

COMMONWEALTH OF MASSACHUSETTS

Suffolk, ss.

Division of Administrative Law Appeals

Board of Registration in Medicine,
Petitioner

v.

Docket No. RM-13-184

Date:

John C. Clapp, M.D.,
Respondent

Appearance for Petitioner:

Gloria Brooks, Esq.
Board of Registration in Medicine
200 Harvard Mill Square, Suite 330
Wakefield, MA 01880

Appearance for Respondent:

James A. Bello, Esq.
Morrison Mahoney, LLP
250 Summer Street
Boston, MA 02210

Administrative Magistrate:

Sarah H. Luick, Esq.

Summary of Recommended Decision

Petitioner has met its burden of showing by a preponderance of the evidence that Respondent, under the particular circumstances found concerning Pt. A, engaged in misconduct in violation of the standard of care of a primary care physician by not timely informing Patient A of the adverse results of his PSA ("prostate-specific antigen") test.

RECOMMENDED DECISION

On February 20, 2013, the Petitioner, the Board of Registration in Medicine ("BORM"), issued a Statement of Allegations ordering the Respondent, John C. Clapp, M.D., to show cause why he should not be disciplined based on misconduct in failing to timely notify Patient A ("Pt. A") of his elevated PSA test result while serving as Pt. A's primary care physician ("PCP"). (Ex. A.) Dr. Clapp answered the Statement of Allegations on or about March 12, 2013, denying

he violated the standard of care in addressing with Pt. A his elevated PSA test result. (Ex. B.)¹

On February 20, 2013, the Petitioner referred the matter to the Division of Administrative Law Appeals ("DALA") for an adjudicatory hearing. (Ex. A.) Following pre-hearing conferences on June 25 and September 30, 2013, a hearing was held on December 13 and 20, 2013, at the DALA offices, One Congress Street, 11th floor, Boston, MA 02114. The hearing was transcribed. The Respondent presented a Motion in Limine to exclude evidence relating to his previous 2006 Consent Order. This Motion was denied the first day of hearing.² Various documents are in evidence. (Exs. 1 - 8.)

The Petitioner presented the testimony of the Respondent, Dr. Clapp, and of its expert witness, Dr. Norman Weinberg. The Respondent also testified on his own behalf with cross examination by the Petitioner, and presented the testimony of his expert, Dr. David August. Both parties made opening statements and filed post-hearing briefs by March 31, 2014 when the record closed. (Exs. C & D.)

FINDINGS OF FACT

These findings are based on the documentary and testimonial evidence presented at the hearing, and the reasonable inferences drawn therefrom.

1. John C. Clapp, MD graduated from medical school in 1969. He did a residency at Roosevelt Hospital, New York City, and a fellowship in cardiovascular medicine in the cardiac catheterization laboratory at the Tufts New England Medical Center, Boston. He has been licensed to practice in Massachusetts under certificate number 35028 since September 30, 1972. He is board-certified in internal medicine and in cardiovascular disease. He had an active private

¹ When the Statement of Allegations was issued on December 1, 2010, the Petitioner ordered the use of a pseudonym for the patient's name. (Ex. A, impounded document.) All documents in evidence, the filings made in the case, and the hearing transcript have redacted the name of the patient and refer to him as Pt. A. (Ex. A.)

² The Consent Order was allowed in evidence but not to re-open any findings made in it.

practice as a PCP from 1974-2008. He has also had a private practice in cardiovascular medicine from 1974. He has practiced hospital internal medicine-critical care medicine from 1974-2003. He has been on the staff of Beverly Hospital in Beverly, MA. He has served as a consultant on staff with the North Shore Medical Center in Salem, MA. (Exs. 2 & 4. Testimony of Dr. Clapp.)

2. Dr. Clapp entered into a Consent Order in March 2006 that resolved his case before the BORM, No. 2006-014. The Consent Order involved his PCP practice and a long time patient. While in Dr. Clapp's care, the patient had PSA test results as follows: 1992 (1.9 ng/lm), 1993 (1.4 ng/lm), 1994 (2.1 ng/lm), 1995 (2.8 ng/lm), 1996 (3.5 ng/lm), 1997 (3.9 ng/lm), 1999 (7.2 ng/lm), and 2000 (12.1 ng/lm). These results showed some "serial increases." Starting in 1997, this patient was seen by Dr. Clapp's nurse practitioner working under his supervision. "Dr. Clapp did not advise ... [this patient] of his elevated PSA or refer him to a urologist until March of 2000, when the PSA level was 12.1." A subsequent biopsy of the patient's prostate showed cancer that led to the patient undergoing prostate removal, bilateral lymph node resection, and radiation treatment. Under the terms of the Consent Order, Dr. Clapp received a reprimand for violating G. L. c. 112, § 5(c) and 243 CMR 1.03(5)(a)(3) by engaging in conduct calling into question his competence to practice medicine, including negligence on more than one occasion with his patient. (Ex. 2.)

3. Pt. A, born in 1950, began treating with Dr. Clapp as his PCP with his first visit on November 10, 2003. Dr. Clapp performed a physical examination, a review of systems, took a medical, social, and family history, and discussed with Pt. A his health profile, his work, and learned what medications he was taking. At this time, Pt. A was taking Lisinopril 10 mg., a hypertension medication. As a result of this visit, Dr. Clapp concluded that Pt. A would likely benefit from an increase in his Lisinopril dosage and prescribed that medication at 20 mg. This

was still a moderate level dosage for Pt. A. Dr. Clapp also issued a requisition to Pt. A for lab work, including for an echocardiogram that was set up to be done on November 26, 2003. Pt. A was also referred to a specialist for setting up a colonoscopy screen test. He informed Pt. A of the need to return in one month for a follow-up visit, scheduled for December 16, 2003, to address what the tests showed and to see how the increase in the hypertension medication was working. (Exs. 1 & 7. Testimony of Dr. Clapp.)

