Patients C through K. The motion was allowed. The allegations set forth in the December 18, 2014 Statement of Allegations pertaining to the Respondent and Patients A and B were as follows:

Biographical Information

1. The Respondent was born on January 26, 1961. He graduated from Harvard Medical School in 1986. He has been licensed to practice medicine in Massachusetts under certificate number 72171 since 1990. He is certified by the American Board of Ophthalmology.
2. On July 18, 2011, the Respondent plead guilty in the United States District Court, District of Massachusetts, to one charge of tax evasion and one charge of obstruction of a tax audit.
3. The Respondent was sentenced to a year and a day in prison, followed by a period of supervised release with special conditions for two years. He was also fined \$60,000.
4. The Respondent has paid all unpaid income taxes, penalties and interest.

5. On January 4, 2012, the Respondent entered into a Consent Order and the Board suspended the Respondent's license to practice medicine with leave to Petitioner for a stay of the suspension after one year. *See in the Matter of Mark Hughes, M.D.*

Adjudicatory No. 2012-001 (Consent Order, January 4, 2012).

Factual Allegations

6. Count fingers vision (CF vision) is considerably worse than 20/200 vision, which constitutes legal blindness.

7. A fluorescein angiography (FA) test is an eye test that uses a special dye to look at blood flow in the retina and choroid. The fluorescein dye is injected into the vein of a patient and circulates through the blood vessels in the retina to the back of the eye.

Photographs are taken with wavelengths of light that show where the dye is present. An FA test will demonstrate where there is: normal circulation; vascular occlusion; and fluorescein dye leaking out of blood vessels.

8. Optical coherence tomography (OCT) is a scan of the thickness of the retina, which lies inside the back wall of the eye. An OCT scan is done using visible light, and allows one, in a noninvasive way, to tell if there is extra fluid, traction, or scar tissue in the retina.

9. Vascular endothelial growth factor (VEGF) is a chemical produced by the cells that promote growth of abnormal blood vessels that leak. Injections into the eyeball of anti-VEGF medication inhibit the production of VEGF.

10. In the treat and extend method, when anti-VEGF injections are started, injections are given on a monthly basis and the eyes are examined for continued leakage and activity. If there is a good response to the injections, then the standard is to extend the

interval in between visits to see if the eye remains stable. At times, an injection can be given after the first six weeks, then eight weeks, and perhaps, extending to a maintenance injection every three months.

Patient A

11. Patient A, a female, was 99-years old when she initially saw the Respondent.
12. The Respondent diagnosed Patient A with an inferior retinal detachment of the right eye.
13. In June 2011, the Respondent performed surgery to repair Patient A's retinal detachment.
14. The Respondent failed to diagnose the choroidal melanoma in Patient A's right eye, which was diagnosed by a subsequent provider.
15. The appropriate course to take with Patient A, a 99-year old patient, would have been to follow conservatively without surgery.
16. The Respondent performed a surgery that was not necessary.
17. The Respondent's care of Patient A was below the standard of care because he failed to diagnose the choroidal melanoma in Patient A's right eye, and therefore, Patient A underwent an unnecessary surgery.
18. Prior to surgery, the Respondent performed multiple FA tests on Patient A. FA tests are not helpful in diagnosing retinal detachments.
19. The FA tests performed by the Respondent were unnecessary.
20. The Respondent's care of Patient A was below the standard of care because he employed multiple FA tests which are not helpful for diagnosing retinal detachments.
21. The Respondent's care of Patient A was below the standard of care.

Patient B

22. Patient B is a male born in 1938.
23. The Respondent treated Patient B from August 2009 to 2011.
24. In August 2009, Patient B's vision in his left eye was 20/30.
25. In August 2009, the Respondent diagnosed Patient B with an epiretinal membrane.
26. In August 2009, the Respondent performed a vitrectomy, lensectomy and a membrane peel on Patient B's left eye.
27. An FA test done at that time did not show any cystoid macular edema nor did the OCT show any retinal membrane or cystoid macular edema.
28. The Respondent's surgery on Patient B's left eye was not indicated.
29. The Respondent's care of Patient B was not within the standard of care because the Respondent performed surgery for conditions which were not present on tests done before the operation.
30. In November 2009, Patient B's vision in the left eye was 20/50.
31. In 2010, Patient B's vision in the left eye was CF vision.
32. In 2010, the Respondent performed multiple FA tests which were non-diagnostic and not helpful in offering a diagnosis.
33. In September 2011, Patient B underwent another FA test and was instructed to return in six months.
34. In 2012, a subsequent provider diagnosed Patient B with a retinal detachment of the left eye and performed surgery to repair it.

35. The Respondent's care of Patient B was not within the standard of care because the Respondent failed to diagnose a retinal detachment that developed after his surgery.

36. The Respondent's care of Patient B was not within the standard of care.

The Respondent filed his Answer to the Statement of Allegations on February 18, 2015. He admitted to the Allegations stated in paragraphs 1, 7, 8, 11-13, 18, 22-26, 30, 32 and 33. He denied the Allegations set forth in paragraphs 6, 14-17, 19-21, 28-29, 31, 35 and 36. He indicated that he was without sufficient information to admit or deny the Allegations set forth in paragraphs 27 and 34.

