

**IN THE MATTER OF**

**\* BEFORE THE MARYLAND**

**Mark G. Midei, M.D.,**

**\* STATE BOARD OF**

**Respondent.**

**\* PHYSICIANS**

**License No. D 30042**

**\* Case Nos. 2009-0364; 2010-0036; 2009-0803**

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**FINAL DECISION AND ORDER**

On July 20, 2010, the Board charged Dr. Mark G. Midei, M.D. (“Dr. Midei”) with violating the Medical Practice Act in his treatment of five patients in whom he inserted cardiac stents. A seven-day evidentiary hearing was held before an Administrative Law Judge (“ALJ”) employed by the Office of Administrative Hearings. Dr. Midei was present for the proceedings and was represented by nine attorneys. The State was represented by Victoria Pepper, Esq., Administrative Prosecutor. The parties presented witnesses and extensive documentary evidence, including extensive medical records and reports.

After the hearing was completed, the ALJ issued a 77-page Proposed Decision which included proposed findings of fact together with proposed conclusions of law that Dr. Midei violated five provisions of the Medical Practice Act, specifically, Md. Health Occ. Code Ann. (“HO”) § 14-404(a)(3)(ii), prohibiting unprofessional conduct in the practice of medicine; § 14-404(a)(11), prohibiting willfully making a false report or record in the practice of medicine; § 14-404(a)(19), prohibiting the gross overutilization of health care services; § 14-404(a)(22), prohibiting violations of the standard of quality care; and §14-404(a)(40),

prohibiting the failure to keep adequate medical records. The ALJ recommended as a sanction that Dr. Midei's license be revoked.

Dr. Midei filed exceptions with the Board, and an oral exceptions hearing was held before the full Board on June 22, 2011. This is the Board's Final Decision and Order in this case. The Board has considered the entire record in this case and now issues the following findings of fact and conclusions of law.

### **Findings of Fact**

The Board adopts the findings of fact proposed by the ALJ. The Proposed Decision of the ALJ is attached to and is hereby incorporated into this Final Decision and Order as Attachment A. With a few exceptions not relevant to the outcome of this case, the Board adopts all of the numbered findings 1 through 190 on pages 3 through 28 of the Proposed Decision. The Board also adopts all of those findings of fact made in the "Discussion" section of the ALJ's Proposed Decision at pages 28 through 64.

Dr. Midei implanted cardiac stents unnecessarily in four of the five patients in question. In every one of the patients, he falsified the extent of blockage of the patients' coronary arteries by reporting that it was 80% when it was in reality lower – and in most cases much lower. In three of the patients, he also falsely reported that they suffered from unstable angina when in fact they did not. In all of the patients he violated the standard of quality care by failing to obtain the Active Coagulation Time ("ACT") and instead simply administered heparin while inserting the catheter – a failure that caused a special risk for Patient B when

Dr. Midei also failed to look at, or disregarded, the hospital's note that the patient had already been given an anti-coagulant and should not be given another.

### **Conclusions of Law**

The Board adopts the conclusions of law proposed by the ALJ at pages 64 through 69 of the Proposed Decision. In summary, Dr. Midei committed unprofessional conduct within the meaning of § 14-404(a)(3)(ii) by failing to deal honestly with patients and colleagues when he falsely reported that three patients suffered from unstable angina and that all patients suffered occlusions of 80%. He made intentional, non-accidental and non-inadvertent false reports that exaggerated the degree of coronary stenosis and reported non-existent unstable angina in order to justify the placement of a stent, thus making willfully false reports in the practice of medicine within the meaning of § 14-404(a)(11). He overutilized health care services when he placed six unneeded stents in four of these patients, in violation of § 14-404(a)(19). He violated the standard of quality care under § 14-404(a)(22) when he used two anti-coagulants in Patient B, failed to obtain the ACT in any of the patients, implanted stents unnecessarily, documented clinical indications inaccurately, exaggerated the extent of stenosis, and failed to consider more optimal therapies. Finally, Dr. Midei failed to keep adequate medical records within the meaning of § 14-404(a)(40) when he inaccurately reported the degree of stenosis and inaccurately reported that three of the patients had unstable angina.

### **Consideration of Exceptions**

Dr. Midei requests that the Board reverse the ALJ on the critical issue of which expert should be believed. The Board recognizes that it has the authority to do so. *See State Board of Physicians v. Bernstein*, 167 Md. App. 714, 761 (2006). The Board declines to do so, however. All of the experts were qualified. The ALJ made her determination based upon the consistency of Dr. Chaco's testimony with the medical records and with the previous professional publications on the issue, as well as his clear presentation and professional demeanor – while the ALJ noted some inconsistencies or equivocations in the testimony of Dr. Midei's primary expert witness, Dr. O'Neill. The Board has taken those factors into consideration to the extent that it can on the cold record. More importantly, however, the Board, using its own expertise, agrees that Dr. Chaco's testimony represents an accurate statement of the standard of quality care. Dr. Midei's position, that it is appropriate for him to write "80%" to describe a blockage that is in fact less than 50%, is a justification for a blatant falsehood that resulted in patients receiving unneeded stents as well as the creation of false records that could follow patients and influence further treatment decisions for the rest of their lives. His expert testimony did not convince the Board differently, nor did the testimony of Dr. O'Neill – to the extent that Dr. O'Neill did try to defend this practice. In other areas as well, the Board has considered all of the testimony but believes that Dr. Chaco's testimony best represents the standard of care as understood by the Board. All of Dr.

Midei's exceptions, to the extent that he requests the Board to reject the opinions of Dr. Chako, are rejected.

The Board, in its findings of fact, has reduced from four to three the number of cases in which Dr. Midei falsely reported that the patients suffered from unstable angina. Of the five patients that Dr. Midei reported the existence of unstable angina, three patients, Patients A, D and E, did not have unstable angina or any record of symptoms that would lead any reasonable physician to conclude that unstable angina was present. Patient C, on the other hand, did have unstable angina, as unequivocally found by the ALJ. (Proposed Decision at 56) The ALJ, however, also found that the State had not met its burden of proving that Patient B had unstable angina. (Proposed Decision at 53-54) The Board agrees. Dr. Gottlieb's report of progressive angina could have been reasonably interpreted by Dr. Midei as unstable angina, and so Dr. Midei should not be faulted for this one particular item in his treatment of patient B (although he falsified medical reports and violated the standard of care in other ways in his treatment of Patient B). The Board has thus reduced from "four," *see* Proposed Decision at 67e, to "three" *see* Findings of Fact above, the number of falsified reports of unstable angina. This change from four to three has no effect whatsoever on the ultimate findings of fact or on the conclusions of law as found by the ALJ and adopted by the Board.

The Board agrees with the ALJ's determination that Dr. Midei was not credible when he testified that he just remembered other symptoms these patients suffered, symptoms that he

had not recorded at the time and that were not found anywhere in the medical records. These later-remembered symptoms were presented to justify the placement of some of these stents. The ALJ found it not credible that Dr. Midei could remember these unrecorded symptoms in the cases of patients who were among thousands that that he saw only once, for very brief periods of time (from 20 to 37 minutes), three years previously. Dr. Midei told the Board that he that he saw 1,500 to 2,500 patients annually for such diagnosis and possible intervention. The Board, like the ALJ, does not believe that Dr. Midei could, without any basis in the medical record, remember these extra symptoms in Patients A through E, symptoms that coincidentally would help to justify his placement of stents in these patients. Unfortunately for Dr. Midei, a significant part of the expert testimony of Dr. O'Neill was also based on these later-remembered, unrecorded symptoms – symptoms that Dr. O'Neill learned about only orally, from Dr. Midei. The fact that Dr. O'Neill based part of his opinion on these later-remembered symptoms is one of the reasons the Board has given more weight to the testimony of Dr. Chako.

The Board agrees with the ALJ that it is “not reviewing the propriety of the peer review investigation” at St. Joseph Medical Center. Because that peer review investigation was mentioned as background material in the charging document, the ALJ allowed Dr. Midei to present extensive argument and documentary evidence on the issue. Nevertheless, the Board fully agrees with the ALJ that “nothing [St. Joseph Medical Center] did or failed to do is relevant to the issues of this case.” The ALJ specifically found that the findings of the Ad-

Hoc Investigative Committee convened by that hospital were irrelevant, and the Board agrees. The Board is thus not basing any part of its decision on the findings of that committee, which findings apparently are being or have been litigated in other proceedings. The Board is concerned only with Dr. Midei's treatment of Patients A through E. Dr. Midei objects to the ALJ's statement that the complaints in this case alleged that 36, then 41 patients were not treated properly. The ALJ at this point was simply reiterating the procedural background of these charges; this decision, however, concerns only Patients A through E.

Dr. Midei argues that the fact that a cardiologist sent a patient to him is in itself evidence of significant symptoms that required his intervention by the placement of stents. (Exceptions at 62-63) This argument is belied by the medical records themselves, which show that Patients A, C, D and E did not have symptoms that required this type of intervention. It is also belied by the expert testimony of Dr. Chako. Nor does this argument comport with the Board's understanding of the purpose of such a referral within the cardiology profession.

The Board has given little weight to the fact that Dr. Midei was not paid per stent inserted. Dr. Midei testified that he understood that he was a big generator of business for the hospital, that the hospital had lost many patients to competition and that its goal was to hold onto the stent business that it saw slipping away.<sup>1</sup> Just at that point, he was offered a position

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<sup>1</sup> See Tr. 1258, 1314, 1317 and 1319. The hospital received from \$10,000 to \$15,000 for each stent inserted. Tr. 1448-49.

as an employee of the hospital running its cardiac catheterization laboratory, at triple his previous salary. Thus, although Dr. Midei was not paid per stent inserted, he was employed under circumstances in which any employee would feel at least some pressure to produce a high volume of stents. The fact that Dr. Midei was not paid per stent is thus not a large factor in the Board's evaluation of the evidence.<sup>2</sup>

Dr. Chako was hired by Maximus, the independent peer review contractor for the Board at that time. Dr. Midei criticizes his testimony on the issue of his expert witness fees. Dr. Chako testified that he performed these services as a professional duty, and the Board believes that that was the primary reason that he performed those services. The financial bottom line is that Dr. Chako was paid \$1,400 for his report and expert testimony, while Dr. O'Neill was paid more than twenty times that much on Dr. Midei's behalf. The Board sees no reason to discredit Dr. Chako's testimony because of either the amount of his fees or his testimony about his fees.

#### Terminology and Drafting Corrections

The Board will correct some drafting and terminology errors on the part of the ALJ. The ALJ stated that Dr. Midei had informed Dr. Naganna of his use of his unique and unsupportable "surrogate" method of reporting coronary artery blockage. (Proposed Decision

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<sup>2</sup> Dr. Midei argued for the admission of one additional document, which he asserted was relevant and which he had no opportunity to submit before. The Administrative Prosecutor disputed these points but did not assert that its admission would compromise the State's right to cross-examine or to present countervailing evidence. Upon acceptance and consideration of the document, it is clear why the prosecutor did not raise a strenuous objection. The document, which concerns the methods of choosing cases for internal hospital peer review, is not relevant to the issues before the Board in this decision, which concern only Dr. Midei's treatment of Patients A through E.



at 17) The ALJ obviously meant that Dr. Midei had *not* informed Dr. Naganna of his use of this false and misleading use of inflated percentage figures. This is clear from the ALJ's other findings that Dr. Midei had told no one about his use of "surrogates." (Proposed Decision at 37, 71) Dr. Midei did not even claim during the hearing that he directly informed Dr. Naganna, or anyone, of his use of this "surrogate." This was obviously a drafting error on the part of the ALJ, and the Board corrects it by adding the word "not" to finding #107 of page 17 of the Proposed Decision. In any case, the Board itself finds, based on the record, that Dr. Midei did not inform Dr. Naganna of his use of this false "surrogate" percentage calculation. The Board also notes that the ALJ mistakenly used the term "PCTA" to refer to diagnostic catheterization. The term "PCTA" should be replaced with "diagnostic catheterization" each time that it appears after page 7 of the Proposed Decision. Thus corrected, the Board adopts those findings. Also, the ALJ, in the middle of her discussion of Patient C, inadvertently inserted the term "Patient A" in finding # 131. The Board reads that term to mean "Patient C" and adopts that finding.

#### Summary of Consideration of Exceptions

Much of the argument in the exceptions attempts to persuade the Board that the ALJ was incorrect in her evaluation of the evidence. The Board rejects these exceptions and specifically affirms the ALJ's evaluation of the evidence. This was a long, complex and vigorously litigated case, and the ALJ's decision distills the issues effectively and, equally importantly, makes clear and definite findings on all of the critical issues. Significantly, the

ALJ did not shrink from making crucial findings regarding the willfully false nature of some of Dr. Midei's reports. The Board has reviewed the entire record in this case, and it has applied its own expertise in its evaluation of the medical records and the medical expert testimony and reports; and the Board has reached the same findings on all of the critical issues as did the ALJ. The exceptions have not convinced the Board that the ALJ made any mistakes, either procedurally or substantively, that would call for any significant changes in the ALJ's findings.<sup>3</sup>

### **Sanction**

Dr. Midei's violations were repeated and serious. They unnecessarily exposed his patients to the risk of harm. They increased the cost of the patients' medical care. Dr. Midei's willful creation of false percentage numbers for the degree of occlusion of coronary arteries is indefensible and amounts to a deliberate and willful fabrication of medical records. Not only were these false findings used to justify unnecessary stent insertions, but they also resulted in significant false entries on the patients' medical records, false entries that might later be used to guide other physicians who evaluate the patient and provide later medical care. Much the same can be said about his false entries of "unstable angina" in some of the patients' records. The ALJ found that the totality of the evidence showed that Dr. Midei acted in bad faith, and the Board agrees. The Board will revoke Dr. Midei's medical license, and it

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<sup>3</sup> During the exceptions hearing, Dr. Midei's counsel inadvertently revealed a recommendation made at the CRC (the Board's settlement conference). The Board may not make any use of such a recommendation. COMAR 10.32.02.03C(7)(d). The Board has thus not considered that statement and will strike that oral reference to the CRC recommendation from the record.

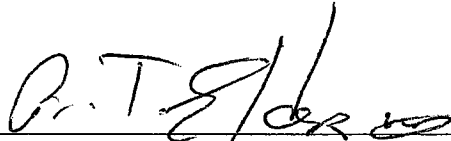
will not entertain any application for reinstatement for at least two years. Reinstatement of a revoked license is at the discretion of the Board.

**Order**

It is hereby **ORDERED** that the medical license of Mark G. Midei, M.D. be, and it hereby is, **REVOKED**; and it is further

**ORDERED** that the Board will not accept any application for reinstatement for at least two years from the date of this Order.

**SO ORDERED** this 13<sup>TH</sup> day of July, 2011.



Paul T. Elder, M.D.  
Board Chairman

**NOTICE OF RIGHT TO APPEAL**

Pursuant to section 14-408(b) of the Health Occupations Article, Dr. Midei has the right to seek judicial review of this decision. Any petition for judicial review shall be filed within 30 days from the date this Final Decision and Order is mailed. This Final Decision and Order is mailed on the date it is executed. The petition for judicial review shall be made as provided for in the Maryland Administrative Procedure Act, Md. Code Ann., State Gov't § 10-222, and Maryland Rules 7-201 *et seq.*

If Dr. Midei files a petition for judicial review, the Board is a party and should be served with the court's process at the following address: **Maryland State Board of Physicians, c/o Christine A. Farrelly, Supervisor, Compliance Administration, 4201 Patterson Avenue, Baltimore, Maryland 21215.** The administrative prosecutor is not involved in the circuit court process and need not be served or copied on pleadings filed in the circuit court.

STATE BOARD OF PHYSICIANS

\* BEFORE MARY R. CRAIG,

v.

\* AN ADMINISTRATIVE LAW JUDGE

MARK G. MIDEI, M.D.,

\* OF THE MARYLAND OFFICE

RESPONDENT

\* OF ADMINISTRATIVE HEARINGS

LICENSE NO. D30042

\* OAH No.: DHMH-SBP-71-10-35281

\* BOARD OF PHYSICIANS CASE NOS:

\* 2009-0364

2009-0803

\* 2010-0036

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**PROPOSED DECISION**

STATEMENT OF THE CASE  
ISSUES  
SUMMARY OF THE EVIDENCE  
FINDINGS OF FACT  
DISCUSSION  
CONCLUSIONS OF LAW  
PROPOSED DISPOSITION

**STATEMENT OF THE CASE**

On July 20, 2010, the State Board of Physicians (Board) issued Amended Charges against Mark G. Midei, M.D., (Respondent) alleging violations of five sections of the Medical Practice Act, Title 14 of the Health Occupations Article of the Maryland Code (2009 & Supp. 2010): (1) Md. Code Ann., Health Occ. § 14-404(a)(3)(ii), prohibiting unprofessional conduct in the practice of medicine; (2) *Id.* § 14-404(a)(11), prohibiting the willful making of a false report or record in the practice of medicine; (3) *Id.* § 14-404(a)(19), prohibiting the gross overutilization of health care services; (4) *Id.* § 14-404(a)(22), prohibiting violation of the standards of care; and (5) *Id.* § 14-

**ATTACHMENT A**

404(a)(40), prohibiting the failure to keep adequate records.<sup>1</sup> The Board forwarded the Amended Charges to the Office of the Attorney General for prosecution.