4. As was his long-standing protocol with his patients, Dr. Clapp informed Pt. A of the need to contact the office if he had not learned of any test results; that no news about the results did not mean they were normal or there was nothing else for the patient to do in regard to any follow-up about the testing. Dr. Clapp had posters in his office explaining that no news is no news as a reminder to his staff and patients about this need to always ensure the patients learned their test results. (Testimony of Dr. Clapp.)

5. Pt. A had the echocardiogram, and the colonoscopy with the results sent to Dr. Clapp. (Ex. 1. Testimony of Dr. Clapp.)

6. Pt. A did not come to his December 16, 2003 follow-up visit with Dr. Clapp. The words "no show" were written on Pt. A's chart for this date. As was Dr. Clapp's long-standing office protocol, if a patient failed to appear for a scheduled visit, he would not view that patient's file in the normal course that day. He would only view the charts of patients who did show up that day for their scheduled visits. Staff mailed to any "no-show" patient a postcard informing him/her of this failure to appear and that he/she should contact Dr. Clapp's office to reschedule the visit. No further detail was listed on the postcard such as what would have been addressed at the missed visit or if it was necessary for the patient to reschedule soon. (Ex. 1. Testimony of Dr. Clapp.)

08/29/14 5:58

7. Pt. A did not reschedule his missed follow-up visit. (Ex. 1. Testimony of Dr. Clapp.)
8. In and around November 2004, Pt. A contacted Dr. Clapp's office for a refill of the Lisinopril prescription. Dr. Clapp had written the prescription for it to run out at and around this time period when Pt. A would have been expected to have an annual physical. The refill was given even though Pt. A did not first have a visit with Dr. Clapp. The renewal was made at the same dosage level of 20 mg. Dr. Clapp considered this to be a moderate dosage for Pt. A, and that it was better to renew the medication than to have him stop taking it. (Ex. 1. Testimony of Dr. Clapp.)
9. Pt. A was not seen again by Dr. Clapp until February 2, 2006. At that time, Dr. Clapp did a review of systems, gave a physical examination, and diagnosed Pt. A with essential hypertension. He discussed with Pt. A the importance of healthy lifestyle choices including stopping smoking. He ordered blood work and told Pt. A. He set up another appointment for Pt. A for March 6, 2006 and set up a chest x-ray for April 14, 2006. Pt. A also had another echocardiogram. Dr. Clapp provided Pt. A with a prescription for Lisinopril at an increased dosage of 30 mg.³ (Ex. 1. Testimony of Dr. Clapp.)
10. Pt. A did not keep his March 6, 2006 appointment. As with the previous missed appointments, Dr. Clapp's office staff sent Pt. A another postcard reminder to reschedule his missed appointment. On March 8, 2006, Dr. Clapp prescribed Ranitidine 150 mg., 90 tablets for Pt. A to be refilled three times.⁴ (Ex. 1. Testimony of Dr. Clapp.)
11. Pt. A had another scheduled visit with Dr. Clapp for April 18, 2006. He again did

³ On January 16, 2006, Dr. Clapp had renewed Pt. A's Lisinopril 20 mg. prescription for another year. This prior prescription seems to have been increased in dosage after Dr. Clapp examined Pt. A. Dr. Clapp was not prescribing Pt. A to take each day one dose of Lisinopril at 20 mg. and one dose at 30 mg.

⁴ There is no information that I could uncover in Pt. A's medical records and no testimony was presented explaining under what circumstances this medication was prescribed for Pt. A. See Exhibit 1.

08/23/14 039

not show for this appointment. He was sent another postcard reminder to reschedule the visit. Another office visit was scheduled for June 12, 2006. Again, Pt. A did not appear for the appointment. Another postcard reminder to reschedule the missed visit was sent. On the June 12, 2006 examination template sheet in his chart-medical record, there is a notation that Pt. A cancelled an appointment due to car trouble. The sheet does not indicate which appointment was cancelled for this reason, and there are references on the same sheet to mailing a postcard to Pt. A to reschedule missed appointments regarding August 28, 2006, April 8, 2007, and April 9, 2007.⁵ (Ex. 1. Testimony of Dr. Clapp.)

12. The next item in Pt. A's chart-medical record is on March 20, 2007 when Dr. Clapp again refilled Pt. A's prescription for Lisinopril 30 mg. There is an indication on the sheet for this date that Pt. A had missed four scheduled appointments with his last in-person visit in February 2006. On June 12, 2007 there is an entry in Pt. A's chart-medical record that he was prescribed Lisinopril 30 mg. again. The entry is signed by Loretta Bergesen as the provider. She worked in Dr. Clapp's office. (Ex. 1.)

13. On June 21, 2007, Pt. A's wife called Dr. Clapp's office to report that Pt. A had a tick bite that had a bullseye around it and that they feared he had Lyme Disease. She sought requisitions for tests to be done to determine if Pt. A had Lyme Disease as well as a request for a prescription for the appropriate medication to start right away. On June 22, 2007, Pt. A was offered an appointment with Dr. Cohen who was in Dr. Clapp's office. Pt. A's wife noted that Pt. A would call about doing this at the start of the following week. On June 25, 2007, Pt. A's wife called Dr. Clapp's office. She reported that what her husband wanted was to do the testing for Lyme Disease and to get the prescription for the Lyme Disease medication. This was done. Dr.

⁵ Although no evidence was presented to show Pt. A had rescheduled office visits, this is likely what happened even if he missed future appointments. No evidence showed Dr. Clapp's office automatically rescheduled missed appointments.

Clapp felt Pt. A and his wife resided in a region where many people have come down with Lyme Disease. The requisition for the testing was produced and Pt. A was prescribed Doxycycline Hyclate 100 mg. (60 tablets). Pt. A's Lyme Disease test results from July 1, 2007 were negative. On July 6, 2007, Dr. Clapp's office contacted Pt. A with these results. On July 13, 2007, Pt. A's wife requested that these test results be mailed to him. Pt. A called Dr. Clapp's office on July 23, 2007 to say that he had not received the test results in the mail. There is an indication in Pt. A's chart-medical record that the test results were mailed to him on July 23, 2007. (Ex. 1. Testimony of Dr. Clapp.)