The Respondent requested that paragraph 2 be stricken. This request was denied. To the extent that the paragraph was not struck, the Respondent answered further that the record of his Federal District Court sentencing hearing reflects that both the prosecutor and the judge commented on his excellence as a physician. Elaborating on paragraph 3, the Respondent answered that, by adding "one day" to his sentence, Judge William Young made him eligible for "good time" benefits which effectively reduced his sentence by two months. With regard to paragraph 4, the Respondent indicated that he repaid all taxes, interest and penalties prior to sentencing. Regarding the Consent Order referred to in paragraph 5, the Respondent answered that, while he had submitted a timely petition for reinstatement, the BRM deferred consideration pending the resolution of a "statutory report" filed by a group of competitors when he became eligible to return to practice. In further response to the Allegation set forth in paragraph 27, the Respondent admitted that earlier in the month of August 2009 he performed both an FA and OCT to determine the presence of edema in the macular. He indicated that the FA showed the absence of cystoid macular edema and that the OCT showed irregular internal limiting membrane

(i.e. trace macular epi-retinal membrane), which was also identified intraoperatively during the August 20, 2009 procedure. He stated that these tests were performed to determine the presence of any conditions that would require additional pre-operative or intraoperative treatment.

With respect to paragraphs 6-10, the Respondent proffered a brief summary of terms and abbreviations that would be used in this case. I have incorporated both the Glossary of Terms set forth in Appendix A of the Respondent's post-hearing brief and any additional terms from in his Answer as Appendix A to this Recommended Decision for reference purposes. I will not render separate findings of fact on the medical meaning of these terms.

I held a hearing on July 20, 21, 27 and 28, 2015 at the offices of the Division of Administrative Law Appeals, One Congress Street, Boston, MA. The hearing was stenographically recorded. The BRM presented the testimony of the following witnesses: Lisa McLellan, Operations Manager for the Medical Records Department at the Mass. Eye and Ear Infirmary; Donna Mancini, Ophthalmology Imaging System Director at the Mass. Eye and Ear Infirmary; and, Darius Moshfeghi, M.D., the BRM proffered expert in Ophthalmology and Vitreoretinal Disease. The Respondent presented the testimony of Reginald Sanders, M.D., his proffered expert in Ophthalmology; Rhonda Zucco, keeper of the medical records in the Winchester, MA office of Kailenn Tsao, M.D.; and Marian Ead, Clinical Investigator for the BRM. The Respondent, Mark Hughes, M.D. also testified in his own behalf. Twenty-eight (28) exhibits were marked over the course of the four-day hearing.

The record was left open for the filing by the parties of Proposed Findings of fact and Conclusions of Law. The last of the submissions was received by the Division of Administrative Law Appeals on December 3, 2015 thereby closing the record.

FINDINGS OF FACT

Based upon the testimony and exhibits presented at the hearing in the above-entitled matter, I hereby render the following findings of fact:

1. The Respondent was born on January 26, 1961. He graduated from Harvard Medical School in 1986. He has been licensed to practice medicine in Massachusetts under certificate number 72171 since 1990. He is certified by the American Board of Ophthalmology.
2. On July 18, 2011, the Respondent plead guilty in the United States District Court, District of Massachusetts, to one charge of tax evasion and one charge of obstruction of a tax audit.
3. The Respondent was sentenced to a year and a day in prison, followed by a period of supervised release with special conditions for two years. He was also fined \$60,000.
4. The Respondent has paid all unpaid income taxes, penalties and interest.
5. On January 4, 2012, the Respondent entered into a Consent Order and the Board suspended the Respondent's license to practice medicine with leave to Petitioner for a stay of the suspension after one year. *See in the Matter of Mark Hughes, M.D.* Adjudicatory No. 2012-001 (Consent Order, January 4, 2012).
6. The Respondent began treating Patient A, a 99 year old female, on June 7, 2010. Prior to this visit, Patient A had undergone cataract surgery. (Exhibit 2.)

7. On June 7, 2010, Patient A presented with a 6 month history of declining vision in both eyes and, based on OCT and FA testing, the Respondent determined that she had significant AMD in both eyes including an active leak (i.e. "wet" AMD) in her left eye. (Exhibits 2, 15 and 27, Sanders Testimony, Hughes Testimony.)

8. With injections of Avastin, the Respondent was able to stabilize Patient A's condition over the next several months in order to curb the leaking and remove the fluid in the left eye. (*Id.*)

9. In September 2010, the Respondent again performed OCT and FA testing and determined that the fluid in Patient A's left eye had halted. (*Id.*)

10. In November 2010, the Respondent referred Patient A to a low vision specialist for assistance with devices to help her get the best use of whatever limited remaining vision she had. (*Id.*)

11. A retinal detachment exists when "the retina is separated from the eye wall and the underlying retinal pigment epithelium." There are three types of retinal detachments: exudative, rhegmatogenous, and tractional. (Moshfeghi Testimony, Sanders Testimony, Hughes Testimony and Exhibits 10 and 15.)

12. An exudative retinal detachment is a "swelling detachment." With an exudative retinal detachment, fluid is leaking not because there is a hole in the retina, but because there is another cause of the leakage. When a retinal detachment is exudative, the physician must "identify the cause and...treat the underlying cause." Typically, the underlying cause is inflammation or a tumor. If there is swelling or an exudative detachment, there will be no hole or tear. This is the least common type of retinal detachment. It is the result of fluid being generated under the retina and pushing it off.