I held a hearing on December 14, 16, and 17, 2010 and January 6, 7, 10, and 11, 2011 at the Hunt Valley, Maryland offices of the Maryland Office of Administrative Hearings (OAH). Md. Code Ann., Health Occ. § 14-405(a) (2009). Stephen L. Snyder, Esquire, Michael B. Snyder, Esquire, Scott A. Snyder, Esquire, Jason A. L. Timoll, Esquire, Daniel J. Miller, Esquire, Tomeka G. Church, Esquire, Jessie E. Cox, Esquire, Grant A. Posner, Esquire, all from the law firm of Snyder & Snyder, as well as Richard B. Bardos, Esquire, of Schulman, Treem, Kaminkow & Gilden, P.A. represented the Respondent, who was present.<sup>2</sup> Victoria H. Pepper, Assistant Attorney General and Administrative Prosecutor, represented the State of Maryland (State).

Procedure in this case is governed by the contested case provisions of the Administrative Procedure Act, the Rules of Procedure for the Board, and the Rules of Procedure of the OAH. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2009 & Supp. 2010); Code of Maryland Regulations (COMAR) 10.32.02; COMAR 28.02.01.

### ISSUES

The issues in this case are:

1. Did the State prove the alleged violations of the Medical Practice Act?
2. If the State proved a violation of the Medical Practice Act, what is the appropriate sanction?

### SUMMARY OF THE EVIDENCE

#### Exhibits

I attached an Exhibit List to this Proposed Decision.

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<sup>1</sup> The Amended Charges amended superseded the Charges the Board issued on June 7, 2010.

<sup>2</sup> Anthony Leon, Esquire, an attorney from Tarpon Springs, Florida, who is not admitted to practice in Maryland, sat at the trial table and assisted Mr. Snyder, but did not present any evidence or argument.

### Testimony

The State presented testimony from Matthews Chacko, M.D., who was accepted (without objection from the Respondent) as an expert in the field of interventional cardiology, including but not limited to the evaluation and management of patients with coronary artery disease, the diagnosis of coronary dysfunction, the performance of percutaneous coronary intervention (PCI), and the placement of coronary stents.

The Respondent testified and was accepted (without objection from the State) as an expert in the field of interventional cardiology. He also presented the testimony of William W. O'Neill, M.D., who was accepted (without objection from the State) as an expert in the field of interventional cardiology, and Stephen H. Pollock, M.D., who was not accepted as an expert.

### FINDINGS OF FACT

Having considered all of the evidence presented, I find the following facts by a preponderance of the evidence:

#### *The Respondent*

1. At all times relevant to this proceeding, the Respondent has been a licensed physician in the State of Maryland, practicing under license number D30042; his license has never been suspended or revoked.
2. The Respondent received his medical degree in 1981, served an internship at The Johns Hopkins Hospital (JHH) from July 1981 to June 1982, a residency at JHH from July 1982 until June 1984, a cardiovascular disease fellowship at JHH from July 1984 until December 1986, and an interventional cardiology fellowship at JHH from January 1987 to December 1987.
3. The Respondent is board-certified in Internal Medicine, Cardiology and Interventional Cardiology.

4. An interventional cardiologist is a physician trained and certified to perform diagnostic angiograms of patients with coronary artery disease and qualified to perform modification of a patient's coronary arteries through PCI.

5. The Respondent held privileges at St. Joseph Medical Center (SJMC), a community hospital, from 1991 until July 8, 2009, when his privileges were suspended by SJMC.

6. The Respondent was the Medical Director of the SJMC Cardiac Catheterization Lab (cath lab) from July 1995 until June 30, 1999.

7. On January 1, 2008, the Respondent was hired as a full-time employee of SJMC. He was a salaried employee of SJMC at all relevant times; he did not receive additional compensation for placing stents into patient's coronary arteries.

8. The Respondent has written numerous articles and some book chapters dealing with interventional cardiology topics.

9. The Respondent performed more than one thousand PCI procedures at SJMC during 2008.

*Matthews Chacko, M.D.*

10. Matthews Chacko, M.D. received his medical degree in 1998 from the University of Kansas, served an internship at JHH in 2001, completed a residency in cardiovascular disease at the Cleveland Clinic in 2005, and completed a fellowship in interventional, peripheral, and structural cardiac interventions at the Cleveland Clinic in 2007.

11. Dr. Chacko is board-certified in Internal Medicine, Cardiology and Interventional Cardiology.

12. Dr. Chacko practices interventional cardiology at JHH.

13. Dr. Chacko is licensed to practice medicine in the State of Maryland.

14. Since 2007 he has been an Assistant Professor of Medicine at The Johns Hopkins University Division of Cardiology, the Director of Peripheral Vascular Interventions, a member of the faculty of the Interventional Cardiology and Coronary Care Unit, and a member of the faculty of the Thaler Firm of the Osler Medical Service at JHH.

15. In the course of his current appointment at JHH, Dr. Chacko daily treats and evaluates patients with all forms of cardiovascular disease. This includes assessment of the patient's history, evaluation of any diagnostic testing, performance of diagnostic angiograms, and performance of interventional cardiology procedures, as well as pre- and post-surgical medical management of patients.

16. Dr. Chacko has performed substantially fewer percutaneous transluminal coronary angioplasty (PCTA) procedures and PCIs than either the Respondent or Dr. O'Neill.

17. Dr. Chacko has written numerous medical articles and presented various lectures in the field of cardiology and interventional cardiology.

18. Maximus, an independent entity that obtains peer reviewers for the Board, retained Dr. Chacko and paid him approximately \$1,400.00 to review 14 of the Respondent's cases and to prepare a report. (T. 441)<sup>3</sup>

19. Dr. Chacko was not paid by the State to testify at the hearings in this case.

20. In preparation for his peer review report and his testimony in this case, Dr. Chacko reviewed the records of Patients A through E obtained by the Board, which are contained in the State's exhibits, and the Board's Amended Charges. He did not meet or speak with the Respondent or any of the patients about the cases.

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<sup>3</sup> The transcript of the hearings in this case will be referred to by "T" followed by the page number.



21. After he prepared his report and prior to his testimony, Dr. Chacko read all of the exhibits in the State's exhibit binders.

*William W. O'Neill, M.D.*

22. Dr. O'Neill is licensed to practice medicine in Florida and Michigan.

23. Dr. O'Neill is board-certified in Internal Medicine, Cardiology, and Interventional Cardiology.

24. Dr. O'Neill graduated from medical school in 1977, completed an internship in Internal Medicine in 1978, a residency in Internal Medicine in 1980, and a fellowship in Cardiology in 1982.

25. Following his fellowship, Dr. O'Neill founded the Angioplasty Program at the VA Medical Center in Ann Arbor Michigan and served as the Director of the Cardiac Catheterization Laboratory at the University of Michigan for approximately five years.

26. He was an Instructor, Assistant Professor, and Associate Professor of Medicine at the University of Michigan Medical School from 1982 to 1987.

27. Dr. O'Neill was the Director of the Division of Cardiovascular Disease at William Beaumont Hospital from 1987 to 2006.

28. Dr. O'Neill has been the Co-Director of the Beaumont Heart Center since 1999.

29. Dr. O'Neill has authored over 300 peer-reviewed papers, 400 abstracts, and more than 40 book chapters.

30. Since 2006, Dr. O'Neill has served as the Executive Dean of Clinical Affairs at the University of Miami's Miller School of Medicine, where he is responsible for overall clinical operations and serves as a Professor of Medicine and a member of the Division of Cardiology.

31. Over his career Dr. O'Neill has performed thousands of interventional cardiology procedures, including PCTAs and PCIs.

32. Dr. O'Neill was one of the members of the Writing Committee that wrote the PCI Guidelines. (See Findings 82 - 85)(S. Ex. 18, p. 1)

33. The Respondent paid Dr. O'Neill \$30,000.00 for his participation in this case as an expert witness.

34. In preparation for Dr. O'Neill's written report, the Respondent and one of his attorneys, Mr. Leon, met with Dr. O'Neill. The Respondent told Dr. O'Neill symptom and history information about Patients A through E that is not contained in their medical records.

#### *The Board Investigation*

35. On November 12, 2008, the Board received a letter from an individual who identified him or herself as a new employee of SJMC (First Complaint). The author indicated a desire for anonymity. The letter stated: "I like (sic) to report medical fraud in regard to the unnecessary procedures by Dr. Mark G. Midei in St. Joseph Hospital, Towson, Maryland. He has performed stent procedures in the coronary (heart) arteries which have insignificant blockages." (S. Ex. 1) The author included a list of 36 patients with the corresponding dates of their procedures, ranging from July through November 2008.

36. Patients A through E were included in the list provided in the First Complaint, identified by medical record numbers and procedure dates.

37. On April 24, 2009, the Board received another letter (Second Complaint) from an individual who identified him or herself as the author of the First Complaint, identifying forty-one patients alleged to have received unnecessary stents from the Respondent, with the dates of their procedures ranging from November 2008 through February 2009. (S. Ex. 2)

38. On July 21, 2009, the Board received a report, required by law, from SJMC that the hospital had summarily suspended the Respondent's privileges.

39. On December 2, 2009, the Board issued SJMC a subpoena duces tecum requiring the hospital to immediately provide the Board with the medical records of twelve patients. (S. Ex. 4)

40. On December 7, 2009, the Board notified the Respondent that it had received a complaint against him. The letter enclosed a subpoena duces tecum requiring the Respondent to produce twelve patients' medical records. (S. Ex. 5)

41. The Board hired Maximus, an independent peer review organization, and sent Maximus the records that the Board had obtained in the course of its preliminary investigation of the Respondent.

42. Maximus hired Dr. Chacko and two other interventional cardiologists, Michael Sung-Chieh Chen, M.D. and Laurence Kelly, M.D., each of whom performed a peer review of a number of the Respondent's cases.

43. Maximus forwarded the three peer review reports to the Board.

44. The Board voted to issue the Charges and the Amended Charges against the Respondent.

#### *Heart Disease, Coronary Angiography, and Cardiac Interventions*

45. The human heart is divided into four chambers. It has two upper chambers which serve to fill the lower chambers called the ventricles, which are the pumping chambers that pump blood either to the lungs or to the heart. (T. 145)

46. The right side of the pumping chamber takes blood that lacks oxygen and pumps it to the lungs, which oxygenate the blood. The oxygenated blood returns to the left side of the

heart. The left ventricle is the pumping chamber that then delivers oxygenated blood to the rest of the body. (T. 145-46)

47. The heart typically has three arteries that perfuse the muscles that allow the heart to beat. The two arteries on the left originate as a common artery, the left main trunk. The left main trunk divides into two major branches that then comprise the left coronary artery. The left anterior descending artery travels down the anterior surface (front wall) of the heart, where it typically reaches and wraps around the apex or tip of the heart. (T. 146)

48. The other branch of the left coronary artery is the left circumflex artery. This artery generally perfuses the lateral wall (far left side) of the heart. (T. 146)

49. The right coronary artery originates from the opposite side of the aorta. It has several branches that feed the right side of the pumping chamber. It then continues around the back side of the heart where it usually terminates as two branches. (T. 146-47)

50. One branch of the right coronary artery is the posterior descending artery, which perfuses the back wall of the heart; the other is the posterolateral ventricular branch, which continues along the back surface of the heart. (T. 147)

51. Patients can have coronary artery disease (CAD) in any of the arteries; the left anterior descending artery (LAD) is a common site of disease.

52. The following terms/abbreviations are commonly used to refer to the parts of the heart:

- a. LAD – left anterior descending coronary artery;
- b. LCX – left circumflex coronary artery;
- c. RCA – right coronary artery;
- d. OM – obtuse marginal artery; and
- e. PDA – posterior descending artery.

55. CAD refers to atherosclerosis, the process of hardening of the arteries. (T. 148)

Over time fatty plaque builds up in the arteries and begins to obstruct the lumen (or inside) of the vessel that carries blood to the heart muscles. (T. 148)

56. In early CAD the vessel undergoes positive remodeling, a process whereby the vessel enlarges to accommodate increasing plaque volume. (T. 148)

57. When the artery can grow no more, the plaque buildup begins to close the artery, limiting the ability of the blood to flow through the vessel, and stenosis or narrowing of the lumen of the coronary artery occurs. (T. 149, 152)

58. The symptoms of stable CAD can be vague. Some patients have chest pain or tightness when exercising, during times of stress, or exertional shortness of breath. (T. 149)

59. Acute coronary syndrome refers to the condition when plaque ruptures, is exposed to the blood stream, and a clot forms at the site. (T. 150) In some cases of acute coronary syndrome, the body's own clot-busting system will overcome the clot and the artery will allow blood to flow through the area. (T. 150) In other cases, the patient suffers a myocardial infarction (heart attack) because the artery stays closed; if it is not reopened promptly, death or heart dysfunction can ensue. (T. 151)

60. Heart attacks include: (a) non-ST elevation myocardial infarction, in which plaque ruptures in a coronary artery, a clot forms in an artery, the body gets rid of the clot, and blood flows through the artery; and (b) ST segment elevation myocardial infarction, in which plaque ruptures in a coronary artery, a clot forms in the artery, and the artery stays closed (occluded). (T. 157-58)

61. A diagnosis of unstable angina is indicated if a patient has chest pain at rest, new chest pain, or chest pain that suddenly increases in severity or duration.

62. CAD is assessed in a variety of ways: (a) the patient's history; (b) examination of the patient; (c) electrocardiograms (EKG); (d) stress tests; and (e) cardiac CT angiography.

63. Cardiac CT angiography is a procedure that involves injection of dye material into the vein, providing images of the heart. (T. 154)

64. PCTA is performed in a hospital cath lab by an interventional cardiologist (also referred to as the "operator"). A coronary angiography involves inserting a catheter into an artery, usually in the leg, threading the catheter to the aorta, and using a set of catheters to engage the origins of the left main trunk and the RCA. Contrast material is then injected into the arteries that feed the heart and an x-ray tube creates a black and white real-time x-ray image of dye flowing through coronary arteries. (T. 155)

65. A diagnostic coronary angiogram is generally a safe procedure. (T. 156)

66. Intravascular ultrasound (IVUS) is a procedure that involves thinning the patient's blood during a catheterization, passing a guide wire down the artery, passing a catheter over the guide wire, and measuring the lumen or opening of the cardiac vessel. (T. 159-60)

67. Fractional flow reserve (FFR) is a procedure that, in effect, performs a stress test of the area of a coronary artery of concern. (T. 161) To measure FFR, the patient's blood is thinned, a coronary guide wire with a pressure sensor on it is passed beyond the narrowed area and a measure of the stress on the area is taken. *Id.*

68. At all relevant times, FFR was not available at SJMC; IVUS was available at SJMC, but the Respondent did not use it. (S. Ex. 14, p. 32)

69. The Respondent did not perform IVUS or FFR on Patients A – E.

70. Ischemia is lack of blood flow to part of the heart muscle. (T. 162)

71. A coronary stent is a mesh device folded up until it is inserted. Once placed in an artery, the stent is expanded to fill the diameter of the artery, and left in place to keep the artery open. The catheter is removed, then the guide wire is removed, and the stent becomes permanent. (T. 163-64)

72. A drug eluting stent is a stent coated with a drug that prevents re-stenosis.

73. The risks of stenting an artery include death, heart attack, stroke, thrombosis (blood clot), reactions to the contrast medium used in the procedure, coronary perforation, bleeding, and irregular heart beat. (S. Ex. 14, p. 37; S. Ex. 18, p. e9) A stent thrombosis, in which the clot closes off the vessel, has a high mortality rate.

74. The benefits of stenting a coronary artery include short-term reduction or elimination of angina and shortness of breath. Cardiac stents do not prevent heart attacks or extend life expectancy in patients with stable angina.

#### *Active clotting time (ACT)*

75. Blood clots can form on the wires and devices used during PCI, leading to an acute heart attack during the procedure. (T. 419)

76. In order to prevent the formation of blood clots, the operator administers a dose of Heparin, a blood thinner, to the patient before wires are inserted into the access artery, usually in the groin.