14. Pt. A was scheduled to see Dr. Clapp on August 14, 2007. He did not appear for the appointment. On the sheet for that visit in his chart-medical record staff wrote that cancelled were echocardiograms for July 2 and 16, 2007, and that Pt. A was mailed a letter on August 27, 2007. A copy of the letter sent is in Pt. A's chart-medical record and reads:

Dear Patient A
We are sorry you were unable to keep your recent appointment.
Please call us today to schedule a time that's convenient for you.
Thank you!
The office of John C. Clapp, MD

(Ex. 1.)

15. The next time there is any chart-medical record entry containing Pt. A's name is October 30, 2007 reporting on various lab testing done, i.e., "HFP, ACP, LIPP, CK, PSA, HOMOC" The PSA result is 0.47 mg/ml. The indicated normal range for a PSA is listed as "0-4.0". Pt. A's father has the same name and was a patient of Dr. Clapp at this time. These October 2007 medical records were his father's and should not have been in Pt. A's file. This error was not uncovered through the time Pt. A treated with Dr. Clapp. (Exs. 1 & 6. Testimony of Dr. Clapp.)

16. The next entry in Pt. A's chart-medical record is dated January 7, 2008 when lab test results are listed for "HFP, LIPP, CK, PSA, HOMOC ..." The PSA test result listed is "11.01 ng/ml" with a normal range being "0-4.0". These were test results properly within Pt. A's chart-medical record and were not his father's test results. Dr. Clapp is unsure what requisition for lab tests Pt. A had used for this January testing. Pt. A had not been compliant in the past with securing the lab testing he had been asked to get, but these prior requisition sheets would have included a PSA test. (Ex. 1. Testimony of Dr. Clapp.)

17. When Dr. Clapp saw the PSA test result he knew it was elevated. He reviewed Pt. A's chart-medical record and came across the October 2007 test results. He was only focusing on the PSA test result from that time and did not review enough of all the lab testing results to recognize that the results were not likely Pt. A's but more likely those of Pt. A's father. Instead, he concluded that Pt. A had done testing in October 2007 with a PSA result that was normal but now had a PSA in January 2008 that was quite elevated over normal. To Dr. Clapp, this was a matter to address further with Pt. A. He learned that Pt. A had an upcoming visit with him on January 22, 2008. Dr. Clapp made a notation of that appointment date on the sheet showing the elevated PSA result. Dr. Clapp did not call Pt. A to report the elevated PSA result and tell Pt. A that a follow-up about this result was necessary. He did not conclude at that time that this sudden rise in the PSA value would likely be due to a very aggressive cancer as that would be highly unusual. Most prostate cancers grow slowly, and with very escalated PSA results over this short a time period, the more likely reason was an unreliable test result or a prostate infection. Dr. Clapp concluded that addressing this situation through a physical examination, redoing the PSA test, and then doing a rectal examination would be the next necessary steps to take. He intended to explain all this to Pt. A at the January 22, 2008 visit. Due to this

assessment, Dr. Clapp found no need to red flag or otherwise highlight Pt. A's elevated PSA result to ensure that Pt. A would be called about this result and about the need to pursue it with a follow-up evaluation in the event that Pt. A did not keep his January 22, 2008 appointment. Dr. Clapp determined to pursue this route even though he would not, as was the existing practice, be given Pt. A's chart-medical record on January 22, 2008 if Pt. A was a "no-show" for the visit. At this time the protocol Dr. Clapp understood was still in place was for staff to send out a postcard to a patient about missing an appointment and encouraging the patient to reschedule it. Dr. Clapp also knew his patients were instructed not to consider unknown test results to be normal, and that the patient should be calling his office for unknown test results. For Dr. Clapp, these two procedures along with having testing done before a scheduled visit increased patient engagement in their care with him. (Ex. 1. Testimony of Dr. Clapp, Dr. Weinberg & Dr. August.)

18. Pt. A never contacted Dr. Clapp's office to reschedule the missed visit during the rest of January and all of February, and even into most of March 2008. On January 14, 2008, Pt. A's prescription for Lisinopril 30 mg. was renewed. On January 21, 2008, Pt. A had an echocardiogram. (Ex. 1.)

19. In December 2007, Pt. A had been alerted in a letter sent to all Dr. Clapp's patients who saw him as their PCP, that he would be shutting down this practice by the end of March 2008. The patients were urged to secure new PCPs for their care. Starting in and around October 2007, Dr. Clapp began transitioning out of his PCP private practice. By January 2008 he was an employee of Northeast Medical Practice. Although he held this changed status, Dr. Clapp's PCP practice continued with no changes in the practice's protocols with patients that he was aware of. By this time, the patients' charts-medical records were computerized. (Exs. 1 &

08/29/14 3:35

5. Testimony of Dr. Clapp.)

20. Pt. A called to speak to Dr. Clapp on March 25, 2008 about his January test results. He had not called Dr. Clapp's office before this time following his January 7, 2008 lab testing. Dr. Clapp explained to Pt. A that he had an elevated PSA result from January 7, 2008. He explained that Pt. A should see a urologist for a follow-up evaluation concerning this elevated PSA. Dr. Clapp explained that the October 2007 PSA result had been normal. Pt. A was aware that he had not had a PSA test in October 2007. This was the last contact Dr. Clapp had with Pt. A. Dr. Clapp stopped his PCP practice by the end of March 2008 as planned. (Exs. 1 & 6.

Testimony of Dr. Clapp.)

21. Pt. A secured a urologist at the Lahey Clinic. He had a repeat PSA test on April 23, 2008 that was 10.9 ng/lm. This prompted a biopsy that showed he had prostate cancer that had not metastasized. He had hormone therapy with surgery postponed so he could have a cardiac workup. He had a "robotic prostatectomy" on September 11, 2008 and was "diagnosed with a Gleason 3+4 = 7/10 adenocarcinoma of the prostate in right mid and right base." He showed "clinical stage II disease; large nodule on digital rectal examination." He is now impotent with mild incontinence. (Exs. 6 & 8.)