Exudative detachments account for less than 1% of all detachments, and within that 1%, approximately .01% at most are caused by tumors. (*Id.* and Exhibits 15-18.)

13. A rhegmatogenous retinal detachment involves a hole or tear(s) in the retina.

This is the most common type of retinal detachment and accounts for approximately 90% of all retinal detachments. (*Id.*)

14. A retinal detachment with choroidal fluid does not necessary mean that it is an exudative retinal detachment. In rhegmatogenous detachments, fluid from the inside of the eye leaks through the breaks in the retina. (Sanders Testimony and Exhibits 15-18.)

15. Tractional retinal detachments are typically the result of scar tissue pulling on the retina and are generally caused by diabetes. (Sanders Testimony.)

16. Patient A returned to the Respondent on April 22, 2011. Her complaint that day was declining vision. The Respondent performed an FA test on that day and determined that there was no active leaking in either of the patient's eyes. (Exhibit 2.)

17. Upon further examination of Patient A, the Respondent identified a retinal detachment in her right eye. Because he did not identify a hole or tear in the retina at that time, he suspected it could be an exudative, rather than a rhegmatogenous detachment. (*Id.* and Hughes Testimony.)

18. The Respondent's clinical examination of Patient A on April 22, 2011 also revealed the presence of a choroidal in her right eye. The Respondent confirmed the presence of the choroidal with a B-scan, and noted that there was fluid, but no mass, under the detachment. (*Id.*)

19. In his electronically signed medical notes pertaining to this visit, the Respondent wrote in the Attending Assessment and Plan section, "NEW EXUDATIVE RD" right eye. It was also noted that there were no holes or tears in the retina. (Exhibit 2.)
20. The B-scan or ultrasound findings in the same note state that Patient A has an "EXUDATIVE" retinal detachment and that there was bullous inferior which was likely resultant from the exudative retinal detachment. (*Id.*)
21. Also on April 22, 2011, the Respondent noted that Patient A had a "Retinal detachment OD, question choroidal effusion OD." A choroidal effusion is "[s]welling in that blood vessel layer that is under the retinal pigment epithelium and under the retina." There is no mention in the April 22, 2011 note that Patient A had a rhegmatogenous retinal detachment. (*Id.*, Exhibit 10 and Moshfeghi Testimony.)
22. The Respondent decided to observe Patient A's condition and scheduled her to return in two weeks. (*Id.* and Hughes Testimony.)
23. Patient A returned to see the Respondent on May 6, 2011 at which time he examined her and performed another B-scan. He determined that the choroidal appeared to be smaller than at the April 22, 2011 visit. He also noted that there was "no mass" visible within her eye. (Exhibit 2.)
24. The May 6, 2011 B-scan also revealed a vitreous hemorrhage in Patient A's right eye. A vitreous hemorrhage is consistent with a peripheral break that may or may not be seen directly. Together with the shrinking of Patient A's choroidal and the finding that there was no mass, the presence of the vitreous hemorrhage caused the Respondent to change his diagnosis of Patient A's retinal detachment to rhegmatogenous. (*Id.*, Sanders Testimony, Hughes Testimony.)

25. In his electronically signed medical note regarding the May 6, 2011 visit with Patient A, he indicated "NO HOLES OR TEARS." Under the Attending Assessment and Plan, he noted "EXUDATIVE" retinal detachment in the right eye. He did not indicate in his medical note on May 6, 2011 that Patient A had a rhegmatogenous retinal detachment. (Exhibit 2.)

26. On the B-Scan interpretation form, the Respondent noted "RD" with a "∞" at a diagonal slant inside of a circle to the left of the letters. (*Id.*)

27. The sonograms from May 6, 2011 indicate that Patient A had a lesion and a retinal detachment. (*Id.*)

28. The Respondent saw Patient A again on May 20, 2011 and again noted that she did not have any holes or tears in the retina. He diagnosed her with a retinal detachment in the right eye. (Exhibit 2.)

29. Also on May 20, 2011, the Respondent wrote a letter to Dr. David Criss wherein he indicated that Patient A had a "new retinal detachment" in the right eye and was "a candidate for a surgical repair for retinal detachment in the right eye." At that time, the Respondent began arrangements for the surgical repair of Patient A's retinal detachment. (*Id.* and Hughes Testimony.)

30. The planning of the surgical procedure is proof of the Respondent's diagnosis of a rhegmatogenous detachment because exudative detachments are not surgically repaired. (Hughes Testimony, Sanders Testimony.)

31. The Respondent saw Patient A again on June 28, 2011 and again noted that there were no holes or tears in her retina. He performed a third B-scan which confirmed that

no mass was present. He again diagnosed her with a retinal detachment and a serous choroidal. (Exhibit 2, Moshfeghi Testimony and Hughes Testimony.)

32. When a patient suffers from a rhegmatogenous detachment, it is the standard of care to perform a vitrectomy to reattach the retina. (Hughes Testimony, Sanders Testimony.)