77. Heparin thins the patient's blood, reducing the risk of a blood clot. The ACT is measured by a blood test that determines how quickly the patient's blood clots. A cardiologist should not introduce a wire or other device into the patient unless an acceptable ACT is achieved; otherwise the patient's safety is jeopardized. (T. 215-16)

78. Lovenox is another blood thinning drug similar to Heparin.

79. A patient who has had a stent placed must take Plavix for a year following the procedure and aspirin for life to prevent a blood clot from forming at the stent. (T. 220-21; S. Ex. 14, p. 72)

80. The potential side effect of Plavix and aspirin is bleeding. (T. 222)

81. The Respondent did not measure the ACT of patients A through E prior to proceeding with the PCIs.

### *Guidelines*

82. In 2005, the American College of Cardiology Foundation, the American Heart Association, Inc., and the Society of Cardiac Angiography and Interventions issued a document entitled "ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention" (Guidelines) (S. Ex. 18)

83. The Guidelines define angina as follows: (a) Class I angina refers to chest discomfort that occurs only with very strenuous activity; (b) Class II angina refers to chest discomfort that mildly limits the ability of a patient to perform their usual activities; (c) Class III angina refers to chest discomfort that markedly limits the ability of a patient to perform their activities of daily living; and (d) Class IV angina refers to chest pain at rest. (T. 170-71)

84. The Guidelines state that PCI is reasonable for patients with Class I or Class II angina if there is a high likelihood of procedural success (of the PCI), the vessel to be dilated supplies a moderate to large amount of heart vessel, and there is a moderate to large amount of ischemia on noninvasive testing, such as a nuclear stress test. (T. 172-73)

85. The Guidelines provide that PCI is not recommended in: (a) patients with asymptomatic ischemia and insignificant disease, defined as less than 50% coronary stenosis; small area of heart muscle at risk; no evidence of objective ischemia; low likelihood of



successful dilation; and other factors specified in the Class III recommendations for Class I or II angina. (T. 173-74; S. Ex. 18, p. e40)

### *COURAGE*

86. The Clinical Outcomes Utilization Revascularization and Aggressive Drug Evaluation (COURAGE) trial, published in 2007, compared the results in patients who received intensive medical therapy with the results in patients who received PCI and intensive medical therapy. (T. 176)

87. The patients enrolled in the COURAGE study had angiographically 80% or greater stenosis or greater than 70% stenosis plus provokable ischemia on noninvasive testing. (T. 176)

88. One-fourth of the patients in the COURAGE trial who received stents had drug eluting stents implanted and three-fourths had bare metal stents implanted. (T. 616)

89. The COURAGE trial showed that there was no reduction in mortality, no reduced risk of myocardial infarction, and no significant long-term relief in angina between those who received stents with medical therapy and those who received only medical therapy. (T. 177-178)

90. As a result of the COURAGE trial, the number of PCI procedures and cardiac catheterizations decreased dramatically at most medical centers. (T. 178)

### *Patient A*

91. At all relevant times, Patient A was a sixty-two year old woman, whose date of birth is July 22, 1946.

92. Prior to her admission to SJMC, Patient A was treated by Chitrachedu Naganna, M.D., a cardiologist in Westminster, Maryland.

93. Patient A had a ten year history of chest tightness with exertion, relieved by rest in five to ten seconds; she had no symptoms of chest pain when she last saw Dr. Naganna.

94. Patient A did not have any change in her chest pain or experience chest pain while at rest. (T. 279-80; S. Ex. 7d, p. MM10995-97)

95. Patient A's family history included a mother who had a heart attack at age 46 (or 50) (and was still living), a father who died of congestive heart failure in his 70s, one brother who died at 53 of a heart attack, and that brother's 53-year-old identical twin brother with high blood pressure and high cholesterol. (S. Ex. 7d, p. MM10997)

96. Patient A was taking aspirin, Nitrostat (sublingual nitroglycerin prescribed to ease chest discomfort), and Nexium (for gastroesophageal reflux disease) prior to her admission to SJMC. Dr. Naganna started Patient A on Crestor, a cholesterol-lowering drug, on August 25, 2008.

97. On May 14, 2008, Patient A's EKG did not show any evidence of ischemia. (S. Ex. 7d, p. MM10999) She had average exercise tolerance and experienced chest discomfort during a stress test, which resolved during the test. *Id.*

98. Patient A had a cardiac CT angiogram performed on August 12, 2008 at Carroll Hospital Center. (S. Ex. 7b, p. MM10869-70) The results of that study indicated a calcium score of 277, significant calcified plaque in the proximal LAD, described in the CT angiogram report as 80%, and calcified plaque in the RCA about 30-40%. *Id.* The left ventricular function appeared normal on the CT angiogram.

99. Dr. Naganna referred Patient A to the Respondent on August 22, 2008 for cardiac catheterization to answer some of the patient and her husband's questions and to explain the findings of the August 12, 2008 CT angiogram. (S. Ex. 7b, p. MM10835-36) Dr. Naganna sent

the Respondent a detailed written report regarding Patient A. There was no mention of unstable angina in Dr. Naganna's report.

100. On August 29, 2008, the Respondent performed an elective PCTA on Patient A at SJMC and inserted a single drug eluting stent in Patient A's LAD. The entire procedure took approximately 25 minutes.

101. Patient A had at most a moderate calcification of the mid LAD; the stenosis was less than 50%.

102. There was no flow-limiting lesion or plaque rupture visible on Patient A's angiogram.

103. The Respondent administered 7,000 units of Heparin to Patient A at 10:03 a.m., did not obtain or record an ACT prior to proceeding with the PCI, and did not record an ACT in Patient A's medical records.

104. The Respondent did not consider that Patient A's medical therapy had just started and that a course of optimum medical therapy should be tried before implantation of a stent.

105. On August 29, 2008, the Respondent dictated a cardiac catheterization lab report (cath report) concerning Patient A in which he falsely noted that the indication for the angiography study was unstable angina and that Patient A had an 80% obstruction in the mid LAD. The Respondent did not refer to the cardiac CT in his cath report. (S. Ex. 7b, p. MM10852)

106. The Respondent wrote a report to Dr. Naganna on August 29, 2008, informing him that Patient A's "[c]atheterization revealed a heavily calcified mid LAD with an 80% obstruction. This was stented successfully." The Respondent did not include any reference to the cardiac CT in his report. (S. Ex. 7d, p. MM10982)

107. The Respondent did inform Dr. Naganna that he was using 80% as a proxy for a moderate lesion.

*Patient B*

108. At all relevant times, Patient B was a 77-year-old man, whose date of birth is December 9, 1930.

109. On September 10, 2008, after moving boxes at his church, Patient B experienced shortness of breath and became fatigued; Patient B did not have chest pain.

110. Patient B was examined by Dineshkumar Kalaria, M.D., a cardiologist in Westminster, at Dr. Kalaria's office on October 6, 2008. Dr. Kalaria reported that Patient B had an abnormal EKG, showing poor R-wave progression and mild ST segment elevation. (S. Ex. 8b, p. MM11158)

111. Dr. Kalaria started Patient B on a beta blocker and aspirin.

112. Patient B had a positive troponin<sup>4</sup> level of 0.117, negative creatine phosphokinase (CPK), normal blood chemistries, and no evidence of heart failure on his chest x-ray.

113. On Dr. Kalaria's recommendation, the patient was hospitalized at Carroll General Hospital on October 6, 2008. *Id.*

114. Dr. Kalaria started Patient B on aspirin, a statin, a beta-blocker, and Lisiniprol (a hypertension medication).

115. On October 7, 2008, Patient B received 80 mg of Lovenox, a blood thinner similar to Heparin, at Carroll General Hospital at 10:23 a.m. before being transferred by ambulance to SJMC for cardiac catheterization. (S. Ex. 8b, p. MM11163, 111206)

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<sup>4</sup> Troponin is an element of the contractile muscle apparatus of the cardiac muscle cell. When a heart muscle cell dies, troponin can be measured in the blood. (T. 318)

116. The Carroll General Hospital transfer summary, which was included in the records from the Respondent's files provided to the Board pursuant to a subpoena, included the notation: "wait 12 hours after full-dose Lovenox before giving SQ or Heparin drip; high alert drug; do not administer Lovenox within 2 hours of Heparin." (S. Ex. 8b, p. MM11206)

117. Upon Patient B's admission to SJMC, Sidney O. Gottlieb, M.D., a staff cardiologist, took a history and performed a physical. (S. Ex. 8b, p. MM11169) Dr. Gottlieb reported that the patient had mild chest discomfort. *Id.* The reasons for the admission included progressive angina and elevated cardiac enzymes. *Id.* Cardiac enzymes were negative according to the lab work performed at SJMC. (S. Ex. 8c, p. MM11234)

118. On October 7, 2008, the Respondent performed a coronary angiography on Patient B at SJMC and inserted a single drug eluting stent in Patient B's LAD. The entire procedure took approximately 36 minutes.

119. The Respondent administered 6,000 units of Heparin to Patient B at 1:34 p.m. and did not obtain or record the ACT in Patient B's medical records. (St. Ex. 8b, p. MM11188)

120. On October 7, 2008, the Respondent dictated a cath report concerning Patient B in which he noted that the procedure was performed that day. The indications for the study were noted as "unstable angina" and "elevated enzymes." (S. Ex. 8b, p. MM11164) The Respondent recorded that Patient B had a 30% obstruction proximally and an 80% obstruction in the mid LAD. *Id.*

121. The patient did not have an 80% obstruction in the LAD; the obstruction was in the moderate range, i.e., less than 80%.

122. The Respondent wrote a report to Dr. Kalaria on October 7, 2008, explaining that “catheterization revealed critical LAD disease for which stenting was performed.” (S. Ex. 8d, p. MM11336)

*Patient C*

123. At all relevant times, Patient C was a 63-year-old man, whose date of birth is July 8, 1945.

124. Patient C had stents placed in the LAD and RCA on March 12, 2007 by another doctor.

125. Dr. Pollock was Patient C’s cardiologist.

126. On September 10, 2008, Patient C came to the SJMC emergency room with symptoms of new chest pain, which he described as similar to those he experienced prior to having the 2007 stents inserted.

127. Dr. Gottlieb took Patient C’s history and performed a physical in the emergency room at SJMC on September 10, 2008. Patient C told Dr. Gottlieb that over the previous week he had experienced increasing dyspnea, or shortness of breath, with minor physical activity. He also told Dr. Gottlieb that he had chest pain at rest for about 15 minutes that morning. (S. Ex. 9b, p. MM11496)

128. Patient C had a normal EKG, negative cardiac enzymes, normal complete blood count (CBC), and normal chemistries. (S. Ex. 9b, p. MM11497)

129. On September 10, 2008, the Respondent performed an emergency PCTA on Patient B at SJMC and inserted three drug eluting stents: one in Patient C’s LAD past the previous stent site; and two in his RCA next to the 2007 stent. The entire procedure took approximately 37 minutes.

130. The Respondent administered 6,000 units of Heparin to Patient C at 1:27 p.m. and did not obtain or record the ACT in Patient C's medical records. (St. Ex. 9b, p. MM11520)

131. On September 10, 2008, the Respondent dictated a cath report concerning Patient C in which he noted that the indication for the study was "unstable angina." (S. Ex. 9b, p. MM11473) The Respondent inaccurately recorded that Patient A had an 80% obstruction in the LAD and an 80% obstruction in the RCA. *Id.*

132. Patient C had a mild stenosis (less than 50%) in the LAD and a mild to moderate (less than 50%) stenosis in the RCA. (T. 361-62)

133. The previous stents in the LAD and RCA were patently open with no filling defect. (T. 363)

134. There was no flow limiting lesion, thrombus or plaque rupture in Patient C's arteries.

135. The Respondent did not consider whether aggressive medical therapy for an acute coronary syndrome would be the most prudent course of therapy. (T. 363)

#### *Patient D*

136. At all relevant times Patient D was a 67-year-old man, with a date of birth of September 23, 1941.

137. Patient D's cardiologist, Ketan P. Parikh, M.D., of Westminster, Maryland, referred Patient D to SJMC for cardiac catheterization on September 20, 2008. (S. Ex. 10b, p. MM12084)

138. Patient D had a history of coronary atherosclerosis, hypertension, and dyslipidemia. He reported to Dr. Parikh that he had discomfort in his chest from time to time

since age 30, with or without activity. The chest discomfort resolved in a few minutes with an antacid. (S. Ex. 10b, p. MM12084)

139. Patient D had a significant family history of CAD: his father died of coronary artery disease at age 54, his mother had a cardiopulmonary arrest at age 74, his brother had a stroke at age 69 and coronary artery disease at 71, another brother had a heart attack at 64, another brother had CAD at age 61, and a fourth brother had CAD at age 30. (S. Ex. 10b, p. MM12084)

140. Patient D had an Echocardio study performed on January 4, 2005, which showed left ventricular ejection fraction<sup>5</sup> of 65% with trace mitral and tricuspid regurgitation and mild pulmonary hypertension. (S. Ex. 10b, p. MM12085)

141. Patient D had a Cardiolute stress test performed on March 28, 2005, which did not show any abnormalities. He walked on a treadmill using the Bruce protocol for 7 minutes and 30 seconds reaching 92% of his maximum age-predicted heart rate without EKG changes. (S. Ex. 10b, p. MM12085; T. 374-75)

142. Patient D had cardiac catheterization at Carroll General Hospital on March 15, 2007, which showed mild irregularities of the LAD. (S. Ex. 10b, p. MM12085)

143. On September 30, 2008, Dr. Parikh recommended that Patient D take aspirin, consider treatment with ACE inhibitors, and modify his diet to lower cholesterol. (S. Ex. 10b, p. MM12085)

144. During the first two weeks of October 2008, Patient D's symptoms of lightheadedness and dizziness worsened and he consulted Dr. Parikh. (S. Ex. 10b, p. MM12086)

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<sup>5</sup> Left ventricular ejection fraction, a measure of the proportion of blood that is ejected with each beat of the heart, is considered normal at about 60-65%. (T. 196)



145. Patient D had an exercise Myoview stress test on October 13, 2008. He walked on the treadmill for four minutes, 55 seconds, achieving 81% of his maximal age-predicted heart rate. (T. 378) Patient D was experiencing lightheadedness and dizziness, but no chest pain, pressure, or shortness of breath. *Id.* Perfusion to the nuclear images showed a small area of minimal to mild inferolateral ischemia.

146. Inferolateral ischemia refers to the interior surface of the heart, and usually indicates a malperfusion in the RCA or the LCA, depending on how the patient's circulation is configured. (T. 378-79)

147. Dr. Parikh recommended that the patient have cardiac catheterization, and the patient told his doctor that he wanted to have the test completed the following day. Dr. Parikh contacted the Respondent, who agreed to perform it. (S. Ex. 10b, p. MM12087)

148. Patient D was admitted to SJMC on October 16, 2008 for a cardiac catheterization. (S. Ex. 10b, p. MM12069)

149. On October 16, 2008, the Respondent performed an elective PCTA on Patient D at SJMC and inserted one drug eluting stent in the LAD. (S. Ex. 10b, p. MM12101) The entire procedure took approximately 20 minutes.

150. On October 16, 2008, the Respondent dictated a cath report in which he recorded the indication for the study as unstable angina. (S. Ex. 10b, p. MM12101) The Respondent documented that he performed a left heart catheterization, coronary arteriography, and LAD angioplasty and stenting. *Id.* The Respondent reported that there was an 80% obstruction proximally in the LAD and a 50% obstruction in the junction between the mid and distal portions of the LAD. (S. Ex. 10b, p. MM12101)

151. Patient D had a mild to moderate nonobstructive coronary atherosclerosis in the LAD; the stenosis was 30% to 50%. (S. Ex. 13, p. 7; T. 389)

152. The Respondent administered Heparin 6,000 units at 12:04 p.m. and failed to obtain or record Patient D's ACT. (S. Ex. 10b, p. MM12105)

153. On October 16, 2008, the Respondent wrote a report to Dr. Parikh, stating that Patient D had "a history of borderline coronary disease dating back two years ago and recurrence of symptoms associated with anteroseptal ischemia." (S. Ex. 10c, p. MM12188) The Respondent further reported that "[c]atheterization revealed critical proximal LAD disease along with borderline mid LAD disease." (S. Ex. 10c, p. MM12188)

154. Anteroseptal ischemia refers to the front wall of the heart that is typically supplied by the LAD. (T. 382)

155. There is no reference to anteroseptal ischemia in Patient D's medical records prior to the Respondent's October 16, 2008 report.