22. Pt. A sought his medical records from his care with Dr. Clapp, and in May 2010, he filed a complaint intake form with the BORM about how Dr. Clapp addressed with him his elevated PSA test result. Pt. A felt that he had undergone an "annual check-up" in January 2008 with Dr. Clapp as his PCP. There is no information in Pt. A's chart-medical record that he had a visit with a physical examination with Dr. Clapp in January 2008. Pt. A's complaint form did not elaborate more concerning this annual check-up. Pt. A acknowledged in his complaint form that he knew by January 2008 that Dr. Clapp was stopping his PCP practice and would not be his

08/29/14 SSA

PCP after March 31, 2008. Pt. A acknowledged that he had to secure a new PCP as a result. Pt.

A wrote the following:

I hadn't received the results of my bloodwork or cardiogram from Jan. so I called the office 3/08. Dr. Clapp himself spoke to me and said the results should be fine but after looking them up he sounded alarmed and advised me to see a urologist because my PSA was elevated. I did so and it was confirmed that I had advanced prostate cancer with a PSA of over 10.

Once Pt. A secured his medical records, he saw that Dr. Clapp wrote that the PSA was normal in October 2007. Pt. A wrote in the complaint form: "However, that was because he [Dr. Clapp] was looking at the wrong chart as my father went to him in Oct. 07 and his PSA was normal."

(Ex. 6.)

23. On February 20, 2013, the BORM issued a Statement of Allegations concerning Dr. Clapp's care of Pt. A in regard to the elevated PSA result. In the Statement of Allegations the BORM referred to the 2006 Consent Order involving Dr. Clapp. In terms of the elevated PSA, the Statement of Allegation charged:

In January 2008, Patient A had blood drawn prior to his annual check-up. He did not receive the results of his PSA test or his cardiogram ... Shortly after Patient A's appointment, he received a letter stating that the Respondent would be retiring effective March 31, 2008 and Patient A needed to find a new primary care physician ... In March 2008, Patient A called the Respondent's office to inquire about his test results. Patient A spoke to ... [Dr. Clapp] who said that the results should be fine ... After ... [Dr. Clapp] looked at Patient A's results, he sounded alarmed and told Patient A he needed to see an urologist because his PSA level was elevated ... Patient A saw an urologist who confirmed that Patient A had advanced prostate cancer with a PSA level over 10 ... Patient A had a prostatectomy as a result of the cancer.

(Ex. A.)

24. In response to the Statement of Allegations, Dr. Clapp answered that he denied any misconduct in connection with his care of Pt. A, including his handling of the elevated PSA test result. (Ex. B.)

08/23/14 1:53 PM

25. Dr. Norman Weinberg, MD, reviewed Dr. Clapp's care of Pt. A to opine whether Dr. Clapp had met the standard of care in addressing Pt. A's elevated PSA result. He was retained by the BORM. Dr. Weinberg is licensed to practice in Massachusetts and has been a primary care board certified internist from 1979. He has had experience on primary care medicine review councils and committees. He was the chair of the Care Improvement Council-Partners Community Healthcare, Inc. from 1997-1999. He was chair of the Physician Subcommittee Care Improvement Council-Partners Community Healthcare, Inc. from 1999-2001. He was medical director of the Emerson Hospital Physician Hospital Organization from 1998-2001. He was project coordinator of the Quality Improvement Committee for the Emerson Hospital Department of Medicine from 2004-2005. He has served as the medical director of the Lincoln-Lexington-Bedford Medical Group at Emerson Hospital, taught at Emerson Hospital doing weekly medical conferences for the Department of Medicine for about ten years, led reviews of quality of care issues for the Emerson Hospital Department of Medicine, and has supervised and led quality improvement discussions at weekly group meetings of the Lincoln-Lexington-Bedford Medical Group internists. He has done research, made presentations, and has published concerning quality of care issues. (Dr. Weinberg's C.V. Ex. 3. Testimony of Dr. Weinberg.)

26. Dr. Weinberg has a PCP practice with many long-term patients and a sizeable older patient population, mostly males. Much of his practice focuses on preventative care, overseeing-managing chronic conditions, and ensuring the patient has appropriate screening tests as well as tests based on patient complaints. He orders follow-up tests after performing routine tests on his patients. He monitors the effectiveness of the treatments and medications his patients are receiving. He answers patients' questions. He supervises one nurse practitioner. His female

physician partner in his PCP practice sees primarily female patients. He routinely orders PSA tests for patients who have a life expectancy of at least ten years and for those patients with a family history of prostate cancer. Dr. Weinberg is aware that a clinical rectal examination where the prostate is palpated may not uncover cancer hidden inside, i.e., the prostate feels normal without induration, hardness or lumps. He recognizes that the purpose of the PSA test is to detect cancer. He does four to five physical examinations a day. He orders typically two or three PSA tests a day. (Testimony of Dr. Weinberg.)

27. Dr. Weinberg reviewed Pt. A's medical records with Dr. Clapp, the Lahey Clinic records on the treatment of Pt. A's prostate cancer, Pt. A's complaint form to the BORM, and information on Dr. Clapp's expert in a letter from Dr. Clapp's counsel. He found that the medical records do not contain much information, but show outcomes of test results and information on Pt. A's need to increase his dosage of Lisinopril. (Exs. 1, 6 & 8. Testimony of Dr. Weinberg.) He reviewed "a few records from as far back as 2003, but the patient was not in the office for hardly any visits." (Testimony of Dr. Weinberg, Vol. I at pages 133-34.) The BORM asked Dr. Weinberg to;

look at the patient complaint and determine whether or not ... there were legitimate concerns from the point of view of the medical care delivered [by Dr. Clapp] and whether the patient's complaints were justified ... to opine [if Dr. Clapp met the standard of care] ... which is the responsibility of the physician to relay tests, normal or abnormal, to a patient. [Dr. Weinberg noted:] It's hard to find specific guidelines for that, but it's a general rule certainly from the ethics manual from the American College of Physicians. The primary purpose of a clinician is to act for the benefit above all of the well-being of the patient.