33. On June 30, 2011, the Respondent performed a vitrectomy on Patient A's right eye to repair a rhegmatogenous retinal detachment. The operative report identified the detachment as such. In his notes from the surgery, he wrote "good cryo takes", which reflects that he located holes or tears in Patient A's retina and was able to repair them. (Exhibit 2 and Hughes Testimony.)

34. The operative note does not mention the location of any hole(s) that may have been surgically repaired. (Exhibit 2 and Moshfeghi Testimony.)

35. Post-operatively, Patient A had ten more visits with the Respondent during which time she remained stable. During the post-operative period, the Respondent continued to monitor the choroidal in Patient A's eye. During the time Patient A remained in his care, the retina in her right eye remained attached. (Exhibit 2 and Hughes Testimony.)

36. Patient A had no medical history of cancer. (Exhibit 2 and Moshfeghi Testimony.)

37. In the record of a December 6, 2011 visit with Patient A, the Respondent noted that the choroidal lesion was stable. In his assessment, he indicated that the lesion may have been a melanoma. (Exhibit 2.)

38. Subsequent providers also noted the possibility of a melanoma/lesion and documented a clear plan for treating Patient A. The treatment agreed upon by Dr. Leo A.

Kim, Patient A, and her daughter was monitoring of the melanoma. This falls within the standard of care. (*Id.*)

39. Patient B is a male born in 1938. (Exhibit 3.)

40. In March 2007, Dr. Kimberly McNulty performed a cataract procedure on Patient B's left eye that resulted in complications of retained lens fragments. The retained lens fragments caused "floaters" (small, moving spots in the field of vision), blurred vision and problems with night vision. Patient B complained to Dr. McNulty about these problems over the course of two years after his cataract surgery. (*Id.*)

41. In July 2009, Dr. McNulty referred Patient B to the Respondent for a vitrectomy to address the retained lens fragments, floaters and blurred vision. (*Id.*)

42. The Respondent first examined Patient B on August 3, 2009. With the aid of a slit lamp biomicroscopy, a dilated fundus examination and an FA test, the Respondent noted "inflammatory debris" in Patient B's left eye. He also noted that Patient B had a cataract developing in his right eye. (*Id.*)

43. Through this and other testing, the Respondent also identified trace cellophane maculopathy, or "epiretinal membrane" in both of Patient B's eyes. He determined that the retained lens fragments were a cause of Patient B's symptomatic floaters. (*Id.*)

44. Patient B was clear that he did not want to have cataract surgery in his right eye until the vision symptoms he was suffering in the left eye were corrected. (*Id.* and Hughes Testimony.)

45. Patient B had 20/25 vision in the left eye on August 3, 2009. This means that he had good vision. There were no issues with the interocular pressure of Patient B's eye and his ocular nerve appeared to be normal. Additionally, he was at low risk for

glaucoma and was experiencing no inflammation in the eye. (Exhibit 3 and Moshfeghi Testimony.)

46. On August 14, 2009, the Respondent noted that OCT images of Patient B's left eye showed normal findings. He also noted that Patient B's vision in the left eye was 20/30. He found the cornea to be clear, the anterior chamber to be deep and quiet and no neovascularization. Patient B was scheduled for surgery. (Exhibit 3.)

47. On August 20, 2009, the Respondent performed a vitrectomy with a lensectomy (removal of retained lens fragments) on Patient B's left eye without complication. At the same time, he performed a membrane peel to address the epiretinal membrane in the left eye. In his operative note, he identified "vitreous floaters" as one of the three pre-operative diagnoses. (*Id.* and Hughes Testimony.)

48. Seventy per cent (70%) of retinal surgeons perform vitrectomies to remove floaters. (Sanders Testimony.)

49. The outcome of the surgery on August 20, 2009 was good and Patient B was happy with the improvement in his vision. (Exhibit 3 and Hughes Testimony.)

50. In anticipation of serving his prison sentence and refraining from the practice of medicine for one year, on November 23, 2011, the Respondent entered in to an Asset Purchase Agreement on behalf of his professional corporation, Vitreal Retinal Associates. He conveyed a large percentage of his practice to Massachusetts Eye and Ear Associates, Inc. (MEEA). The asset purchase was effectuated on December 21, 2011. (Exhibits 8 and 24.)

51. In December 2011 following his guilty plea in the United States District Court and subsequent sentencing, the Respondent entered into Consent Order with the BRM

which required that he be out of the practice of medicine for one year. His intention was to return to the practice of medicine in Brookline, MA with his wife, Delia N. Sang, M.D. at the end of the one year hiatus and upon approval by the BRM. (Exhibit 20 and Hughes Testimony.)

52. On February 12, 2013, the Respondent, through counsel, filed his Petition to Lift the Suspension. (Exhibit 21.)

53. In a letter dated January 25, 2013 to Edith Rathbone, Data Repository Counsel at the BRM, Attorney Michael Kendall of McDermott, Will & Emery indicated that he was writing on behalf of his clients, Mass. Eye and Ear Associates, Inc.(MEAA) and certain of its physicians, whom he identified only as health care providers under G.L. c. 111, §1, in order to express their certain concerns regarding the Respondent pursuant to the reporting requirements of G.L. c. 112, § 5F¹ and 243 CMR 1.03 (5)(a). Mr. Kendall indicated that his clients had begun to treat many of the Respondent's former patients and wished to report the following areas of concern to the BRM: misdiagnoses; over prescription of Bromday; overuse and misuse of FA testing; overuse of OCT scans; and, potential improper billing for services. (Exhibit 24.)