#### *Patient E*

156. At all relevant times Patient E was a 69-year-old woman, with a date of birth of September 7, 1938. (S. Ex. 11a, p. MM12706)

157. On July 15, 2008 Patient E was seen by Ketan P. Parikh, M.D., a cardiologist in Westminster, Maryland. She reported that she experienced left neck and shoulder pain with left arm numbness. The patient's father had a heart attack in his early 70s and had open heart surgery in his 70s. (St. Ex. 11a, p. MM12722)

158. The patient had an EKG performed on July 7, 2008, which showed sinus rhythm with nonspecific changes. (S. Ex. 11a, p. MM12722)

159. Patient E had an exercise Myoview stress test performed on July 7, 2008, during which she walked on the advanced Bruce protocol for 3 minutes reaching 90% of her maximal age predicted heart rate. Perfusion images showed small mild anterior reversible ischemia with normal wall motion. Her ejection fraction was 69%. (S. Ex. 11a, p. MM12722)

160. Dr. Parikh started the patient on aspirin, Bystolic (a beta-blocker), and scheduled her for cardiac catheterization. (S. Ex. 11a, p. MM12722)

161. On July 16, 2008 the Respondent performed a left heart catheterization and coronary angiography. He placed one stent in Patient E's RCA. (St. Ex. 11a, p. MM12740) The procedure lasted 34 minutes. (S. Ex. 11a, p. MM 12744-45)

162. The Respondent administered 6,000 units of Heparin to Patient E and failed to obtain or document the ACT. (S. Ex. 11a, p. MM12744)

163. On July 16, 2008, the Respondent dictated a cath report regarding Patient E. (S. Ex. 11a, p. MM12740) He noted that the indications for the study were unstable angina and a positive exercise stress test. *Id.* The Respondent documented that there was an 80% obstruction in the RCA proximally. *Id.*

164. Patient E did not have an 80% stenosis in the RCA; the stenosis was in the range of 30% to 40%.

165. On July 16, 2008, the Respondent wrote a report to Dr. Parikh, in which he stated that the patient had "significant obstruction in the mid RCA." (S. Ex. 11b, p. MM 12883) The Respondent did not characterize the obstruction with any percentage of occlusion.

*The St. Joseph Medical Center Peer Review Process*

166. At all relevant times, the Respondent was a salaried employee of SJMC; he did not receive any additional compensation for placing a stent in a patient.

167. Following receipt of a complaint, SJMC retained Donald Cutlip, M.D., Director of The Cardiac Catheterization Lab in the Cardiology Institute at Beth Israel Deaconess Medical Center in Boston, Massachusetts, as a consulting angiographer, to review the records of sixteen of the Respondent's patients and provide a report to the SJMC Credentials Committee, a committee of SJMC.

168. The twelve members of the Credentials Committee members were all physician peers of the Respondent and members of the SJMC medical staff. (S. Ex. 14, p.3)

169. Dr. Cutlip reviewed the cardiac cath reports, cardiac cath films and medical records for sixteen of the Respondent's patients. (S. Ex. 14, p. 4, 11)

170. Dr. Cutlip reported to the SJMC Credentials Committee that, in his opinion, the Respondent significantly overestimated the degree of stenosis in seven cases, may have met the standard of care in four cases, and met the standard of care in five cases. Dr. Cutlip also reported that there were inconsistencies in the Respondent's medical documentation. (S. Ex. 14, p. 4)

171. The Respondent was provided access to the patients' records and an opportunity to respond to Dr. Cutlip's findings. The Respondent explained why he placed stents in the patients, making reference to the patients' clinical histories, symptoms, and the Guidelines. (S. Ex. 14, p. 4)

172. On or about May 12, 2009, the administrators at SJMC asked the Respondent to cease all activity at the SJMC cath lab and to stay home on paid time off while issues raised regarding quality of care in the cath lab were being investigated. (S. Ex. 14, p. 4) The Respondent agreed to do so. (S. Ex. 14, p.7)

173. On May 26, 2009, the Credentials Committee voted to recommend to the SJMC Medical Executive Committee (MEC) that a broader investigation of the Respondent's cases be initiated.

174. The MEC members consist of nineteen physicians, each of whom is a member of the SJMC medical staff, and the Interim Chief Operating Officer and Interim Chief Executive Officer of SJMC, neither of whom is a physician. (S. Ex. 14, p. 6)

175. On May 28, 2009, the MEC accepted the Credentials Committee's recommendation, retained the American Medical Foundation for Peer Review and Education (AMF), an independent peer review organization, to conduct an independent peer review of the Respondent's practice, and ordered AMF to review a larger sample of the Respondent's cases.

176. Four independent interventional cardiologists retained by AMF reviewed 157 of the Respondent's cases. (S. Ex. 14, p. 56)

177. On May 28, 2009, the MEC appointed an Ad-Hoc Investigative Committee (AHIC) to review the Respondent's cases and the operation of the SJMC cath lab.

178. The members of the AHIC included the following: Gail Cunningham, M.D., Chair; Harry Brandt, M.D., President of the SJMC Staff; Margaret (also referred to as Alma) Lynch-Nyhan, M.D., SJMC Department of Radiology; David Brinker, M.D., SJMC Department of Pathology; and James Kleeman, M.D., SJMC Department of Medicine. (S. Ex. 14, p. 10)

179. From June 19 to 21, 2009, four independent interventional cardiologists retained by AMF reviewed the medical records of 100 to 150 of the Respondent's patients.

180. The AHIC permitted the Respondent to review the medical records of the sixteen patients before he met with the AHIC to discuss his treatment of these patients.

181. The AHIC met with the Respondent and his attorney on June 29, 2009, and permitted him to make a statement regarding the investigation, the Sentinel case, and the cases which Dr. Cutlip found problematic. The Respondent explained to the AHIC that he used 70%, 80% and 90% as “surrogate” or “default” numbers to indicate mild, moderate and severe levels of stenosis or blockage of the artery, respectively. (S. Ex. 14, p. 35-36)

182. The AHIC reviewed the result of the AMF review, interviewed the AMF interventional cardiologists who performed the review of the Respondent’s cases, and interviewed the Respondent for a second time. Each of the AMF reviewers was a board certified interventional cardiologist and the Director of a hospital cath lab.

183. The AMF reviewers prepared a written report to the AHIC stating their findings that the Respondent often overestimated the degree of occlusion that he saw during cardiac catheterizations, resulting in percutaneous interventions which were not clinically indicated. (S. Ex. 14, p. 71) The AMF doctors also reported that there were deficiencies in the Respondent’s documentation, and that he failed to obtain ACT levels prior to the start of intervention. *Id.*, 71-72.

184. Based upon all of the information obtained during its investigation, the AHIC recommended that the MEC authorize a summary suspension of the Respondent’s medical staff privileges. (S. Ex. 14, p. 73)

185. On July 8, 2009, the MEC summarily suspended the Respondent’s Medical Staff membership and clinical privileges. (S. Ex. 14, p. 79)

186. Under the SJMC Medical Staff Bylaws, the Respondent had the right to a hearing to contest his suspension.

187. SJMC management made it clear that the hospital would not allow the Respondent to return to his practice there.

188. Rather than contest his suspension under the Medical Staff Bylaws, on November 18, 2009, the Respondent and SJMC entered into an Agreement and Release (R  lease). The MEC terminated the summary suspension, the Respondent resigned from the Medical Staff, and SJMC agreed to give the Respondent a neutral letter of reference, i.e., a letter indicating the dates of his employment.

#### *Overutilization of Health Care Services*

189. A diagnostic PCTA costs the patient (or the responsible third party) approximately \$250.00 for the physician's service and approximately \$4,500.00 to \$5,000.00 for the hospital's service.

190. A PCI costs the patient (or the responsible third party) approximately \$690.00 to \$720.00 for the physician's service and approximately \$10,000.00 to \$15,000.00 for the hospital's service.

### **DISCUSSION**

The Board may reprimand any licensee, impose probation, or suspend a license of the licensee for any violation of section 14-404(a). Md. Code Ann., Health Occ.   14-404(a) (Supp. 2010). This provision establishes the underlying authority for, and the necessary legal elements of, the Amended Charges in this matter.

The Board charged the Respondent with violating the following sections of the Medical Practice Act:

**§ 14-404. Denials, reprimands, probations, suspensions, and revocations – Grounds.**

(a) *In general.* Subject to the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of the quorum, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:

- ... (3) Is guilty of ... (ii) unprofessional conduct in the practice of medicine;
- ... (11) Willfully makes or files a false report or record in the practice of medicine;
- ... (19) Grossly overutilizes health care services;
- ... (22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State; and
- ... (40) Fails to keep adequate medical records as determined by appropriate peer review....

The State, as the moving party, has the burden to prove: (1) appropriate standards as determined by appropriate peer review; and (2) failure to meet those standards. Md. Code Ann., Health Occ. § 14-405(b)(2) (2009); Md. Code Ann., State Gov't § 10-217 (2009); *Comm'r of Labor and Indus. v. Bethlehem Steel Corp.*, 344 Md. 17, 34 (1996) citing *Bernstein v. Real Estate Comm'n*, 221 Md. 221, 231 (1959). *See also Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005). The standard is the preponderance of the evidence. *Md. Board of Physicians v. Elliott*, 170 Md. App. 369, 433-34 (2006), *cert. denied* 396 Md. 12 (2006).

The Board charged the Respondent with violating the Medical Practice Act in his care of five patients at SJMC. It alleged that the Respondent placed stents in the patients in violation of the standard of care. The alleged violations vary in each patient's case, but a general summary is necessary at this point to provide context.



The State contends, among other things, that the Respondent failed to accurately document the clinical symptoms that led to his decision to place a stent, exaggerated the degree of stenosis and used this as a clinical justification for the placement of stents, unnecessarily placed stents in five patients' coronary arteries, failed to consider other, non-invasive treatments for the patients' coronary artery disease, and failed to obtain and document ACT prior to the start of PCI procedures. The State asks that I recommend that the Board revoke the Respondent's license to practice medicine.

The Respondent contends that the Board was misled by SJMC into charging him with violations of the Medical Practice Act. The Respondent contends that SJMC was the subject of a federal investigation into alleged criminal activities at the hospital and the management of SJMC summarily suspended him in order to cast the blame on him and away from the true target of the investigation, SJMC. The Respondent alleges that the peer review conducted by SJMC was flawed and conducted in bad faith with a predetermined goal – to blame the Respondent for the conduct giving rise to the federal investigation. As discussed below, these contentions are not pertinent to the issues before me.

The Respondent also denies each and every one of the charges leveled against him by the Board. He contends that any differences between the cath reports that he dictated and the degree of stenosis seen on the angiograms in evidence are the result of stenosis inflation and operator variability. He denies that he intentionally exaggerated the degree of stenosis in any of the five patients. The Respondent contends that the treatment he rendered accorded in every respect with the standard of care for the placement of stents and the documentation of medical treatment. The Respondent asks that I recommend dismissal of all of the charges.

### *1. The Expert Witnesses*

Three experts testified in this case: Dr. Chacko, Dr. O'Neill, and the Respondent.<sup>6</sup> Dr. Chacko testified as the State's sole witness. Without a doubt, Dr. Chacko has far less experience in interventional cardiology than either Dr. O'Neill or the Respondent. Notwithstanding that, Dr. Chacko was confident in his opinions. I found Dr. Chacko's explanation of the process of CAD, the procedures used in PCI, and the standard of care for PCI to be soberly-considered, well-informed and persuasive. He was thoroughly knowledgeable about the Guidelines and the COURAGE study. Dr. Chacko was able to explain complex medical terms and procedures in a manner that a layperson could understand. Dr. Chacko's demeanor in this case was a model of professional decorum. Dr. Chacko conducted a thorough review of the available records. He prepared an accurate, succinct, compelling report of the facts he considered in forming his opinion.

Dr. Chacko was subjected to unacceptable harassment and intimidation by Mr. Snyder, the Respondent's attorney. On the first day of the merits hearing, Mr. Snyder approached Dr. Chacko in the hallway at OAH and made statements to him that were rude, insulting, and intended to intimidate Dr. Chacko. When this was brought to my attention, I noted it on the record and chastised Mr. Snyder, who apologized (after his attempt to downplay his behavior failed); Dr. Chacko calmly and sincerely accepted Mr. Snyder's apology.

Throughout Dr. Chacko's testimony, Mr. Snyder repeatedly interrupted, attempted to confuse, demean, and bully him, and made subtly threatening comments to him. Mr. Snyder's many attempts to rattle Dr. Chacko were unsuccessful. I found Dr. Chacko to be extremely knowledgeable and thoroughly professional. He never became agitated, no matter how many

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<sup>6</sup> Dr. Knopf's report was admitted into evidence, but he did not testify. As Dr. Knopf was not accepted as an expert and was not subject to examination, I gave his report no weight.

times Mr. Snyder insulted him. When Mr. Snyder asked Dr. Chacko a question which assumed facts not in evidence or misstated his testimony, Dr. Chacko quickly and dispassionately corrected him. When a lawyer asking the questions became confused about the symptoms and treatment of the five patients at issue, Dr. Chacko had complete, accurate recall of all of the relevant facts. Dr. Chacko did not exhibit any animus toward the Respondent, and he acknowledged the Respondent's status in the medical community. For all of these reasons, I have given Dr. Chacko's testimony great weight.

As discussed later in this Proposed Decision, at times I found Dr. O'Neill's testimony contradictory and evasive.<sup>7</sup> Dr. O'Neill, who has a long and distinguished career in interventional cardiology, testified at length on matters that are not relevant to this case. He was quite passionate in his description of the unfairness of the SJMC peer review process to the Respondent. He was also obviously moved by what he perceived as the injustice of revoking the Respondent's license to practice medicine in Maryland, both in terms of the devastating effect that a revocation would have on the Respondent, for whom medicine is a life's work, and the loss of the Respondent's skills to patients in the future.

While I respect Dr. O'Neill's experience and I believe that he offered these views in good faith, I have to decide the case before me. This is not a hospital peer review proceeding or a criminal prosecution.<sup>8</sup> Although some of Dr. O'Neill's views are relevant to the sanction to be proposed to the Board, they do not, in my view, have any relevance to the issue of whether the State has proven the allegations in the Amended Charges.

Dr. O'Neill spent very few minutes testifying about the patients' individual cases. As a

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<sup>7</sup> For example, Dr. O'Neill testified on direct that four of the patients had intermediate lesions and one had a severe lesion. (T. 1117) On cross-examination, Dr. O'Neill corrected himself, agreeing with Ms. Pepper that all five patients had moderate or intermediate lesions. (T. 1171)

<sup>8</sup> Dr. O'Neill discussed his work with the FBI in a criminal investigation and his opinion about the Duke lacrosse rape investigation; this testimony was not relevant to this administrative proceeding.

result, I did not give much weight to his opinions on the treatment of those patients.

Likewise, the Respondent spent very little time discussing the individual patients. Many of the questions that Mr. Snyder posed to the Respondent in that area were leading. The Respondent has an obvious bias in this case. For those reasons I gave the Respondent's testimony on the treatment of the patients less weight than Dr. Chacko's.

I did not observe anything else about the experts' demeanor during the hearing which affected my decision about their credibility. *See State Board of Physicians v. Bernstein*, 167 Md. App. 714 (2006).

It is well accepted that "the data used by an expert to reach an opinion is very important in determining what, if any, weight to afford the opinion." *Taylor v. State*, 407 Md. 137, 175 (2009) (Bell, J., dissenting). Dr. Chacko reviewed all of the records regarding the patients collected by the Board, viewed the angiogram studies of the procedures, and wrote his own report. He did not speak with the Respondent or any of the patients, although he conceded that doing so would have resulted in a more thorough report.

Dr. O'Neill reviewed the same records and met with the Respondent, Dr. Knopf, and Mr. Leon, an attorney from Florida, prior to issuing his report. Dr. O'Neill also included information provided by the Respondent during this meeting in his report and referred to it in his testimony, particularly history and symptom information about each of the patients, some of which was not contained in their medical records. Each of Dr. O'Neill's "Clinical Information" sections of his report begins, "[f]rom interacting with [the Respondent] and reviewing the records...." (Resp. Ex. 16, p. 7, 9, 11, 12, 14)(emphasis supplied).

The Respondent testified from alleged memory about Patients A - E's symptoms and history, providing information that was not contained in any of the referring physicians' files or

the reports of testing performed prior to the PCI procedures. This is the information the Respondent told Dr. O'Neill during their meeting.

I have given the undocumented information about the Patients' symptoms and history no weight. The Respondent performed a high volume of procedures every year, estimated to be 1250 annually. There was nothing remarkable about these five patients, i.e., none of them experienced death, uncontrolled bleeding, or any other unusual complications. None of the patients sued or threatened to sue the Respondent. As an interventional cardiologist, the Respondent did not have an ongoing relationship with the patients; he saw them only when he performed the coronary angiography and inserted the stent. In each case, the procedure was very brief, lasting less than 45 minutes. I do not believe that the Respondent could reliably recall undocumented specifics about these patients' histories and symptoms one to two years later. I have given no weight to the portions of the Respondent's and Dr. O'Neill's testimony about the patients' histories and symptoms that were not documented by test results or by other doctors in the medical records.