(Testimony of Dr. Weinberg, Vol. I at pages 133-34.) In terms of prostate issues, Dr. Weinberg did not see that any rectal exam was ever done and saw PSA results from October 2007 and from January 2008. He saw only two physical examinations done on Pt. A. In terms of his own practice, if a scheduled visit is not kept by his patient, he can uncover this information because

08/28/14 537

he sees a schedule of the patients for each day. If that patient needs to learn of some test result or there is a need to reschedule soon, that information would be provided to the patient who missed the visit. (Ex. 1. Testimony of Dr. Weinberg.)

28. Dr. Weinberg found a PSA test result listed in Pt. A's medical records from October 2007 to be normal and a PSA test result from January 2008 to be "very abnormal." He wondered if this January 2008 test involved some "administrative error" in light of "the BUN creatinine ... normal" versus the "BUN creatinine findings from October 2007." He explained:

That can occur for PSA to go from ... under 1 to 11 in a few months ... but it's uncommon. It can happen with acute prostatitis, sexual activity can effect it to some extent, certainly laboratory error. Never seen a prostate cancer bump a PSA that fast. So that plus the differences in the BUN creatinine raise some question in my mind about the validity of one of those two tests ... [Prostatitis is] an inflammation of the prostate, usually infectious although it can be chronic, and that can raise the PSA terrifically up to in the 30s ... Without further testing ... you would need to have a history to ask questions about prostatitis, typical types of pain, diminished penal discharge ... you would ask that. Obviously on examination if there was a very tender prostate ... that would help clarify that.

(Testimony of Dr. Weinberg, Vol. I at pages 143-44.) Dr. Weinberg found no examination with Pt. A following either the October 2007 or January 2008 PSA testing. He understood Pt. A was a no-show for a visit scheduled after the January 2008 PSA testing. (Testimony of Dr. Weinberg.)

29. Dr. Weinberg explained his protocol in terms of notifying his patients about their test results. His practice uses an electronic record that sends test results for him to review. Then, the patient is sent a letter with the results or the patient can access the results using an electronic patient portal system. Some interpretation by Dr. Weinberg would be given to the patient. In terms of how quickly the patient is sent test results, Dr. Weinberg explained:

It depends on how critical [the results] are. If they are critical, it would be within a day or two, sometimes that same day. For routine types of things it could be one or two weeks.

(Testimony of Dr. Weinberg, Vol. I at page 145.) Dr Weinberg addressed his practice in terms of providing a patient notice of a PSA test result when a result went from 1 to 11. He would label that development as an urgent situation where he would at least want to repeat the test especially if just a few months prior to the elevated result the PSA result was normal. He would also inform the patient about a necessary follow-up visit, including any needed timetable to accomplish the follow-up further testing and examination. He would not wait for the patient to contact him to receive the result of the elevated PSA test under such circumstances where the normal PSA result was in October and the elevated PSA result was in January. To Dr. Weinberg, because of the possibility that the PSA result of 11 could signal cancer and be possibly life-threatening, there would need to be a visit with the patient soon. Dr. Weinberg opined that if Pt. A had kept his scheduled visit January 22, 2008, that would have been standard of care to do the follow-up needed, but a visit much later than that, even a month later, would be beyond a reasonable standard of care. This is why Dr. Weinberg would have directly contacted a patient such as Pt. A with the PSA test result along with his direction to the patient on the need to do the follow-up further evaluation soon. If Pt. A had not shown up for his January 22, 2008 scheduled visit, Dr. Weinberg sees the standard of care as requiring that Pt. A be notified not just to reschedule his missed appointment, but to be given the reason why and to reschedule to a time very soon. Dr. Weinberg recognizes there can be a number of non-cancer possible outcomes in terms of what a suddenly elevated PSA result might mean. He still finds this kind of attention and time-table for the follow-up is needed in order to meet the patient's best interests which is standard of care practicing under these circumstances. (Testimony of Dr. Weinberg.)

30. Dr. Weinberg disagrees that the standard of care was met by Dr. Clapp because in April 2008, Pt. A was found at the Lahey Clinic not to have fast developing or metastasized

cancer. Rather, he opined that standard of care is determined by Dr. Clapp's conduct on or about January 22, 2008. The fact that Pt. A called Dr. Clapp's office at the end of March 2008 to learn his test results was not timely notice to Pt. A of the abnormal PSA result and of the need to have it further evaluated soon. To Dr. Weinberg, the issue is not that Dr. Clapp failed to fully recognize the need for Pt. A to have the follow-up evaluation of the abnormal PSA result, it is his failure to give timely notice to Pt. A of the need for this follow-up around the time of January 22, 2008 due to the risk of Pt. A having prostate cancer needing further evaluation soon. (Testimony of Dr. Weinberg.)

31. Dr. David August, MD, reviewed Dr. Clapp's care of Pt. A to form an opinion whether Dr. Clapp met the standard of care in how he addressed Pt. A's elevated PSA result. Dr. August is an internist licensed to practice in Massachusetts from 1986. He is a diplomate of the American Board of Internal Medicine from 1986 and was a diplomate of the American Board of Internal Medicine in Geriatrics for ten years. At Harvard Medical School, he was a clinical instructor from 1986-2008, an assistant professor after that through 2013, and is now a clinical assistant professor. He teaches medical students about performing primary care medicine including how to; conduct annual physical examinations, document care given to patients, and manage medications prescribed. He teaches how to screen for prostate cancer using PSA testing, and how to review laboratory test results with patients. From 1986, he has been on the active staff at Beth Israel Deaconess Medical Center. He has worked as an internist at the Dimock Community Health Center, 1986-1994; with the Urban Medical Group, 1986-1997; with the Affiliated Physicians Group, 1997-2004; with Healthcare Associates, 2005-2013; and in his own private practice starting in October 2013 through the present. Dr. August has had a patient load of as many as 1100 patients and sees patients daily. Dr. August was a physician advisor in the

Quality Assurance Department at Beth Israel Hospital, 1994-1996. He was the medical director of the Beth Israel Deaconess Physicians Organization, 1996-2000. He has been involved in efforts at improving the delivery of primary care medicine including how best to address laboratory testing and x-ray results with patients. He served from 1994-1996 on the Inpatient Utilization Committee as its chair covering Tufts/Beth Israel Hospital. He did internship and residency electives at a hospital in Haiti 1984 and 1986. He volunteered in 2009 for an organization called Keep Sound Minds. (Dr. August's C.V. Ex. 7. Testimony of Dr. August.)