54. The BRM deferred any decision on the Respondent's Petition to Lift the Suspension until the issues raised in the January 25, 2013 letter were resolved. (Statement of Allegations.)

55. Through a subpoena and a series of back and forth letters, Mr. Kendall submitted medical records ostensibly supporting the MEEA allegations to the BRM. (Exhibits 1, 22 and 23.)

¹ G.L. 112, § 5F: Any health care provider, as defined in section one of chapter one hundred and eleven, shall report to the board any person who there is reasonable basis to believe is in violation of section five, or any of the regulations of the board, except as otherwise prohibited by law.

56. Marian Ead, a clinical investigator with 34 years of clinical nursing experience, was assigned as the investigator of this matter for the BRM. She engaged the services of the BRM's initial expert, Dr. Kenneth Diddle, who found a basis to challenge the Respondent's care of eleven patients.

57. The investigation culminated in the December 18, 2014 Statement of Allegations. (Ead Testimony.)

58. After the Respondent filed his Answer to the Statement of Allegations, Dr. Diddle refused to testify. (Eads Testimony.)

59. The BRM hired a new expert, Darius Moshfeghi, M.D. who narrowed the case to Patients A and B. (*Id.*)

CONCLUSIONS AND RECOMMENDED DECISION

The BRM has the burden of establishing the allegations set forth in the Statement of Allegations by a preponderance of the evidence. *Craven v. State Ethics Commission*, 390 Mass. 191 (1983). In order to meet this burden, the BRM must produce sufficient evidence that "it is made to appear more likely or probable-in the sense that actual belief in its truth, derived from the evidence, exists in the mind or minds of the tribunal, notwithstanding any doubt that may linger there." *Sargent v. Massachusetts Accident Co.*, 307 Mass. 246 (1940). A fact is proved by a preponderance of the evidence if the tribunal has "a firm and abiding conviction in the truth of" the proposition advanced by the Board. *Stepakoff v. Kantar*, 393 Mass. 836 (1985.)

After a thorough review of all of the evidence in this case, I have concluded that the BRM has not met its burden of proving by a preponderance of the evidence the assertions in the Statement of Allegations that the Respondent's treatment of either

Patient A or B was below the standard of care. Accordingly, the BRM has not proven that the Respondent violated several of the statutory and regulatory sections cited in the Statement of Allegations.

I have reached this conclusion without discrediting the BRM's expert, Daruis Moshfeghi, M.D. He is eminently qualified in his field and he provided a lucid expert opinion on the Respondent's treatment of Patients A and B. He did modify some of his testimony on cross examination and he also admitted that the charts and test results in the record were not all that clear in his eyes. He was also confused as to which of Patient A's eyes certain test results pertained. However, these are not the reasons that I fail to adopt his conclusions.

The standard of care is the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession." *Brune v. Belnikoff*, 354 Mass. 102, 109 (1968). The standard of care is the level of care and skill that is commonly possessed by other physicians in the same specialty. *Palandjian v. Foster*, 446 Mass. 100, 105 (2006).

The standard of care leaves room for physicians to make reasonable choices between alternative treatment approaches. *Barret v. Hight*, 353 Mass. 268 (1967). A physician's choice may be within a reasonable range of medical judgment. (*Id.* at 276). I believe that the three physicians who testified during the hearing in this case all thoroughly reviewed (and/or were aware of) the treatment records of Patients A and B; and, that each testified after his assessment of either the clinical presentations of the two patients or the clinical findings and tests themselves and rendered opinions and conclusions after employing their best professional and clinical judgment.

Both Drs. Sanders and Hughes, the Respondent in this case, are also eminently qualified. Their testimony was credible, explicit and lucid as well. The argument by the BRM that, due to his conviction for tax evasion, the Respondent cannot be considered a credible witness, is without merit. This argument is predicated upon a quantum leap of logic and belies the proven fact that no professional complaints have been filed against the Respondent throughout his career. His testimony was confined to his professional experience and his treatment of Patients A and B. I have credited his testimony in this case. Therefore, I simply cannot conclude, that by a preponderance of the evidence, Dr. Moshfeghi's testimony should carry the day. Ergo, I am compelled to find that the BRM did not support its Statement of Allegations.

Patient A

When Patient a first saw the Respondent in June 2010, she complained of declining vision in both eyes. The Respondent performed a clinical examination and administered diagnostic testing. Both the OCT and FA tests led him to diagnose her with age related macular degeneration (AMD) in both eyes. Based upon the FA results, he was able to determine that the AMD in the left eye was wet and that the eye was actively leaking. All of the physician witnesses at the hearing agreed that FA tests are the definitive diagnostic tool for diagnosing and evaluating AMD activity. The Respondent conducted regular FA testing in order to monitor the wet AMD until the leaking stopped. He also administered the Avastin injections. Thus, while FA tests may not be helpful in diagnosing retinal detachments, the Allegation set forth in paragraphs 19 and 20 that the FA tests were unnecessary are patently false.