## *2. The Standard of Care*

There is no single document providing the standard of care for PCI. As in most aspects of the medical field, the standard of care is a combination of many factors. In this case, however, one document played a prominent role in describing the standard of care. The Guidelines, a report published by the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (S. Ex. 18), has the following statement of purpose:

The practice guidelines produced are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. **These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific**

**evidence and are intended to improve patient care.** If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.

(S. Ex. 18, p. e9)(emphasis added).

The effect of the Guidelines was disputed. Dr. Chacko testified that the Guidelines contribute to but do not provide the sole basis for the standard of care in PCI. Dr. O'Neill, who participated in writing the Guidelines, maintained that they did not establish the standard of care for PCI. He wrote:

One cannot merely look at the ACC Guidelines as black and white determinations of whether the applicable standards of care were met in a particular case because the ACC Guidelines are just that – guidelines. The ACC Guidelines themselves expressly recognize this guiding principle:

[t]hese guidelines are to be viewed as broad recommendations to aid in the appropriate application of PCI. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment.

(Resp. Ex. 16, p. 4, quoting the Guidelines, S. Ex. 18, p. e169)

The Respondent contended that he followed the Guidelines in his care of these patients. On December 17, 2009, the Respondent's then-attorney wrote a letter to Danielle Sutton, Compliance Analyst for the Board, explaining the Respondent's treatment decisions. (S. Ex. 7a, p. MM10813) The Respondent signed the letter, indicating that he approved its content. In describing his care of the patients, the Respondent noted that "[a]ll of the cases were performed under the guidelines that existed at the time as published by the American College of Cardiology in 2005." (S. Ex. 7a, p. MM10814)<sup>9</sup>

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<sup>9</sup> The Respondent was commenting in that letter on Patients A through C; Patients D and E were not addressed in the letter to Ms. Sutton.

When he explained his treatment of the patients to the AHIC, the Respondent told the committee that he was aware of and attempted to follow the Guidelines in his practice. (S. Ex. 14, p. 37.) I conclude that at all relevant times, the Guidelines contribute, along with other evidenced-based research and peer-reviewed medical literature, to form the applicable standard of care for PCI.

The COURAGE trial, published in 2007, is another important component of the standard of care. Dr. O'Neill acknowledged that the study "changed the field of cardiology." (T. 1062) Dr. Chacko and Dr. O'Neill agreed that the study informs cardiologists that, in cases of intermediate occlusions of coronary vessels, a stent plus optimal medical therapy has no advantage over medical therapy alone. (T. 177-78, 1062)<sup>10</sup> In patients with intermediate stenosis, the COURAGE study informed cardiologists that stents (plus medical therapy) do not reduce the risk of a heart attack, do not improve long-term angina relief, and do not improve survival. (T. 178) Optimal medical therapy is defined as medication and life style changes, such as weight loss, exercise, and dietary changes. (T. 1192)

Dr. O'Neill testified that the COURAGE study resulted in a 15% decline in stents nationwide; Dr. Chacko agreed that the number of PCI procedures "went down dramatically at most centers" after the COURAGE study was published. (T. 178, 1062) At the time in 2008 when the Respondent performed the PCI procedures on these five patients, the 2005 Guidelines and the COURAGE study formed a part of the applicable standard of care.

Regarding medical record-keeping, it is undisputed that the standard of care requires a physician to accurately document the indications for a PCTA and PCI, the findings made during the procedures, and the reason for the insertion of a stent. It is further undisputed that

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<sup>10</sup> The COURAGE study does not apply to patients with unstable angina.

interventional cardiologists use 80% to describe a severe stenosis, not a moderate or intermediate stenosis.

### *3. The Respondent's Cath Reports*

#### *a. 80% Stenosis*

In each of the five cases under investigation, the Respondent created a cath report, which served as his entry into the formal patient record. In each cath report, the Respondent recorded that he found and stented an 80% stenosis in one (or more) of the patient's coronary arteries and that unstable angina was one of the indications for the procedure.

The Respondent had a personal practice of using 70%, 80% and 90% as surrogates to describe mild, moderate (or intermediate), and severe coronary vessel occlusions (stenosis or blockage), respectively. Before the AHIC investigation, the Respondent did not tell anyone he was using this method of recording stenosis. At the hearing, the Respondent provided no explanation why he chose these numbers. I conclude that the Respondent's practice violated the standard of care in the medical profession that requires an interventional cardiologist to accurately record in the medical record the extent of any stenosis observed during a procedure.

Dr. Chacko and Dr. O'Neill agree that there is no standard of care requiring an interventional cardiologist to describe the severity of a lesion in a particular way; they agree that the standard of care requires an interventional cardiologist to describe the patient's stenosis as accurately as possible. (T. 559) Interventional cardiologists recognize that any visual estimate is inexact. Research has shown that an observer's estimate of the degree of stenosis in a vessel with an intermediate occlusion often varies as much as 20% from the degree of occlusion measured in



a laboratory.<sup>11</sup>

Recognizing that fact, the standard of care requires doctors to use adjectives such as mild, moderate and severe to describe lesions, or to refer to ranges of percentages. Dr. Chacko testified that most operators would understand an 80% stenosis to be severe. (T. 421) He further testified that he has never heard of anyone using the percentage system that the Respondent employed and that, by the Respondent's method, nearly every patient would receive a stent because interventional cardiologists consider a 70% occlusion as the high end of an intermediate lesion, bordering on severe. (T. 522)

Dr. O'Neill testified that any percentage estimation of stenosis is inexact, and for twenty years he has taught that cardiologists should never use percentages. (T. 1072) In his opinion, providing a percentage degree of stenosis is improper because it is misleading and assumes a level of accuracy that does not exist. *Id.* Dr. O'Neill considers any single percentage number to be "silly." (T. 1073)

Surprisingly, Dr. O'Neill testified that, although he met and had extensive discussions with the Respondent, they never discussed the Respondent's proxy method. (T. 1160) Although, in general, I found Dr. O'Neill to be responsive to questions asked at the hearing, in this area he did not answer directly, fully, and truthfully. For example, Ms. Pepper and Dr. O'Neill had the following exchange:

**Q. [referring to Dr. O'Neill's expert report in this case] In the second paragraph, you indicate that you had spent extensive time with [the Respondent] reviewing patient films and getting his thought process. Is that a fair representation of that paragraph?**

A. Yes

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<sup>11</sup> This principle does not apply to other types of occlusions; most interventional cardiologists viewing a coronary artery with no stenosis, a totally occluded artery, and arteries with mild or severe stenosis would agree with the diagnosis of the degree of occlusion. The difficulty comes in estimating the degree of stenosis of an intermediate lesion, i.e., the mid-range of 30 to 70%.

**Q. At that time, were you aware of his use of surrogate or default percentages in his records?**

A. We talked about it. We tried to understand what he was referring to, and it was a – it was a practice that’s common. People use percentages, knowing that there’s no scientific basis behind that, but inferring from that. And he was doing things that basically were being done as a widespread practice in the field.

...

**Q. Are you aware that he was using 70 percent, for instance, to indicate a mild stenosis and 80 percent to indicate an – in his own mind, an intermediate stenosis, and 90 percent to be a severe stenosis?**

A. No. We never got into that discussion. (T. 1159-60)

In this exchange Dr. O’Neill contradicted himself, first saying he and the Respondent discussed the surrogate or default percentages and then saying that he did not know about the Respondent’s percentage system. In the follow-up exchange with Ms. Pepper, Dr. O’Neill equivocated and evaded, indicating to me that Dr. O’Neill knows the Respondent’s use of the surrogate or default percentages was a violation of the standard of medical care.

The Respondent never gave a satisfactory answer to the question of why he wrote 80% on all five cath reports. Even at the AHIC, after he reviewed the records of Patients A through Patient C, including the angiography videos, and met with the AHIC to explain his treatment decisions, the Respondent was at a loss to explain his method. The AHIC and the Respondent agreed to limit their in-depth discussion to the patients whose treatment Dr. Cutlip found problematic. (S. Ex. 14, p. 32)<sup>12</sup> Patients A and C were in that category.<sup>13</sup> With respect to Patient A, the Respondent recorded the lesion at 80%, Dr. Cutlip (after reviewing the angiogram videos) read it as less than 50%, and the Respondent told the AHIC that he saw it as about 50% after his

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<sup>12</sup> Dr. Cutlip did not review the records for Patient D and Patient E.

<sup>13</sup> There is an inconsistency in the June 29, 2009 Minutes of the AHIC on the issue of Patient B. The AHIC and the Respondent agreed to exclude from their discussion the cases that Dr. Cutlip did not find problematic. (S. Ex. 14, p. 32) They then went on to discuss Patient B’s case, presumably a case that Dr. Cutlip found to have problems. But in describing, very briefly, Patient B’s case, the AHIC Minutes state that “Dr. Cutlip acknowledged the medically appropriateness of the procedure.” (S. Ex. 14, p. 34) Because of this unexplained contradiction, I have not considered anything in the Minutes of June 29, 2009 regarding Patient B.

review of the video. (S. Ex. 14, p. 33) With respect to Patient C, the cath report states that the patient had 80% LAD and 80% RCA blockages. Dr. Cutlip read the LAD stenosis at 30-40% and the RCA stenosis at 30%. After further review, the Respondent read the stenosis at 50% in both arteries. (S. Ex. 14, p. 35)

The AHIC asked the Respondent to explain why his cath reports stated 80%, when on re-review of the videos, he concluded that the stenosis was much lower. The Respondent's response was recorded as follows:

[H]e still would have performed all of the stenting procedures in the interest of patient care. However, in looking back at his own work, it came as a "little bit of a surprise" to him that he had an established pattern of overestimating the degree of stenosis by consistently using the default figures of 70%, 80% or 90% to represent mild, moderate, and severe disease respectively. While he did not have a clear explanation for this, he stated that he looked at blockages in binary terms (i.e. whether the blockage was significant enough for the patient to benefit from a stent or not).

(S. Ex. 14, p. 35)<sup>14</sup>

I conclude from all of this evidence that the Respondent repeatedly recorded moderate stenosis as 80%, a practice that is in violation of the standard of care. The standard of care required the Respondent to accurately record the patients' conditions. Using 80% to indicate a moderate stenosis violated the standard of care because an 80% stenosis is a severe occlusion.<sup>15</sup> The cath reports did not contain an explanation of the surrogate system, and the reports he created were false and potentially misleading to patients and other physicians. (T. 525)<sup>16</sup> I conclude that the State proved by a preponderance of the evidence that the Respondent violated section 14-404(a)(11), (22) and (40) of the Medical Practice Act when he falsely recorded in

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<sup>14</sup> The Respondent testified that this report paraphrased what he told the AHIC. (T. 1338-39)

<sup>15</sup> In his letters to Patient B's and Patient E's referring physicians, the Respondent referred to the findings as "critical disease," and "a significant obstruction," respectively, without stating any percentage. (S. Ex. 8d, p. MM11336; S. Ex. 11b, p. MM12833) The Respondent did not write a separate report to Patient C or Patient D's referring physician.

<sup>16</sup> The Respondent reported to Patient A's referring physician that she had an 80% stenosis. (S. Ex. 7d, p. MM10982)

Patient A – E’s cath reports that the patients each had an 80% stenosis, when he actually diagnosed a moderate stenosis. (S. Ex. 7b, p. 10852; S. Ex. 8b, p. MM11164; S. Ex. 9b, p. MM11473; S. Ex. 10b, p. MM12101; S. Ex. 11a. p. 12740)

*b. Stenosis Inflation and Operator Variability*

The Respondent argued that a principle known in medical literature as stenosis inflation accounted for his overestimation of the lesions. I reject that argument for the following reasons.

Simply put, stenosis inflation is a principle, accepted among interventional cardiologists, that “visually estimating the degree of coronary stenosis...is subject to significant operator variability.” (Resp. Ex. 1, p. 208) Further, operators who estimate stenosis visually and without verifying the degree through FFR or IVUS tend to estimate high, *i.e.*, call a 50% lesion as 70%. *Id.* at p. 208-209. This is the result of the limits of x-ray technology in amplifying the degree to which a vessel is occluded.

Operator variability is a principle, also recognized in the field of interventional cardiology, that, if two different cardiologists view the same angiography video, they may estimate the degree of stenosis differently (inter-operator variability). Similarly, the same operator viewing a patient’s videos in different settings may estimate the degree of stenosis differently each time (intra-operator variability).

I reject these explanations for the Respondent’s use of 80% because 80% denotes a severe stenosis. All of the patients involved in this case had – at best – moderate stenosis. As a very experienced operator, the Respondent knows the difference between moderate and severe stenosis when he sees it. He has performed thousands of PCTA procedures. If he had called these lesions moderate, no one would have faulted him for *not* using a percentage number. If he chose to use a range, e.g., 40% to 60%, he would have adequately described the lesions that he saw to

be moderate. He chose to use the misleading number of 80%, knowing that any cardiologist who read the cath reports would believe that he found a severe lesion. That was misleading.

Furthermore, the Respondent, an experienced cardiologist, knows about stenosis inflation and operator variability. Before he met with the AHIC, he reviewed the patients' medical records, including the videos of their procedures. At that time, he expressed "surprise" that he "had an established pattern of overestimating the degree of stenosis by consistently using the default figures of 70%, 80% or 90%...." (S. Ex. 14, p. 35) The Respondent did not offer operator variability or stenosis inflation as an explanation for the pattern or the difference between what he saw in the cath lab and what he saw on later review. If these principles could explain the discrepancies, the Respondent would have used them to explain his actions in the setting of the AHIC.<sup>17</sup>

The Respondent argues that Dr. Kelly's peer review report is evidence of operator variability. I reject that argument because it is not supported by the facts. Dr. Kelly, an interventional cardiologist from Washington, D.C., reviewed patient records for Maximus as part of the Board's peer review investigation. He reported that the Respondent complied with the standard of care in every respect. (Resp. Ex. 14) However, Dr. Kelly did not read the stenosis as 80% in any case. Dr. Kelly reported a less than 50% stenosis in Patient A's mid LAD. (Resp. Ex. 14, p. 3) After a review of the records regarding Patient B, Dr. Kelly saw a 30-50% distal LAD stenosis. *Id.* In the case of Patient C, Dr. Kelly read the file to show a 30-50% stenosis of the left anterior descending artery and the right coronary artery. *Id.* at p. 4. In Patient D, Dr. Kelly saw a 50-70% stenosis in the mid LAD. *Id.* In Patient E, Dr. Kelly read the mid RCA stenosis as 30-

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<sup>17</sup> Similarly, I have considered the Respondent's testimony that the number of pixels in the angiography images stored on the CDs was different from the pixels displayed in the cath lab. (T. 1364-1367) The Respondent acknowledged that this could not account for the different estimates of the degree of occlusion. I am unconvinced that degradation of the images on the videos explains the Respondent's diagnosis of 80% stenosis in these cases.

50%. (*Id.* at p. 6) Dr. Kelly never agreed with the Respondent's report of a severe or 80% stenosis. I conclude for these reasons that stenosis inflation and operator variability do not explain why the Respondent exaggerated the degree of stenosis.

*c. Unstable Angina*

In all five of the patients under consideration, the Respondent recorded unstable angina as an indication for the procedure in the patient's cath report. I shall discuss each of the patient's cases individually, but in view of the extensive testimony regarding the criteria for unstable angina and the standard of care for treating it, I shall explain my conclusions on those issues in this section before moving to the individual patients.

The standard of care requires the doctor performing the PCI to document the reasons for the stent. The diagnosis of unstable angina is an important issue in this case because, if a patient has a moderate occlusion and stable angina, the standard of care provides that the patient should not receive a stent unless medical therapy has been tried and has failed.

As Dr. Chacko explained, generally a stent may be indicated for a patient with an 80% or severe stenosis and unstable angina. A patient with unstable angina and a mild to moderate stenosis should not receive a stent unless the area of stenosis can be diagnosed as the culprit lesion, i.e., the lesion likely causing angina.<sup>18</sup> Other factors that are important under the standard of care to determining whether a stent should be placed in a patient with unstable angina include: whether the area of the lesion has slow flow, indicating restricted blood flow through the lesion; signs of a blood clot in that area of the lesion; or any sign that plaque has ruptured.

The distinction between stable and unstable angina is as follows:

[T]here is a clear, clear difference between chronic stable exertional angina and unstable angina, which is what is reported in virtually every one of the cardiac catheterization reports for the cases that we've just reviewed.

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<sup>18</sup> Dr. O'Neill explained the meaning of "culprit lesion." (T. 1135)

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Unstable angina. There is a clear difference, both in terms of presentation and outcomes to the patient. So, to say a patient has unstable angina, you imply that there is – there are symptoms at rest, not with exertion, and you are implying that that patient has had some evidence of plaque rupture within the artery, a sudden event, not something that has happened over years of time.