32. As a PCP, Dr. August does annual physical examinations, routine and follow-up testings and screenings, and diagnoses chronic illnesses or acute problems. He manages the patient's interactions with specialist physicians. Dr. August is familiar with the standard of care in 2008 for a PCP in regard to notifying patients of their test results including PSA results. He views good care that meets the standard of care to include "what is done by competent, qualified physicians in the community which is now really a national community ... a blend of what the latest research and expert opinion is about the right way to do things and what physicians are doing in the real world." Dr. August opines that if as the PCP you ordered lab tests for your patient, you are ultimately responsible for receiving the results and interpreting them with the patient in a timely manner. (Testimony of Dr. August.)

33. Dr. August reviewed Pt. A's medical records with Dr. Clapp and with the Lahey Clinic in regard to the prostate cancer after Pt. A left Dr. Clapp's PCP practice. He reviewed a letter setting forth information about the BORM's expert in this proceeding. He was present for testimony given by Dr. Clapp at the hearing. (Testimony of Dr. August.)

34. Dr. August concluded that Pt. A used Dr. Clapp as his PCP despite missing many scheduled visits and not always having all requisitioned lab testing done since starting care with

Dr. Clapp in 2003. Dr. August found Pt. A attended just two in-person examinations-visits with Dr. Clapp until he stopped care with Dr. Clapp in March 2008. Nevertheless, Dr. August found significant that Pt. A did have recommended echocardiograms, a colonoscopy, and filled prescriptions for his hypertension medication. He also contacted Dr. Clapp to receive help when he felt he might have Lyme Disease including getting pertinent testing and taking prescribed medication. Dr. August felt he also has had this kind of patient. Dr. August noted as significant that Dr. Clapp would renew a prescription for a short time as a way to try to get Pt. A to come to scheduled follow-up visits, and would send out a letter or postcard informing Pt. A to reschedule a missed appointment. Dr. August emphasized that the PCP cannot force the patient to return for a follow-up visit or to comply with doing requisitioned lab testing. He does not find there is a standard of care to have to directly call a patient who missed a scheduled visit. In terms of the template Dr. Clapp used for physical examinations and evaluations, Dr. August found the template to be adequate and standard. In reviewing the two in-person visits with Dr. Clapp that Pt. A had, Dr. August found that Dr. Clapp did a review of systems, took a social, family and medical history, and did a physical examination that led him to conclude that Pt. A had essential hypertension, smoked cigarettes, and was obese. Dr. August had no issues with Dr. Clapp prescribing the Lisinopril for Pt. A's hypertension. Dr. August found proper Dr. Clapp scheduling Pt. A for follow-up monitoring visits a month after a full examination and evaluation. Dr. August found reasonable and proper to instruct patients who have not learned of their test results to contact the physician's office to learn the results. Dr. August also does this. Dr. August found in Dr. Clapp's practice a number of protocols in place to cause the patient to be proactive in keeping office visits, and in keeping follow-up evaluations. These included Dr. Clapp having his office send a postcard to the patient who was a "no-show" for a scheduled visit

36. Dr. August finds that having staff and not having the PCP contact a patient who has missed a scheduled visit to be within the standard of care so that the PCP is not juggling patient visits and telephone calls. In addition, a big help is having the testing done prior to the office visit as it has been shown to lead to a higher percentage of kept office visits by patients. Dr. August did not find in Pt. A's medical records any notice or information that a note went out to Pt. A about rescheduling his missed January 22, 2008 visit with Dr. Clapp. But, he concluded that Dr. Clapp reasonably relied on the ongoing protocol Dr. Clapp always had in place that such a note would be routinely sent out to any patient who failed to show for a scheduled office visit. Dr. August did not view Dr. Clapp's practice of seeing the files of only the patients that do show up on any given day to be a quality of care issue. He did not see a standard of care violation for Dr. Clapp not to learn who did not show up for a scheduled appointment. Dr. August understood this is what happened concerning Pt. A on January 22, 2008. Dr. August addressed what he labeled the "one Achilles heel" in a PCP practice:

[i]t's rare that someone will come in for their labs, come for their echo and disappear. The patients see it as a package but it can happen, and so you should have something in place if that piece doesn't happen. But from a systems point of view, the number of lab results that don't get followed up on is much lower when you do them in advance [as Dr. Clapp did] ... [Pt. A] didn't get ... [the general notice to reschedule the missed visit but he] picked up the phone and said what are my results.

(Testimony of Dr. August, Vol. II at page 453.) Dr. August explained that only when the test result is a red flag situation will the PCP be needing to call the patient with the result soon after getting it in order to be within the standard of care. Like Dr. Clapp, Dr. August would not have labeled Pt. A's January 8, 2008 PSA test result a red flag situation. Dr. August would also not have made the situation with Pt. A's elevated PSA result an urgent matter just because Pt. A often failed to keep his scheduled appointments. Dr. August did not find that Dr. Clapp needed

to ensure that in January 2008 when his practice was fully taken over by Northeast Medical Services and he was their employee, that the reminder postcards were still being sent out; that it was reasonable for Dr. Clapp to assume this kind of standard practice notice to "no-show" patients was being done. (Testimony of Dr. August.)