When Patient A returned to see the Respondent in April 2011 with complaints of deteriorating vision in both eyes, the Respondent again performed an FA test in order to ascertain whether her eye was leaking again. After doing so, he was able to rule out active leakage. The FA test at that time assisted him in his approach. After performing the test, the Respondent examined Patient A with a 20 diopter lens. He identified a retinal detachment in the right eye. Because this initial examination showed no hole or tear in the retina along with the presence of a choroidal, his initial diagnosis was an exudative retinal detachment, the result of fluid beneath the detachment. He noted unequivocally that there was no mass or tumor present. Dr. Sanders confirmed that the B-scan did not reveal a mass or tumor.

The Respondent chose a "wait and see" approach and followed up with Patient A in two weeks. On May 6, 2011, the Respondent noted that the choroidal looked less than it had during the previous visit. However, the B-scan revealed a vitreous hemorrhage, a finding consistent with a peripheral break, or rhegmatogenous retinal detachment.

The choroidal did not increase in size throughout the remainder of the Respondent's active treatment of Patient A. The decrease in size between April 22 and May 6, 2011 supports the notion that it was not a melanoma or a mass at that time. The diagnostic studies do not support this conclusion, either. Further, Patient A had no medical history of cancer. Accordingly, the BRM has not proven that the Respondent failed to diagnose a growing, non-pigmented tumor. Further, there is no evidence that his not rendering this diagnosis prior to the June 2011 surgery was below the standard of care or that the surgery was unnecessary.

It necessarily follows, then, that there is no proof in the record, beyond the Respondent's initial suspicion, that Patient A had an exudative retinal detachment in her eye and that the vitrectomy was unnecessary. A vitrectomy is the correct approach to repair a rhegmatogenous retinal detachment, which was the Respondent's actual diagnosis. The Respondent determined that the fluid in Patient A's eye was leaking through a break and he made arrangements for her to undergo surgery and noted "RD" in his handwritten notes.

The retinal detachment was ultimately repaired in late June 2011, and Patient A's retina remained attached. Thus, the vitrectomy achieved its objective of repairing the tears and there was no growing tumor at that time which forced the retina to detach. The BRM has failed to prove the Allegation set forth in paragraphs 16 and 17 that the surgery was unnecessary.

There were no real issues raised regarding the September 2011 visit between the Respondent and Patient A. At their December 2011 visit, the Respondent revisited the question of whether the choroidal, which had remained stable, could "perhaps" be a melanoma. No definitive diagnosis was rendered.

The next visit noted in the record was between with Dr. Leo Kim and Patient A in February 2012. Dr. Kim did not diagnose a melanoma, but rather a "possible melanoma" at that time.

One month later, on March 13, 2012, Dr. Gragoudas noted that the choroidal "most likely represents a melanoma." This is an equivocal finding and not a definitive diagnosis.

As such, no definitive diagnosis of melanoma was ever rendered from the time the Respondent stopped treating Patient A through March 2012 at the earliest. The record is void of any medical notes beyond that point in time. It should also be noted that, nearly a year following the successful vitrectomy, there was no definitive diagnosis of a melanoma.

If any criticism can be levied against the Respondent pertaining to his treatment of Patient A, it is in the failure to correct the electronic records which, following the two May 2011 visits, continued to reflect the diagnosis of exudative retinal detachment notwithstanding the diagnostic evidence and the course of treatment that was chosen. In a perfect world, he should have modified the electronic record or made a new electronic record on May 6, 2011 to reflect the diagnosis of rhegmatogenous retinal detachment. Carry-over electronic medical records may contain errors ranging in severity from typographical to substantive. All records should be sufficiently detailed to reveal the doctor's clinical reasoning with lucidity.

The Respondent's somewhat deficient record keeping practices arguably may have violated 243 CMR 2.07(13)(a) which provides that a physician must maintain a medical record for each patient which is adequate to enable the licensee to render a proper diagnosis and treatment; or maintain a patient's medical record in a manner that permits the former patient or successor physician access to and insight into them. This is the primary reason for the Allegations against the Respondent regarding his treatment of Patient A. That being said, the Respondent is not subject to discipline for these violations because they were not specifically alleged in the Statement of Allegations. The BRM's ability to sanction him is limited to its ability to prove the allegations set forth therein and

not raised for the first time during the hearing. See *D'Armor v. Board of Registration in Dentistry*, 409 Mass. 572 (1990). For this reason, no discussion of any differences in the Respondent's notations in the records of Patients D and J is warranted here. Further, the BRM moved to dismiss the allegations pertaining to all of those patients, and the motion was allowed.

Patient B

Patient B was referred to the Respondent after long-time complaints of floaters that had bothered him for two years following cataract surgery. He was referred to the Respondent to undergo a vitrectomy. During their first visit in early August 2009, the Respondent diagnosed Patient B with an epiretinal membrane. According to the testimony of Drs. Sanders and Hughes and reflected in the ASRS PAT Surveys in the record, 70% of retinal specialists would have performed a vitrectomy on that basis alone. The vitrectomy procedure is within the standard of care when addressing the problem of troublesome floaters.

While it may have been too late for the removal of lens fragments, the floaters were surgically removable, and many were removed during the procedure. More importantly, Patient B participated in his own health care decision and was ultimately satisfied with the improvement in his vision.