And so in the unstable angina population, clearly there is an advantage if you have high risk – and this, again, straight from the guidelines – and there are tools to assess risk for somebody with unstable angina, but that is a clear, distinct disorder compared to somebody with a chronic stable angina.

(T. 582-82, Chacko)

Unstable angina is a medical emergency; the standard of care requires a doctor whose patient is experiencing symptoms of unstable angina to send the patient to a hospital and treat the patient immediately with aggressive medical therapy. (T. 207)

Crescendo unstable angina is a diagnosis appropriate for a patient who is experiencing progressive symptoms or the same symptoms after less exertion. Crescendo unstable angina may be a sign that the patient is moving toward developing unstable angina. (T. 279)

As Dr. Chacko explained, a patient with stable angina experiences chest discomfort in the form of tightness or pain, on exertion, e.g., when lifting something, climbing stairs, etc. Some patients have no symptoms of angina but still have serious CAD. Some patients, particularly women and the elderly have shortness of breath signifying CAD, but do not experience chest discomfort.

Dr. O'Neill testified that stents are "valuable" for patients with heart attacks and unstable angina; those patients make up about two-thirds of the patients who come to the cath lab. (T. 1058) Dr. O'Neill conceded that all five of the patients under consideration had moderate or intermediate lesions. He opined that all of them had unstable angina, relying in large part on information the Respondent told him which is not contained in the medical records. I shall

discuss those issues in the following sections. In Dr. O'Neill's opinion, if a patient has angina and is not having a heart attack, stents relieve symptoms, i.e., chest discomfort and/or shortness of breath. (T. 1059) He implied that for these patients, since the patients are not harmed if they get a stent, placement of the stent is appropriate; in other words, no harm, no foul. While Dr. O'Neill was expressing his opinion on the standard of care, he did not explain the source for his opinion, other than his years of work in the field of interventional cardiology.

I reject that opinion for the following reasons. It was undisputed that for patients who do not have unstable angina and are not having a heart attack, stenting "doesn't decrease mortality, and it doesn't prevent recurrent heart attacks." (T. 1062, O'Neill) However, it is also undisputed that inserting a stent into a patient carries its own risks. Patients who have a stent in place must take prescriptions for a year and aspirin, which subjects them to potential bleeding, a side effect of those drugs.

Dr. Chacko testified that he disagreed that stents are appropriate to relieve the symptoms of stable angina. (T. 1059) He testified that he knew of no doctor who would place a stent to relieve stable angina. (T. 473) Dr. O'Neill admitted that the COURAGE trial fundamentally changed the standard of care; in Dr. O'Neill's words, "COURAGE has given us the courage to wait," meaning the scientific support for *not* stenting moderate lesions in patients with stable angina allows interventional cardiologists to prescribe medical therapy and leave a blockage untouched without concern that they will be sued for not intervening if the patient has a heart attack. (T. 1062)<sup>19</sup>

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<sup>19</sup> The Respondent testified that, although diagnostic procedures decreased after the COURAGE study was published, in his view the study was largely irrelevant because 97% of the study participants had bare metal stents implanted. (T. 1286) Dr. Chacko said that 75% of the patients in the COURAGE study had bare metal stents. (T. 616)



I found Dr. Chacko's testimony more convincing than Dr. O'Neill's (and the Respondent's). Dr. Chacko described the basis for each of his opinions, reviewed each view of the cath lab videos, describing his observations, and expressed his opinions in response to Ms. Pepper's non-leading questions. The Respondent and Dr. O'Neill, however, moved through the discussion of each patient's case very quickly, answering many leading questions posed by Mr. Snyder. (T. 1078, 1123-24, 1128, 1130, 1132, 1135-36, 1139-40) Furthermore, on cross-examination, Dr. Neill was evasive when pressed for details to support his opinions. (T. 1163-64) He admitted *many times* that his opinions were based not on the patients' medical records but on information that the Respondent told him. (T. 1182-83 (Patient A's symptoms); 1184-85 (Patient A's medical therapy); T. 1189 (Patient A's symptoms and indications for PCI); T. 1192 (failure of Patient A's medical therapy); T. 1201, 1207 (Patient D's PCTA was urgent); T. 1209-10 (Patient E's medical therapy failure)).

I conclude from all the evidence that, for patients without unstable angina and with a mild or moderate lesion, the standard of care provides that the patient should not receive a stent; medical therapy is the appropriate treatment.

I further conclude that, even if a patient has unstable angina, the standard of care requires a cardiologist to determine through PCTA whether there is a stenosis of at least 50% that can be a likely culprit for the angina. If there is a mild or mild to moderate lesion that does not limit flow, no thrombus (clot) or plaque rupture, the standard of care requires the operator to refrain from placing a stent, unless a greater degree of occlusion is verified through FFR or IVUS.

*d. Duty to Make Accurate Medical Records*

I conclude that the standard of care also requires an interventional cardiologist to review the patient's history and symptoms, read any available studies, and accurately record the

symptoms and the indications for any intervention in the medical record. Dr. Chacko, Dr. O'Neill and the Respondent agreed on this point. Dr. Chacko testified that the Respondent failed to comply with the standard by exaggerating the degree of stenosis, misstating the indications for the procedures, and recording this information in the cath reports, his entry into the patients' medical records.

Dr. O'Neill's report states that the Respondent complied with the standard of care in all respects, but in his testimony Dr. O'Neill stopped short of endorsing the Respondent's record-keeping practices. Dr. O'Neill testified that the Respondent's method of quantifying the degree of stenosis was inaccurate, but he contended that it could be corrected with a five minute conversation. (T. 1075-76) He testified that the record-keeping matter could have been handled with an "educational letter, at most, and then follow-up with proctoring...." (T. 1076) Taking all of Dr. O'Neill's testimony into consideration, I conclude that he conceded that the Respondent failed to comply with the standard of care for making medical records.

*e. Active Clotting Time*

The State alleges that the Respondent breached the standard of care in failing to obtain and document the ACT before proceeding with PCI in these cases. The Respondent admits that he did not obtain or document the ACT; he contends that the standard of care does not require him to do so.

It is undisputed that the introduction of wires and catheters during a coronary procedure bears a risk of clotting and that it is standard practice to thin a patient's blood before introducing foreign items into the vessel in order to reduce the risk of a clot. Dr. Chacko testified convincingly that "most interventional cardiologists would take the time to wait five minutes to check ACT to assure therapeutic anticoagulation for the procedure." (T. 297) Dr. O'Neill opined

that because the Respondent administered Heparin himself into the artery, he was sure that the patient achieved proper anti-coagulation.

The Respondent testified that he knew of no one in Baltimore who was waiting for the ACT before proceeding, although he understands that, since his case has become well known, operators have been using ACT. (T. 1372-73) The Respondent testified that he has not been measuring ACTs for 25 years. (T. 1374)

Dr. O'Neill testified that it is well accepted in the field of interventional cardiology that blood must be sufficiently thinned to prevent clots. He explained how, when the field was beginning, doctors used to take some blood onto their fingers to test anticoagulation. (T. 1101) He admitted that, since 2000, it has been the practice to use ACT:

So, the pattern and practice that [the Respondent's] developed really basically is a dinosaur of how we practiced before, when many of us were doing procedures without ACT. The more [recent] graduates in the field, from 2000 on, most of them have sort of become used to using ACT, so it has become part of the – part of the practice, but it's not necessary to do it.

(T. 1103)

I accept Dr. Chacko's opinion over Dr. O'Neill's and conclude that the standard of care required the Respondent to obtain and document ACT. Regardless of whether the Respondent has ever done it or knows others who do it, Dr. O'Neill's testimony, together with Dr. Chacko's testimony, established that the procedure is an important tool to assure anti-coagulation and prevent clots. The procedure is simple, takes a few minutes, and provides a reliable gauge of whether the patient's blood is sufficiently thinned. There is no reason to refrain from doing it other than the need for speed, which is not a factor in these cases. As in other aspects of Dr. O'Neill's testimony, the fact that no patient actually suffered a blood clot is immaterial.

#### 4. *The Five Patients*

##### a. *Patient A*

Patient A had chronic stable angina and at most a moderate calcification of the mid LAD. There was no flow-limiting lesion or plaque rupture visible on her angiogram. A recent coronary CT performed at Carroll General Hospital reported an 80% lesion in the LAD, but the PCTA performed by the Respondent did not confirm that finding. If the Respondent wanted to rule out the CT finding, he could have performed IVUS, but he chose not to do so.

The Respondent inaccurately recorded in the cath report that the patient had unstable angina. The patient's referring cardiologist, Chitrachedu Naganna, M.D., dictated a detailed letter to the Respondent on August 22, 2008, describing the patient's history and symptoms. (S. Ex. 7b, p. MM10835-36) Dr. Naganna accurately described the patient's history:

This 62 year-old female has an interesting cardiovascular problem but she definitely needs a cardiac catheterization to answer a lot of questions that patient and her husband have.

She presented to me this year with tightness of the chest off and on that goes back for about ten years. In the past she had a cardiac work up and was told to have normal findings. **The tightness is precipitated by exertion and relieved by rest in five to ten seconds.** She has been quite active and she has been questioning why she has tightness in the chest.

(S. Ex. 7b, p. MM10835)(emphasis added).

Describing the impressions of the patient, Dr. Naganna wrote:

Abnormal CT angiogram; the patient has two vessel disease out of which LAD seems to be significant lesion. Minimally elevated calcium score noted. **The patient had no further symptoms at this time but in the past she had intermittent chest tightness for many years unexplained and was found to have normal cardiac workup in the past.**

(S. Ex. 7b, p. MM10836)(emphasis added).

Dr. Naganna did not report that the patient was experiencing chest discomfort at rest or any increase in longstanding angina symptoms. (S. Ex. 7b, p. MM10835-56) In short, there is nothing in Dr. Naganna's medical records to support the diagnosis of unstable angina. The Respondent performed an elective PCTA a week after Dr. Naganna's report.

For an explanation of why he reported that the indication for the PCTA was unstable angina, the Respondent testified that Dr. Naganna told him that the patient's symptoms had increased recently (T. 1378-79), but I reject that testimony for the reasons stated above. I conclude that Dr. Naganna, who wrote a thorough report, would have indicated that the Patient's symptoms had "taken a turn" recently (as the Respondent testified) if that were the reason for the study. (T. 1378-79) Dr. Naganna described chest pain on exertion and no chest discomfort at the time of the last office visit, not unstable angina.

Similarly, I reject Dr. O'Neill's testimony that the patient had unstable angina. Dr. O'Neill admitted on cross-examination that the source of his information about the alleged change in the patient's symptoms came from the Respondent's memory, not the medical records. (T. 1122, 1181-83)

In his letter to the Board explaining his treatment of this patient, the Respondent stated:

The patient had progressive symptoms refractory to attempts to manage them medically, an abnormal exercise test, an abnormal Coronary CT, and a significant lesion in the LAD. Stenting is a reasonable treatment strategy since she was not doing well with conservative management, and is within the standard of care.

(S. Ex. 7a, p. MM 10816)

I conclude that the Respondent inaccurately told the Board that this patient had "progressive symptoms."

Next, the Respondent wrote in his cath report that he performed the PCI because the patient had an 80% obstruction in the LAD. The Respondent testified that that LAD obstruction was 70 or 80%. (T. 1383-84; S. Ex. 7b, p. MM10852) He described it to the Board as a significant obstruction. However, when the Respondent met with the AHIC on June 29, 2009, he described the lesion as 50%. He further explained the difference between his then assessment of 50% and the cath report by explaining that 80% was a surrogate for an intermediate lesion. As described above, I conclude that the use of such a surrogate violated the standard of care. I further conclude that Patient A did not have a severe or 80% lesion of the LAD.

Dr. Chacko testified that based on the angiogram, the lesion in the patient's LAD was less than 50%. (T. 231)

After considering all of the evidence I conclude that Patient A's LAD was less than 50% occluded. I further conclude that the Respondent exaggerated the degree of stenosis when he recorded that it was 80%.

The Respondent argued that he was justified in stenting the LAD because the condition of the LAD that he observed during the PCTA correlated with the findings of the patient's cardiac CT angiogram. Patient A had a negative nuclear perfusion scan and borderline ST changes on her stress EKG. (S. Ex. 7c, p. MM10960) She had a cardiac CT angiogram performed at Carroll General Hospital on August 12, 2008, and according to the report of that study, the test showed as follows in the LAD:

There appears to be some soft plaque in the proximal portion of the artery, takeoff of the left circumflex. The vessel becomes very hypodense just prior to a large amount of calcified plaque. This appears to be consistent with significant narrowing. There is then large plaque with hypodensity in the middle of this plaque. No significant blooming artifact in this region, but significant narrowing of 80% cannot be excluded.

(S. Ex. 7d, p. MM10972)

All three of the expert witnesses agreed that the findings on the CT angiogram were important. Dr. Chacko testified that CT angiograms are most useful in their negative predictive value, i.e., in ruling out stenosis. He testified further that, while an invasive cardiologist gives weight to the CT angiogram results, the invasive cardiologist must make an independent assessment of the vessels during the PCTA. Dr. O'Neill and the Respondent testified that a CT angiogram usually correlates strongly with the findings on PCTA.

I reject the Respondent's suggestion that the CT angiogram was a decisive factor in his diagnosis of this patient for the following reasons. First, the cath report, which serves as the Respondent's entry into the patient's medical record, is silent regarding the CT angiogram. Dr. Naganna reported the recent, concerning CT angiogram to the Respondent, but the Respondent did not mention it. Furthermore, when the Respondent wrote to Dr. Naganna explaining the PCI, he never mentioned the CT angiogram. (S. Ex. 7d, p. MM10982) I conclude that the findings on the CT angiogram did not justify placement of the stent in Patient A's LAD.

I accept the opinion of Dr. Chacko and I conclude that the standard of care for Patient A required that she not receive a stent; rather, this patient should have been treated medically, continuing with the medication started by Dr. Naganna shortly before the PCTA performed by the Respondent on August 29, 2008. (T. 294)

In summary, I conclude that the State proved the allegations regarding the Respondent's treatment of Patient A, as alleged in paragraph 21 of the Amended Charges that:

(a) Charge: The Respondent failed to accurately document the clinical indications, including Patient A's symptoms, upon which he based his decision to perform PCI and place a stent.

My conclusion: violation proven.

(b) Charge: The Respondent exaggerated the degree of mid-LAD stenosis and used this as clinical justification for placement of the stent.

My conclusion: violation proven.

(c) Charge: The Respondent placed a coronary stent in Patient A and needlessly exposed her to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications.

My conclusion: violation proven.

(d) Charge: The Respondent failed to consider that a trial of more optimal medical therapy would be a more appropriate form of treatment for Patient A rather than placement of a stent.

My conclusion: violation proven.

(e) Charge: The Respondent failed to obtain and document Patient A's ACT prior to the start of the PCI procedure after administering intra-arterial unfractionated Heparin.

My conclusion: violation proven.

*b. Patient B*

In this case, I am not convinced by the State's evidence that this patient had stable angina. Patient B had symptoms that were consistent with a mild heart attack prior to his emergency admission at SJMC. After considering Dr. Chacko's testimony on this patient, I conclude that his opinion was more tentative and qualified than with the other patients.

The referring cardiologist obviously was concerned that Patient B might be having a heart attack, as he hospitalized him and started medical therapy. The patient came to SJMC in an ambulance. Dr. Gottlieb, an attending cardiologist, recorded that the patient had progressive angina and mild chest discomfort, along with increased cardiac enzymes. The Respondent accurately documented in the cath report that one of the indications for the PCTA was elevated enzymes. (S. Ex. 8b, p. MM11164)

The Respondent also documented that the patient had unstable angina. The Respondent inaccurately recorded that the patient had several weeks of chest pains; the only reference to chest pain is in Dr. Gottlieb's report, and he recorded mild chest pain on admission. However, the Respondent was entitled to rely on Dr. Gottlieb's report that Patient B had progressive



angina, and angina that changes or worsens can be referred to as unstable angina. The State has the burden of proving that the Respondent inaccurately indicated that the patient had unstable angina, and I am unconvinced by the State's evidence on this point.

The Respondent inaccurately recorded that the patient had an 80% obstruction in the mid LAD. *Id.* The obstruction was in the moderate range.

I find that Patient B had elevated enzymes, recent increased fatigue and shortness of breath, and symptoms consistent with a heart attack. I accept that the patient had a moderate stenosis, but in view of the patient's urgent presentation at SJMC, Dr. Gottlieb's report of his history, and the results of his physical examination, I conclude that the Board failed to prove that the Respondent placed a stent in Patient B in violation of the standard of care.