BORM'S BASIS FOR PROPOSED RELIEF

The Statement of Allegation lists grounds for disciplining Dr. Clapp's conduct concerning Pt. A's elevated PSA result in January 2008. Included grounds are; Dr. Clapp engaged in conduct placing into question his competence to practice medicine including gross misconduct, practicing fraudulently, or practicing beyond his authorized scope, or practicing with gross incompetence, or practicing with gross negligence on a particular occasion or practicing negligently on repeated occasions. In addition, the Statement of Allegations cites the BORM's authority to discipline a physician for misconduct or negligence even if just on one occasion, and for conduct that undermines the public confidence in the integrity of the medical profession. *Raymond v. Board of Registration in Medicine*, 387 Mass. 708 (1982) and *Levy v. Board of Registration in Medicine*, 378 Mass. 519 (1979). (243 CMR 1.03(5)(a)3.)

The BORM has a number of options for discipline that do not reach revocation or suspension of the license such as "admonishment, censure, reprimand, fine, the performance of uncompensated public service, a course of education or training or other restrictions upon the Respondent's practice of medicine." In the *Matter of Walter L. Kaufman, M.D.*, Board of Registration in Medicine No. 98-12-XX (April 15, 1998). And, when the BORM determines an appropriate discipline for substandard care, it considers; how far the physician deviated from the standard of care, how many patients were involved, and whether there were any mitigating circumstances. See *In the Matter of Viorel Boborodea, MD*, Board of Registration in Medicine

No. 04-61 (March 15, 2006). I conclude based on the findings made that Dr. Clapp's conduct regarding the propriety and sufficiency of his efforts to give timely notice to Pt. A of the elevated PSA result from January 2008 is within the realm of negligence and competency to practice involving a single event, and is the conduct to consider as possible misconduct.

Conclusion and Recommendation

Between November 2003 and March 2008, Pt. A had only two in-person office visits with Dr. Clapp. On both occasions, Dr. Clapp provided what the findings show were appropriate and standard of care evaluations for a PCP to perform, including physical examinations and having a follow-up plan. Pt. A was not compliant in keeping his scheduled appointments. He did not keep any follow-up appointments set-up after a visit with Dr. Clapp. But, there was other contact Pt. A had with Dr. Clapp though not in person. This occurred when Pt. A or his wife sought refills of the Lisinopril hypertension medication, when Pt. A and his wife sought an evaluation of his possible Lyme Disease infected tick bite, and when Pt. A followed through on Dr. Clapp's treatment plan for him by having echocardiograms and a colonoscopy. It also occurred when Pt. A had lab testing done in January 2008 that included a PSA test. The findings show that Dr. Clapp acted as Pt. A's PCP and that Pt. A treated Dr. Clapp as his PCP.

It is not at all clear how Pt. A came to have an echocardiogram in January 2008 along with the other lab tests, but likely Dr. Clapp was correct that Pt. A was using requisition sheets Dr. Clapp had issued to him for tests some time ago. Or, in light of Pt. A's scheduled January 22, 2008 visit, perhaps these requisitions were issued in connection with that scheduled visit. Maybe Dr. Clapp's December 2007 letter to Pt. A, a form letter sent to all Dr. Clapp's patients that he was ending his PCP practice at the end of March 2008, triggered in Pt. A the desire to get these tests done before Dr. Clapp's care of him ended. Since Pt. A had a practice of not showing

08/29/14 09:55

up for scheduled follow-up visits, he may have realized that he would need to be contacting Dr. Clapp's office to learn about his test results. Pt. A did not testify.

Dr. Clapp's testimony was believable that he knew there was a need to discuss soon with Pt. A his elevated PSA result from testing done January 7, 2008. Dr. Clapp examined Pt. A's medical record and found a normal PSA result from October 2007 that he erroneously thought was Pt. A's test result. It was Pt. A's father's PSA result. The fact that Dr. Clapp opined that Pt. A's sudden change from a normal PSA to an elevated PSA was more likely due to some infection or inflammation or a mistake with the PSA testing, did not impact Dr. Clapp's intention to communicate soon with Pt. A about the need for a follow-up evaluation to determine if he had, or to rule-out, prostate cancer. Dr. Clapp intended to discuss the elevated PSA test result and the need for further evaluation of it at the already scheduled January 22, 2008 appointment. Both Dr. Weinberg and Dr. August took no issue with the plan Dr. Clapp developed for Pt. A, or with discussing the plan with Pt. A in about two weeks time from when the PSA test was done.

The issue that remains is whether Dr. Clapp owed a duty to Pt. A to ensure that Pt. A received timely notice of his elevated PSA test result and of the need for further evaluation, on or just after January 22, 2008, to satisfy the standard of care. At no time did Dr. Clapp initiate a call or write a letter to Pt. A with this information before or after January 22, 2008. No evidence was presented that Pt. A could not have been reached during January 2008 with his PSA test result. One factor raised in mitigation was that in January 2008 Dr. Clapp was no longer the principal of his PCP practice but was an employee-PCP of Northeast Medical Services. Therefore, he could no longer ensure that the support staff would continue to send out postcards to his patients who missed their appointments with a message to reschedule them. Dr. Clapp assumed this kind of standard practice commonly used by PCPs would be continued under

Northeast Medical Services even if by January 2008 Dr. Clapp was closing out his PCP practice by the end of March 2008. Pt. A's medical records do not contain any information indicating that such a reminder to reschedule was sent to Pt. A after he missed his January 22, 2008 appointment. Even if a reminder card had been sent to Pt. A, that card would not have included any further information such as saying that his recent test results have to be discussed with Dr. Clapp. Nothing would have prompted Pt. A to see a need to reschedule his appointment soon.