At their initial visit in early August 2009, the Respondent also diagnosed epiretinal membrane in each of Patient B's eyes. This is scar tissue that can cause a distortion of a patient's vision. Accordingly, during the same August 20, 2009 procedure, he also performed a membrane peel to address the epiretinal membrane in

Patient B's left eye. To reiterate, Patient B was pleased with the positive changes in his vision following the August 20, 2009 surgery.

Statutory Report

The challenges to the Respondent's treatment of Patients A, B, and others came to the attention of the BRM through a purported "statutory report" from Attorney Kendall and his clients, MEEA and individual physicians. To begin with, given the evidence proffered in this case and the applicable law, these observations may be tantamount to nothing more than differing opinions of competent physicians in the field of ophthalmology. Similar to those that fall within the standard of care cases cited previously herein.

I find the Respondent's argument regarding the illegality of the "statutory report" persuasive. G.L. c. 112, § 5F calls for the report of a medical provider(s). In this case, Attorney Kendall registered the concerns regarding the Respondent and failed to name the individual complaining physicians. As such, this is not a bona fide statutory report. I reach this conclusion without assessing this issue of timeliness of the filing since I have been unable to locate, and have not been cited, any regulation dealing with the mandatory time frame for filing a statutory report pursuant to G.L. c. 112, § 5F.

Nonetheless, as the BRM aptly noted, the Statement of Allegations was based upon the BRM's investigation and the feedback from Drs. Diddie and Moshfeghi. Based upon the BRM's assertions in the Statement of Allegations and, the evidence presented

during the summer 2015 hearing in this case, I conclude, for reasons previously set forth, that the BRM has not met its burden of proving that the Respondent rendered substandard care to or performed unnecessary tests and/or surgery on Patients A and B.

DIVISION OF ADMINISTRATIVE LAW APPEALS:

By:



Judithann Burke
Administrative Magistrate

DATED: March ~~30~~, 2016

APPENDIX A GLOSSARY OF TERMS

Age-related Macular Degeneration (AMD): A “bilateral disease” of the eye that presents a risk of deteriorating vision in both eyes. AMD can either be dry or wet. If there is active leaking, it is called “wet” AMD, otherwise, it is called “dry.” Sanders, Vol. III at 345-46.

Amelanotic: Describes a non-pigmented melanoma. They represent only about 15% of choroidal melanomas. Moshfeghi Vol. II at 262, lines 18-22; 265, lines 7 and 24.

Anti-VEGF: Drugs used to block VEGF (vascular endothelial growth factor), including Macugen (Partial), Lucentis, Avastin, and Eyelea. Respondent’s Answer

ANCHOR: Anti vascular endothelial growth factor (VEGF) antibody for the treatment of predominantly classic choroidal neovascularization (CNV) in Age-related Macular Degeneration. *Id.*

ASRS PAT Survey: An annual survey released by the American Society of Retina Specialists (ASRS) regarding clinician’s Preferences and Trends (PAT). Since 1999, the PAT Survey has provided a yearly snapshot of ASRS members’ practice patterns and retina treatment choices. The ASRS is the largest retinal organization in the world, representing over 2700 members in all 50 US states, the District of Columbia, Puerto Rico, and 59 countries. (American Society of Retina Specialists.)

Avastin: Medication that is injected into the eye to treat Wet AMD. Avastin injections are accepted as the standard for treating Wet AMD. Sanders, Vol. iii at 341, lines 18-19.

Choroid: The “vascular tissue” in the back of the eye that provides the blood supply and other important nutrients to parts of the retina Sanders, Vol. III at 352, lines 4-7 and illustrations offered as Exhibits 17 and 18.

Choroidal: A “bump, an elevation and the wall of the eye...sort of like a blister if you will. Hughes, Vol. IV at 557, lines 13-16.

Serous Choroidal: A choroidal elevation that has fluid underneath it.” A serous choroidal can look like a mass or tumor, but it is distinguished by darker acoustical reflectivity on ultrasound examination. Sanders, Vol. III at 355, lines 11-12; Hughes, Vol. IV at 562, lines 9-19.

Choroidal Excavation: Choroidal excavation appears as a “shadow or an echo” in an ultrasound where the “mass...reduces the sound wave image from the choroidal layer.” Hughes, Vol. IV at 565. It is among the “characteristic findings” for melanoma. *Id.*

Choroidal neovascularization (CNV): Subretinal neovascularization (SRNV)
Respondent’s Answer

Cryopexy/Cryotherapy: Cryopexy stimulates scar formation, sealing the edges of a retinal tear. In the event of a retinal detachment, the irritated tissue forms a scar, which brings the retina back into contact with the tissue underneath it. It is a repair procedure by which the cryopexy “acts like glue” to reattach the retina. Sanders, Vol. III at 404, lines 15-19.

Cystoid Macular Edema (CME): A painless disorder which affects the central retina or macula, where multiple cyst-like areas of fluid appear in the macula and cause retinal swelling. It is “sometimes seen with inflammation or after cataract surgery.” Sanders, Vol. III at 431, lines 7-10.

Differential Diagnosis: The list of diagnoses that a patient may have. Hughes, Vol. IV, at 622.

Epiretinal Membrane (ERM): “Scar tissue over the macula” that can “cause distortion of vision.” Also known as “macular pucker” or “trace cellophane maculopathy.” Sanders, Vol. III at 429, lines 14-16; Hughes, Vol. IV at 598, lines 18-22.