The Respondent did, however, violate the standard of care by injecting Patient B with Heparin and failing to obtain and record the ACT. I have explained above why the failure to obtain and document the ACT was improper. This patient was administered Lovenox before he left Carroll General Hospital, and it is documented in the transfer summary. The standard of care required the Respondent to refrain from administering Heparin within twelve hours after the Lovenox was administered. By failing to do so, the Respondent improperly over anti-coagulated this patient. As Dr. Chacko credibly testified, administering Heparin to this patient, who had a full dose of Lovenox, placed him at a very high risk for bleeding.

Dr. O'Neill's opinion regarding the administration of Heparin to this patient is found at page 10 of his report. (Resp. Ex. 16, p. 10) Dr. O'Neill wrote that "information about the timing and dosing of [Lovenox] is not always available at the time of transfer." The Respondent testified that he ordinarily reads the transfer summary before performing a procedure, but he could not remember if he did so in Patient B's case. (T. 1435) The Respondent possessed Patient

B's transfer summary; it was included within the documents sent to the Board by the Respondent. (S. Ex. 8b, p. MM11205-8) Carroll General Hospital documented that Lovenox had been administered to this patient and warned the Respondent not to administer Heparin within twelve hours. (S. Ex. 8b, p. MM11206) The Respondent did not heed the warning.

Dr. O'Neill also wrote that "[t]he only potential complication of over-coagulation is bleeding, which did not occur in this case." (Resp. Ex. 16, p. 10) The standard of care does not look back upon the effects of a medical error and judge the validity of what the physician did based on whether the patient was harmed. Standards of care within the medical profession are aimed at protecting patients from harm. I reject Dr. O'Neill's justification for the Respondent's administration of Heparin to Patient B. Lack of injury to a patient is not a factor in determining the standard of care.

In summary, I conclude as follows regarding the allegations involving the treatment of Patient B in paragraph 21 of the Amended Charges:

(a) Charge: The Respondent documented an exaggerated degree of stenosis and used this as clinical justification for placement of the stent.

My Conclusion: violation proven.

(b) Charge: The Respondent documented symptoms that were not present elsewhere in Patient A's chart as clinical indications for stent placement.

My conclusion: violation not proven.

(c) Charge: The Respondent failed to recognize that Patient B's angiogram was reassuring with a 50% stenosis or less in the LAD and did not support the placement of the stent.

My conclusion: violation not proven.

(d) Charge: The Respondent placed a coronary stent in Patient B and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications.

My conclusion: violation not proven.

(e) Charge: The Respondent failed to document Patient B's ACT.

My conclusion: violation proven.

(f) Charge: The Respondent's administration of unfractionated Heparin prior to performing PCI after [Patient B] had already been fully anti-coagulated with low molecular weight heparin (Lovenox) put Patient B at a much higher risk for bleeding complications.

My conclusion: violation proven.

*c. Patient C*

This patient had unstable angina, and the Respondent accurately documented it.

However, he did not have an 80% stenosis as reported by the Respondent. The patient had received two stents in 2007, and he came to the SJMC emergency room complaining of symptoms similar to those experienced before his earlier stents. The PCTA did not confirm those symptoms. The previous stents were both open with no filling defect. There was no thrombus or plaque rupture evident. The RCA had a mild to moderate stenosis in the area of the 2007 stent. The LAD had mild stenosis past the 2007 stent.

I find that the Respondent appropriately performed PCTA, but when the procedure did not clearly identify a culprit lesion, the standard of care required the Respondent to refrain from placing a stent. The standard of care required that, before proceeding with PCI, the Respondent use FFR or IVUS to either confirm or rule out the areas as the culprits for the patient's symptoms; he failed to use IVUS, which was available at the time. The patient was taking aspirin, Plavix and Vytorin (an anti-cholesterol medication), an adequate medical regimen; once the Respondent saw that the lesions were mild and mild to moderate, the standard of care required him to refrain from stenting and to permit the patient to remain on medical therapy.

Dr. Chacko described his opinion regarding Patient C in detail, including explaining what he observed on every view of the angiogram videos. Dr. O'Neill and the Respondent, on the other hand, gave summary testimony regarding the specifics of this case, often in response to counsel's leading questions. Dr. O'Neill did not discuss the degree of stenosis in Patient C. The

Respondent acknowledged that all the previous stents were open with no filling defect and that there was no thrombosis or plaque rupture evident in the LAD and RCA. I conclude that Dr. Chacko's testimony is entitled to more weight than the Respondent's and Dr. O'Neill's.

In one respect I conclude that the State has failed to prove the allegations regarding Patient C. Paragraph 38(b) of the Amended Charges alleges that the Respondent failed to consider alternate causes of Patient C's symptoms. I have reviewed Dr. Chacko's report and his testimony carefully, and I am not convinced by the State's evidence on this point. Dr. Chacko's testimony at pages 350-372 of the transcript, did not touch on this subject.

In summary, I conclude as follows regarding the Respondent's treatment of Patient C, as alleged in paragraph 38 of the Amended Charges:

(a) Charge: The Respondent exaggerated the degree of stenosis and used this as clinical justification for placement of the stent.

My conclusion: violation proven.

(b) Charge: The Respondent failed to consider alternate causes of Patient C's symptoms.

My conclusion: violation not proven.

(c) Charge: The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case.

My conclusion: violation proven.

(d) Charge: The Respondent placed a total of 3 coronary stents in 2 of Patient C's coronary arteries and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications.

My conclusion: violation proven.

(e) Charge: The Respondent failed to obtain and document Patient C's ACT prior to the start of the PCI procedure after administering unfractionated Heparin.

My conclusion: violation proven.

*d. Patient D*

Patient D had been experiencing chest pain for more than 30 years. His referring cardiologist sent him for an exercise Myoview stress test on October 13, 2008. That test showed

no ischemic ST segment changes and minimal/mild inferolateral ischemia in the RCA.<sup>20</sup> Patient D was able to exercise for about 5 minutes at a workload of 81% of his maximum age-predicted heart rate with some dizziness at peak exercise but no chest pain.

His EKG showed sinus brachycardia and poor R wave progression. He had an echocardiogram on October 13, 2008 that showed normal left ventricular ejection fraction (60%), indicating very minor leaking of the mitral valve. The cardiologist referred him to the Respondent for PCTA based on the results of the Myoview stress test, not due to any change in the chest pain the patient experienced.

The Respondent performed PCTA on October 16, 2008 and falsely indicated the reason for the test to be unstable angina; in fact, the patient had long term stable angina. The Respondent recorded in the clinical summary that the patient had anteroseptal ischemia on stress testing, which is not documented elsewhere in the medical records. The patient's records showed inferolateral ischemia, not anteroseptal ischemia.

The PCTA showed a mild to moderate area of non-obstructive CAD in the LAD; the Respondent falsely stated in the cath report that the obstruction was 80%. (T. 389) The Respondent performed a PCI of the LAD. He failed to obtain or document the ACT.

Dr. O'Neill testified that the Respondent told him that the referring cardiologist told the Respondent that Patient D had new onset chest pain. I have given this testimony no weight because it relied upon information that was not in the patient's medical records. Dr. O'Neill further testified that the Respondent told him that the findings on the patient's stress test were so worrisome to the referring doctor that the doctor called the Respondent to arrange for an urgent catheterization. (T. 1207) The Respondent testified to the same thing. (T. 1397) Again, I reject

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<sup>20</sup> Dr. Chacko explained that "inferolateral ischemia usually indicates a malperfusion in either the right coronary artery or, occasionally, the left circumflex artery, depending on how [the patient's] circulation is configured." (T. 379)

the testimony because it is not supported by the medical records. Furthermore, the referring cardiologist's report dated October 15, 2008 states:

Results of Myoview stress test, echo were explained to the patient and at this time patient would like to proceed with cardiac catheterization. Procedural details, risks and benefits were explained to him. Patient would like to have this done tomorrow, 10/16/2008 at SJMC. I did discuss this with Dr. Mark Midei who will perform this tomorrow at SJMC.

(S. Ex. 10b, p. MM12087)

It appears from the medical records that the *patient* was in a hurry to have the PCTA performed, not that the doctor thought it was urgent. It is apparent that the Respondent spoke with the referring physician on October 15, 2008, but there is no reason to conclude that the referring physician, who dictated extensive, detailed records regarding his patient, would omit from the records new onset chest pain or the need for an urgent PCTA.

Dr. Chacko described his opinion regarding Patient D in detail, including explaining what he observed on every view of the angiogram videos. (T. 372-398) Dr. O'Neill and the Respondent, on the other hand, gave summary testimony regarding the specifics of this case, often in response to counsel's leading questions. (T. 1134-37; 1397-1401) Dr. O'Neill wrote that the LAD had a moderate stenosis; as discussed above, 80% is not a moderate lesion. (Resp. Ex. 16, p. 13) I conclude that Dr. Chacko's testimony is entitled to more weight than the Respondent's and Dr. O'Neill's.

The Respondent referred in his cath report to anteroseptal ischemia. Patient D had 30 years of atypical chest pain and a small zone of ischemia referable to the RCA, not the LAD (the artery stented). Mr. Snyder did not ask Dr. O'Neill about the apparent error, but Dr. O'Neill wrote in his report that "the notation of anteroseptal ischemia on the stress testing was incorrect."

(Resp. Ex. 16, p. 13) On cross-examination, Dr. O'Neill clarified that the Respondent's cath report was an error, not the stress test report. (T. 1206-07)

The Respondent's testimony regarding his diagnosis of anteroseptal ischemia illustrates why I did not give any weight to the evidence of undocumented symptoms. It also confirms the reason why thorough, accurate medical records are essential. The following colloquy occurred between Ms. Pepper and the Respondent on cross-examination:

**Q. Under your clinical history, you state, "Recurrence of symptoms and anteroseptal ischemia."**

**What portion of the anteroseptal wall -- which coronary artery does that typically feed?**

A. Typically, the LAD.

**Q. Okay. And Dr. O'Neill stated that was an error on your part. Do you agree with him?**

A. Well, I'm not really sure about that. Again, this was a patient that was communicated to me by telephone from Dr. -- Dr. Parikh's office, I think late in the day, and I scheduled him for a case the following day, and so it would have been difficult for all of the information to be transcribed and gotten to St. Joseph in that short amount of -- period of time.

So, I'm not really sure if I had all of the information, and so I may have relied upon Dr. Gottlieb's assessment or Dr. Pollock's assessment, as well as my own assessment, and my communication with Dr. Parikh over the telephone.

**Q. Where is Dr. Pollock or Dr. Gottlieb's assessment?**

A. Well, I'm not sure. I mean, I'm assuming that one of them saw him --

**Q. Wouldn't that be in the record?**

A. Well, I'm assuming it -- because they always saw one of the patients or one of them would have seen the patient.

(T. 1429-30). This exchange confirms what I observed many times during the hearings. When confronted with a problem in one of the cases, the Respondent reverted for an explanation to undocumented information that he claimed he learned either from the patients or their referring

doctors. This information was not reliable.

The Board alleged in paragraph 48(e) that the Respondent failed to obtain sufficient visual documentation of the PCI. I conclude that the State failed to prove as alleged in paragraph 48(e) that the Respondent violated the Medical Practice Act by failing to obtain sufficient visual documentation of the PCI. I have reviewed Dr. Chacko's report and his testimony carefully. Dr. Chacko discussed the images that the Respondent captured during the PCI at page 388 of the transcript, but he did not explain what the standard of care required. Dr. Chacko did not express an opinion about whether the images were sufficient to comply with the standard of care either. I conclude that the evidence is insufficient to support this allegation.

In summary, I conclude as follows regarding the allegations concerning Patient D in paragraph 48 of the Amended Charges:

(a) Charge: The Respondent incorrectly reported that Patient D had unstable angina and anteroseptal ischemia. Patient D in fact had 30 years of atypical chest pain and a small zone of ischemia referable to the RCA (which was not the artery that was stented).

My conclusion: violation proven.

(b) Charge: The Respondent exaggerated the degree of proximal LAD stenosis and used this as clinical justification to place the stent; there was no 80% stenosis in any coronary artery.

My conclusion: violation proven.

(c) Charge: The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case.

My conclusion: violation proven.

(d) Charge: The Respondent placed a stent in Patient D and needlessly exposed him to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications.

My conclusion: violation proven.

(e) Charge: The Respondent failed to obtain sufficient visual documentation of the PCI; the Respondent obtained only one cine image which shows the stent as already deployed and the wire down the LAD. The Respondent failed to obtain



images of his positioning and inflation of the stent or a final image of the treated vessel with the wire removed.

My conclusion: violation not proven.

(f) Charge: The Respondent failed to document Patient D's ACT after administering unfractionated Heparin for procedural anti-coagulation.

My conclusion: violation proven.

*e. Patient E*

Patient E did not have unstable angina; she had some shortness of breath on exertion. The patient had a Myoview stress test on July 7, 2008, during which the stress portion was normal and the perfusion images showed a small, mild ischemia (lack of blood flow) to the anterior wall of the heart, an area usually referable to the LAD. On July 16, 2008, her cardiologist started her on aspirin and a beta-blocker and referred her to the Respondent for PCTA.

The following day the Respondent performed PCTA and placed a stent in the RCA. He documented the indications for the procedure to be unstable angina and a positive stress test. The Respondent falsely documented that the patient had 80% stenosis of the RCA. The stenosis in the RCA was at most 30% to 40%. (S. Ex. 13, p. 8) The Respondent did not explain how stenting the RCA was consistent with the stress test finding of ischemia to the anterior wall, which is usually referable to the LAD.

Dr. O'Neill testified that the Respondent told him that the referring cardiologist sent Patient E to him for a stent or bypass surgery out of concern that medical therapy had failed. (T. 1210) The Respondent testified to the same thing. (T.1403) There is no record in the referring physician's records or the cath report of failure of medical therapy, and the patient had very recently started taking aspirin and a beta-blocker. (S. Ex. 11a, p. MM12721-22, 12740) The Respondent acknowledged this on cross-examination. (T. 1427)

The Respondent explained why he thought that medical therapy had failed:

**Q. My understanding, sir, is that she was referred to you by Dr. Parikh as a result of what was perceived to be a medical therapy failure.**

A. Well, he – by definition, sending them to me is a medical therapy failure. Whether or not – I mean, whether or not an aggressive medical regimen has been instituted, these patients are all managed by cardiologists who are – who are well in tune with what medical therapy can and cannot do. And so when Dr. Parikh or Dr. Freiji sends the patient to me, they've already – they're already telling me that they've done as much as they think they can do, and they want this patient to be evaluated and treated, if at all possible.

(T.1403-4)

I did not find the Respondent's testimony credible. This assumption about a patient's medical therapy is inconsistent with the Respondent's obligation to evaluate each patient's history and symptoms. The Respondent was not justified if he, in fact, relied on an undocumented "understanding" that all of the patients referred to him by cardiologists had failed to achieve relief with medical therapy. I conclude that the Respondent was not truthful when he testified about the failure of medical therapy for Patient E.

I find that the standard of care required the Respondent to consider that Patient E had not received optimal medical therapy; it required him to refrain from inserting a stent until after a trial of medical therapy.

Dr. Chacko described his opinion regarding Patient E in detail, including explaining what he observed on every view of the angiogram videos. (T. 398-422) Dr. O'Neill and the Respondent, on the other hand, gave summary testimony regarding the specifics of this case, often in response to counsel's leading questions. (T. 1138-40; 1401-06) I conclude that Dr. Chacko's testimony is entitled to more weight than the Respondent's and Dr. O'Neill's.

In summary, I conclude as follows regarding the allegations in paragraph 56 of the Amended Charges:

(a) Charge: The Respondent exaggerated the stenosis and used this as clinical justification for placement of this stent.

My conclusion: violation proven.

(b) Charge: The Respondent failed to recognize that aggressive medical therapy was the appropriate course of treatment in this case.

My conclusion: violation proven.

(c) Charge: The Respondent placed a coronary stent in Patient E and needlessly exposed her to the risks attendant thereto in the absence of medical necessity and sufficient clinical indications. Moreover, the stent was placed in the RCA without any evidence of inferior ischemia noted on the nuclear stress test (which showed a small mild area of anterior ischemia which would be more likely referable to the LAD, which in this case was undiseased).

My conclusion: violation proven.

(d) Charge: The Respondent failed to document ACT after administering unfractionated Heparin for procedural anti-coagulation.

My conclusion: violation proven.

##### *5. The Violations of the Medical Practice Act Summarized*

The Respondent argued generally that he did not violate the Medical Practice Act and that all of the charges should be dismissed; he did not address the specific sections of the Act charged in this case. I shall apply the conclusions reached in the Discussion section above to the five sections charged by the Board.