Both parties presented experts who did not so much dispute what the pertinent standard of care Dr. Clapp had to follow would be, but disputed whether Dr. Clapp practiced medicine negligently and/or incompetently when he failed to treat the elevated PSA result as an urgent or red flag situation that would require him to take an additional step to contact Pt. A directly about the PSA result. If contacting Pt. A directly about the PSA result being elevated was a red flag or urgent situation, both experts agree that even if Pt. A missed his January 22, 2008 scheduled visit, Dr. Clapp should have made direct contact with Pt. A about this matter.

Dr. Weinberg found that due to the risk that could be associated with the elevated PSA result, Dr. Clapp should not have assumed that Pt. A would timely contact his office for his test results or come to the January 22, 2008 visit. Instead, Dr. Weinberg opines that Dr. Clapp should have made sure that by about January 22, 2008, Pt. A learned about the need for having a follow-up evaluation due to his elevated PSA. Dr. Weinberg found it not a defense of Dr. Clapp's conduct or a mitigating factor that Pt. A contacted Dr. Clapp for his test results at the end of March 2008. Dr. Weinberg concluded that the end of March 2008 was too long a wait to start addressing the elevated PSA result, and that by then, Dr. Clapp was in violation of the standard of care. Dr. Weinberg did not find to be a mitigating factor that the prostate cancer found by the Lahey Clinic in April 2008 was not progressing quickly and not requiring

08/28/14 15:38

immediate surgery. This information could not have been known on January 22, 2008. Even if there was reasonable medical cause for Dr. Clapp concluding a sudden elevation of a normal PSA result to a much higher PSA result within a few months was not due to cancer, Dr. Weinberg opined that there should have been a mechanism in place to ensure Pt. A's elevated PSA result would be addressed by or soon after January 22, 2008 because the risk of a fast progressing prostate cancer still existed.

For Dr. August, the possibility that the elevated PSA was a fast progressing prostate cancer was so remote that like Dr. Clapp, he would not have found Pt. A to be in a red flag or urgent situation requiring Dr. Clapp to ensure he made contact with Pt. A by January 22, 2008. Dr. August opined that Dr. Clapp also met the standard of care despite not ensuring notice reached Pt. A about the results of the PSA in January 2008. This was due to a number of useful and good procedures Dr. Clapp used that were aimed at engaging the patient in his or her own care with the PCP such as having tests done prior to a scheduled visit to permit discussion of the test result at that visit, sending out a notice to the patient to reschedule missed visits, and informing the patient on the importance of contacting the PCP's office when he or she has not learned about test results. Dr. August noted that a PCP cannot force a patient to engage sufficiently with the PCP.

Neither expert weighed in on the Consent Order from 2006 concerning a failure to give a patient timely notice of a number of PSA results. I do not find Dr. Clapp's conduct with Pt. A shows that he was simply pursuing an established pattern of conduct of not adequately ensuring that his patients timely learned about their PSA results as was set forth in the Consent Order. Just one PSA of concern was involved with Pt. A's situation. Dr. Clapp was credible in explaining that he planned to discuss the PSA test result at the January 22, 2008 visit that was

08/28/14-339

only about two weeks away. There are not sufficient findings in the Consent Order to show Dr. Clapp's conduct with Pt. A was the same kind of conduct involved in the Consent Order for which he accepted a reprimand.

I conclude that Dr. Weinberg's assessment best fits the particular facts found. Pt. A's elevated PSA result should have been communicated to Pt. A directly by Dr. Clapp within January 2008 even if Pt. A missed his January 22, 2008 appointment. Although Dr. Clapp recognized that Pt. A would need to do a follow-up evaluation as a result of the elevated PSA to address possible prostate cancer, Dr. Clapp did not take any extra steps to ensure that Pt. A would timely learn about this need even if he was a no-show for his scheduled visit of January 22, 2008. I found persuasive Dr. Weinberg's opinion that on or around January 22, 2008 would have been the latest time period for the needed contact and discussion with Pt. A to occur. Dr. Clapp's credible testimony shows he also felt January 2008 was the time that made sense for discussing the elevated test result with Pt. A, but when it did not happen, it was negligent for Dr. Clapp not to have formed a plan for contacting Pt. A even if he missed his January 22, 2008 appointment or did not soon reschedule it.

If in October 2007, Dr. Clapp or his staff erroneously placed Pt. A's father's PSA test result in Pt. A's chart-medical record, that is an error that Dr. Clapp is responsible for. It would seem he could have reviewed that October 2007 sheet of test results and wondered why in January 2008 the values of not just the PSA testing but the results of other testing were different. It would seem he would have examined Pt. A's chart and found that there was no scheduled visit for Pt. A that was sometime after but close in time to when the October 2007 testing was done. No testimony was given that Dr. Clapp did any investigation concerning the October 2007 PSA test result information; that he simply checked Pt. A's medical records and noted this October

08/29/14 3:30

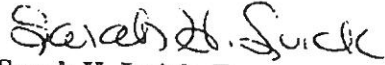
2007 PSA test result. If the only PSA result Pt. A had was from January 2008, Dr. Clapp might have viewed the January 2008 PSA test result as a red flag or urgent situation and he might have directly contacted Pt. A within January 2008.

Dr. Clapp never had in place any procedure, unless he red flagged a patient's situation, to learn about a necessary and timely discussion he needed to have with his patient. Dr. Clapp did not testify that in instructing his patients who have not learned about a test result to be sure to contact his office for the result within a month's time following the testing. Pt. A seemed to satisfy Dr. Clapp's instruction to his patients about contacting his office for unknown test results when he called his office in late March 2008, but as Dr. Weinberg found, that was too long a wait for Pt. A to begin his follow-up evaluation of the elevated PSA result to be a standard of care notification.

Dr. Clapp engaged in misconduct that is either negligence and/or incompetence in the practice of medicine in failing to ensure that Pt. A timely received the results of his PSA test and of the need to do further evaluation before the end of March 2008.

I also recommend that the Motion to Dismiss filed by Dr. Clapp at the conclusion of the evidence be denied.

**DIVISION OF ADMINISTRATIVE
LAW APPEALS**


Sarah H. Luick, Esq.
Administrative Magistrate
Date:

AUG 27 2014