Floaters: A “very common” visual symptom typically manifested as “little black spots [or] cobwebs.” Floaters can occur from many different etiologies, including retained lens material post-cataract surgery and debris from vitreous detachments. Most of the time, floaters are benign but can occasionally “become very bothersome,” requiring surgical intervention. Sanders, Vol. III at 423-25.

Fluorescein Angiography (FA): This is a diagnostic study performed by a technician who takes digital pictures of the eye that are stored electronically in a computer. At a physician’s discretion, select images are aggregated on a contact sheet. Due to the curvature of the retina, FA images cannot capture the periphery of the eye. Sanders Testimony, Vol. III at 359, line 5, 360, line 3.

Fundus Photography: Typically part of an FA test, but prior to the injection of fluorescein dye, fundus photography uses colored filters to document the retina, with the pupil used as both an entrance and an exit for the fundus camera’s illuminating and imaging light rays. Ophthalmologists use these retinal photographs to follow, diagnose, and treat eye diseases.

Contact Sheet: A printed sheet containing a subset of color fundus and FA images, selected generally by the technician. In some cases, however, physicians will “direct the technician which ones to put on the contact sheets.” Only a “minority” of FA images are printed to a contact sheet. Sanders, Vol. III at 360, lines 19-24.

Lensectomy: A procedure that usually involves the partial or total removal of the vitreous gell. The procedure can also involve the removal of cortical lens material retained in the vitreous cavity after cataract surgery. Sanders, Vol. III at 431, lines 19-21.

Lesion: A generalized term for an abnormal change in structure of an organ or part due to injury or disease. (Merriam-Webster.com)

Macula: A "small...specialized part of the retina" that contains 95 percent of one's vision. Sanders, Vol. III at 368, lines 2-12. It is an oval-shaped, pigmented area near the center of the retina with a diameter of approximately 5.5 millimeters. (Exhibit 17.)

Mass: A growth of tissue which may or may not be malignant and appears white or grey on an ultrasound. Sanders, Vol. III at 353, lines 4-15.

Melanoma: A cancerous mass or tumor. In this case, a choroidal melanoma is the most common primary intraocular (occurring inside the eye) tumor in adults. Choroidal melanomas are "solid, meaty pieces of tissue" typically observed via a high-reflectivity acoustic response during an ultrasound examination, contrasted with the dissimilar ultrasound echo of fluid-based swelling. Hughes, Volume. IV at 562. Choroidal melanomas are extremely rare and total incidence rate in the United States is about 2000 per year. Moshfeghi, Vol II at 265, lines 18-23.

Metastatic: A descriptor of cancerous tumors that are the result of spreading from malignant tumors in other parts of the body.

OD: Oculus Dexter, referring to the right eye

Optical Coherence Tomography (OCT): A technique used for capturing high-resolution cross-sectional imaging. OCT is analogous to ultrasound imaging, except that it uses light instead of sound. OCT can provide cross-sectional images of tissue structure on the micron scale in position and real time. (National Institute of Health.)

OS: Oculus Sinister, referring to the left eye.

OU: Oculus Uterque, referring to both eyes.

Retina: The retinal is a thin layer of tissue that lines the inside of the back of the eye. It is located near the optic nerve. The purpose of the retina is to receive light that the lens has focused; convert that light into neural signals, and send these signals to the brain for visual recognition. Moshfeghi, Vol. I at 124 line 24 and 125 line 2; Sanders, Vol. III at 351, lines 20-24; Exhibits 17 and 18.)

Ultrasound/B-scan: A test employed by ophthalmologists, retina specialists and technicians that uses high-frequency sound waves to get measurements and produce detailed images of the eye. Ultrasounds provide a much more detailed view of the inside of the eye than is possible during a routine eye exam. The B-scan allows the physician to

see clearly into the back of the eye. Sanders at 349, lines 5-13; Hughes at 562, lines 10-22.

Visual Acuity: A quantitative measure of a patient's sharpness or clarity of vision, measured by the ability to discern letters or numbers at a given distance according to a fixed standard. Visual acuity is typically measured while fixating, i.e. as a measure of central vision.

Vitrectomy: A surgical procedure involving the removal of some or all of the vitreous from the eye. Vitrectomies are typically used to address the more serious retinal detachments, and increasingly, in recent years, to treat patients suffering from symptomatic floaters. Sanders, Volume III at 424, line 14, 425, line 4.

Vitreous Debris: A term for a variety of debris and materials located in the vitreous of the eye. Two common causes of vitreous debris are retained cortical lens material after cataract surgery and detachments of the vitreous from the wall of the eye, which occurs as part of the normal aging process. Sanders, Vol. III at 426-427.

Vitreous Gell: The "clear substance in the back of the eye" that fills the space between the lens and the retina of the eye. As humans age, the vitreous jell shrinks and can detach from the wall of the eye, resulting in a vitreous detachment. Sanders, Vol. III at 426, lines 20-24.

Vitreous Hemorrhage: The leakage of blood into the areas in and around the vitreous. Among several causes, a tear in the retina can allow fluids from the eye to leak in behind the retina, which may cause retinal detachment. Hughes, Vol. IV at 568, line 6 and 569, line 2.