- a. Did the Respondent engage in unprofessional conduct in the practice of medicine in violation of section 14-404(a)(3)(ii)?*

The diagnosis and treatment of cardiac stenosis is undeniably included with the statutory definition of the “practice of medicine.” Md. Code Ann., Health Occ. § 14-101(n)(1) (Supp. 2010). *See also McDonnell v. Commission on Medical Discipline*, 301 Md. 426, 436-37 (1984). In *Cornfeld v. Board of Physicians*, 174 Md. App. 456, 480 (2007) *cert. denied* 400 Md. 647 (2007), the Court of Special Appeals found that misconduct “must be sufficiently intertwined with patient care as to pose a threat to patients or to the medical profession....” The Court further

stated that “physician’s conduct relates to the effective delivery of patient care.” In *Dr. K. v. State Board of Physicians*, 98 Md. App. 103, 110 (1993), the Court of Special Appeals cited the American Medical Association principles of medical ethics that “a physician shall deal honestly with patients and colleagues....”

The Respondent admitted that he made up his own measure for reporting the degree of stenosis in a cardiac artery. (T. 1359, 1420) He recorded any artery that he found to be moderately occluded as 80%, although there is no support for such an approach in the profession. He could not explain why he did so, other than to say he was “careless and cavalier” and did not think the degree of occlusion mattered. (T. 1355-57) The Respondent’s use of a personal and unsupported measurement was unprofessional conduct in the practice of medicine.

In addition, the Respondent indicated in four cases that unstable angina was the indication for the procedure, even though the diagnosis was unsupported in the medical records.

b. *Did the Respondent willfully make or file a false report in the practice of medicine in violation of section 14-404(a)(11)?*

In order to prove that the Respondent’s false statements in the medical records were “willful,” the State was required to prove that the Respondent committed the acts “voluntarily and intentionally, as opposed to ... through inadvertence, accident, or ordinary negligence.” *Kim v. Maryland State Board of Physicians*, 196 Md. App. 362, 379 (2010), citing *Deibler v. State*, 365 Md. 185, 195 (2001). Applying this standard, I conclude that the Respondent’s actions were intentional, non-accidental and non-inadvertent.

It is important to note that, in each case under review, the Respondent not only recorded the degree of stenosis incorrectly; in *every* case he exaggerated the degree of stenosis. Thus, the

Respondent's diagnosis and documentation of an 80% stenosis was not the result of carelessness. He deliberately exaggerated every time to justify the placement of a stent.

The same is true of the four cases in which the Respondent wrote that the patients had unstable angina. Unstable angina is a serious cardiac condition. The Respondent was not careless in his use of this term. He did not, for example, record unstable angina incorrectly in some cases and stable angina incorrectly in others. In all four of the cases the Respondent deliberately recorded unstable angina as the indication for the procedure absent any evidence of that condition in the medical records. He exaggerated the symptoms to justify the placement of a stent in four cases.

I conclude that the State proved by a preponderance of the evidence that the Respondent violated section 14-404(a)(11) of the Medical Practice Act when he intentionally and falsely recorded in Patient A – E's cath reports that the patients each had an 80% stenosis, when each had a mild or moderate stenosis, significantly less than 80%. (S. Ex. 7b, p. MM10852; S. Ex. 8b, p. MM11164; S. Ex. 9b, p. MM11473; s. Ex. 10b, p. MM12101; S. Ex. 11a. p. MM12740) In four of the cases, the State proved that the Respondent violated the same section when he intentionally and falsely recorded that the patients had unstable angina as an indication for the procedures he performed.

c. *Did the Respondent grossly overutilize health care services in violation of section 14-404(a)(19)?*

As Discussed above, I conclude that the State proved that the Respondent needlessly inserted a total of six stents in Patients A, C, D and E. The Respondent testified that the cost of a stent was approximately two to three times the cost of a diagnostic PCTA. Therefore, I conclude that the Respondent placed stents that were not medically indicated, resulting in unnecessary charges for health care.

d. *Did the Respondent fail to meet appropriate standards of care in violation of section 14-404(a)(22)?*

For the reasons set forth above, I conclude that the State proved that the Respondent failed to meet appropriate standards of care in violation of section 14-404(a)(22) by: (1) inaccurately documenting his patients' clinical indications, including symptoms; (2) exaggerating the degree of stenosis and using this as a clinical justification for the placement of stents; (3) placing stents in patients in violation of the standard of care, in the absence of medical necessity and sufficient clinical indications; (4) failing to consider that more optimal medical therapy was a more appropriate treatment than placement of stents; (5) failing to obtain and document ACT prior to the start of the PCI procedure after administering Heparin; and (6) using two anti-coagulants in the case of Patient B.

e. *Did the Respondent fail to make or keep adequate medical records in violation of section 14-404(a)(40)?*

For the reasons set forth above, I conclude that the State proved that the Respondent violated section 14-404(a)(40) of the Medical Practice Act when he falsely recorded in Patient A – E's cath reports that the patients each had an 80% stenosis, when he actually diagnosed a moderate stenosis, which is less than 80%. (S. Ex. 7b, p. MM10852; S. Ex. 8b, p. MM11164; S. Ex. 9b, p. MM11473; S. Ex. 10b, p. MM12101; S. Ex. 11a, p. MM12740) I further conclude that the State proved a violation of section 14-404(a)(40) by establishing that the Respondent recorded that four of the patients had unstable angina and by failed to document the patients' ACT.

#### 6. *SJMC Peer Review*

The Amended Charges allege that "SJMC...conducted its own investigation of the Respondent's placement of stents. The findings of SJMC's investigation (which were not

provided to the Board's peer reviewers) are consistent with those of the peer reviewers.”

(Amended Charges, p. 16, para. 57; *see also* para. 58-59) I am not reviewing the propriety of the peer review investigation at SJMC. That is a matter for another forum, and apparently the Respondent is pursuing it there. An evaluation of the SJMC peer review is unnecessary to my Proposed Decision. I would have reached the same decision in this case regardless of the outcome of the SJMC investigation.

Because the Amended Charges refer to that investigation, however, I permitted the Respondent to offer evidence about it. Mr. Snyder vigorously, repeatedly and thoroughly argued that this case was all about what happened at SJMC. I permitted the Respondent to testify, call and cross-examine witnesses, and offer documentary evidence on this issue. In closing argument Mr. Snyder stated, “Now, I’m really not going to spend any more time on the five cases. I don’t think it’s necessary. That is not what this case is about.” (T. 1524). I disagree; this case is all about the five patients. I conclude that nothing SJMC did or failed to do is relevant to the issues in this case.<sup>21</sup>

Although it is not relevant, the AHIC conducted a thorough investigation of many of the Respondent’s cases, permitted the Respondent to review the patients’ records, and met with him twice to hear his explanation of his decisions. A group of four independent Cath Lab Directors reviewed many of the Respondent’s files, including the angiogram videos and the patients’ medical records.<sup>22</sup> The AMF doctors found that the Respondent repeatedly overestimated the degree of occlusion in about one-third of the 157 cases reviewed. (S. Ex. 14, p. 71) At the conclusion of the process, the AHIC recommended summary suspension, and the MEC agreed,

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<sup>21</sup> The Respondent is a party to numerous other lawsuits involving SJMC. I have not considered the claims and defenses raised in any of those cases in reaching my Proposed Decision.

<sup>22</sup> The AMF reviewers included doctors who were the Cath Lab Directors at Pennsylvania State University, Yale University, St. Luke’s Roosevelt Hospital, and Lacey Clinic Medical Center. (S. Ex. 14, p. 70)

concluding that the Respondent “displayed a repeated pattern of placing stents in patients based on [his] overestimation of the degree of stenosis in the cardiac catheterization reports, and without clinical indications of the need for percutaneous intervention.” (S. Ex. 14, p. 82)

The Respondent argued that SJMC misled the Board because it failed to advise the Board that SJMC lifted his summary suspension. This argument is not important to my Proposed Decision. The suspension was withdrawn as part of a settlement between the hospital and the Respondent. According to the By-laws at SJMC governing peer review, the Respondent had the right to a hearing before his peers to contest the summary suspension. The Respondent, who was represented by counsel, decided to forego the hearing and submit his resignation. In return, SJMC withdrew the suspension and gave the Respondent a neutral letter of reference. Any suggestion that SJMC misled the Board is sheer speculation.

#### 7. *Proposed Sanction*

Disciplinary proceedings against a physician are not intended to punish the offender but rather to protect the public. *McDonnell v. Comm’n on Medical Discipline*, 301 Md. 426, 436 (1984). The Court of Special Appeals has held that an administrative agency with disciplinary and licensing authority “has broad latitude in fashioning sanctions within [those] legislatively designated limits.” *Cornfeld v. State Bd. of Physicians*, 174 Md. App. at 486, citing *Neutron Prods., Inc. v. Dep’t of Environment*, 166 Md. App. 549, 584, *cert. denied*, 392 Md. 726 (2006) and *Blaker v. State Bd. of Chiropractic Examiners*, 123 Md. App. 243, 264-65, *cert. denied*, 351 Md. 662 (1998)). Although section 14-404 of the Health Occupations Article and COMAR 10.32.02.06 describe possible sanctions, they provide no guidance for assessing sanctions.

The Respondent is subject to a sanction for the violations proven by the State. The Respondent has been licensed in Maryland for many years and has had no prior violations. This



factor favors a penalty short of revocation.

The violations proven were repeated and serious. Although none of the patients suffered any adverse consequence, such as bleeding or blood clots, as a result of the Respondent's care, one of the patients suffered a tear in an artery, requiring the placement of another stent, and the patients were required to take Plavix for a year and aspirin for life after their stents were inserted. The Respondent inserted stents in patients whose clinical symptoms and histories did not warrant the invasive technique. By doing so, the Respondent unnecessarily exposed the patients to risk of harm. This factor warrants a severe sanction.

The Respondent's practice of inserting stents increased the cost of the patients' medical care to the health care system. PCI is much more expensive to a patient, the Medicare program, and insurers than medical therapy.

I have considered the issue of the Respondent's good faith. On the one hand, at least before these charges became public, the Respondent was a recognized leader in the medical and cardiology communities in Maryland. He has a body of work over a professional lifetime that, before this case, any doctor would be proud to own. He was considered one of the top ten interventional cardiologists nationally, in terms of the number of invasive procedures he performed. The Respondent was a salaried employee at SJMC; he had no apparent financial motive for his conduct. The Respondent was devoted to his profession, respected by his peers and co-workers, and had a loyal following of referring physicians.

The Respondent had confidence in his abilities and apparently believed that stents helped almost all of his patients and that, if he could safely insert one, he should do so. This approach is inconsistent with the standard of care in 2008, which required a much more judicious use of stents, given their known side effects and complication rates.

The manner of the Respondent's reports is very troubling. The Respondent's choice of 70%, 80% and 90% as proxies for mild, moderate and severe stenosis is indefensible. While there is no single method used within the profession to describe the degree of occlusion and practitioners in the field recognize that precise estimation of stenosis is impossible from an angiography, the Respondent's classification scheme was a deliberate fabrication of medical records. Using this method, any lesion could be stented, because most invasive cardiologists accept 30% to 70% as the range of moderate stenosis. The Respondent chose a proxy number for mild stenosis that corresponds to the top of the range of intermediate lesions; that is evidence of bad faith and exaggeration to justify the procedures.

Furthermore, the Respondent did not inform the referring cardiologists of his personally-devised scale. Medical records are important to record the actions taken and to guide others who need to use them to provide care to the patient. For the Respondent to use 80% as a proxy for intermediate stenosis without informing anyone of his method potentially endangered the future care of his patients and showed an intention to justify the decision to place a stent regardless of the patient's needs.

I conclude that the record-keeping practice and the consistent over-use of the stenting procedure are evidence of the Respondent's bad faith. In weighing the different factors, I conclude that the Respondent's practices of performing unnecessary medical procedures and his clear bad faith outweighs the positive factors such as his history of no violations and his many years of practicing medicine.

The Board will properly make the decision whether to impose a sanction against the Respondent's license, based on its members' expertise in the field. Based on the Respondent's

pattern of exaggeration and his indefensible proxy system of recording stenosis, I recommend that the Board revoke the Respondent's license.

### CONCLUSIONS OF LAW

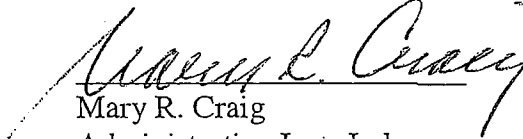
I conclude that the Respondent violated section 14-404(a)(3)(ii), (11), (19), (22), and (40) of the Health Occupations Article of the Annotated Code of Maryland (Supp. 2010). I further conclude that, as a result, the Board may discipline the Respondent. Md. Code Ann., Health Occ. § 14-404(a) (Supp. 2010).

### PROPOSED DISPOSITION

I **PROPOSE** that the Amended Charges filed by the Board on July 20, 2010 against the Respondent be **UPHELD**.

I **PROPOSE** that the State Board of Physicians revoke the Respondent's license to practice medicine in the State of Maryland.

February 23, 2011  
Date Proposed Decision Mailed

  
Mary R. Craig  
Administrative Law Judge

MRC/rbs  
Doc #120349

### NOTICE OF RIGHT TO FILE EXCEPTIONS

Any party may file exceptions, in writing, to this Proposed Decision with the Board of Physicians within fifteen days of issuance of the decision. Md. Code Ann., State Gov't § 10-216 (2009) and COMAR 10.32.02.03F. The Office of Administrative Hearings is not a party to any review process.

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STATE BOARD OF PHYSICIANS

v.

MARK G. MIDEI, M.D.

RESPONDENT

LICENSE NO. D30042

\* BEFORE MARY R. CRAIG,

\* AN ADMINISTRATIVE LAW JUDGE

\* OF THE MARYLAND OFFICE

\* OF ADMINISTRATIVE HEARINGS

\* OAH No.: DHMH-SBP-71-10-35281

\* BOARD OF PHYSICIANS CASE NOS:

\* 2009-0364

2009-0803

\* 2010-0036

\* \* \* \* \*

**EXHIBIT LIST**

I admitted the following exhibits on behalf of the State:

1. November 10, 2008 letter to Board from anonymous source
2. April 20, 2009 letter to Board from anonymous source
3. July 8, 2009 (received by Board on July 21, 2009) Report of Disciplinary Action from SJMC)
4. December 2, 2009 subpoena duces tecum (SDT) from Board to Office of Risk Management, SJMC
5. December 7, 2009 letter from Board to Respondent with attached SDT
6. December 17, 2009 letter from Respondent's then-counsel to Board
7. Patient A
  - a. December 17, 2009 Respondent's response (MM10813 – 9)
  - b. Respondent's Certification of Medical Records, SDT and Respondent's records – Patient A (MM10820 – 10876)
  - c. SDT and SJMC records – Patient A (MM10877 – 10967)
  - d. SDT and Dr. Naganna's records – Patient A (MM10968 – 11000)
  - e. SDT and Dr. Lanham's records – Patient A (MM11001 – 11144)
  - f. SDT – Patient A cardiac angiogram film (MM11145 – 6)
  - g. Patient A – August 29, 2008 cardiac angiogram
8. Patient B
  - a. December 17, 2009 Respondent's response (MM11147 – 53)
  - b. SDT and Respondent's records – Patient B (MM11154 – 11213)
  - c. SDT and SJMC records – Patient B (MM11214 – 11311)
  - d. SDT and Dr. Kalaria's records – Patient B (MM11312 – 11344)
  - e. SDT and Dr. Faustino's records – Patient B (MM11345 – 11456)

- f. SDT – Patient B cardiac angiogram film
  - g. Patient B – October 7, 2008 cardiac angiogram
9. Patient C
- a. December 17, 2009 Respondent’s response (MM11459 – 65)
  - b. SDT, Respondent’s Certification of Medical Records and Respondent’s records – Patient C (MM11366 – 11531)
  - c. SDT and SJMC records – Patient C (MM11532 – 11673)
  - d. SDT and Dr. Hernandez’ records – Patient C (MM 11674 – 11733)
  - e. SDT to Respondent
  - f. Patient C – September 10, 2008 cardiac angiogram
10. Patient D
- a. SDT to SJMC – Patient D’s records (MM 12066 – 7)
  - b. SDT and SJMC records – Patient D (MM 12068 – 12152)
  - c. SDT and Dr. Goldstein’s records – Patient D (MM 12153 – 12196)
  - d. SDT to SJCM – Patient D cardiac angiogram film
  - e. Patient D – October 16, 2008 cardiac angiogram
11. Patient E
- a. SDT and SJMC records – Patient E (MM 12703 – 12791)
  - b. October 15, 2009 letter from Board to Dr. Freji, SDT and Patient E’s records (MM 12793 – 12905)
  - c. Cardiovascular Consultants of Carroll County records – Patient E (MM 12906 – 12927)  
Cardiac Consultants of Carroll County records – Patient D (MM 12928 – 12948)
  - d. SDT to SJMC – Patient E cardiac angiogram film (MM 12949 -50)
  - e. Patient E – July 16, 2008 cardiac angiogram
12. Curriculum Vitae – Matthews Chacko, M.D.
13. Peer Review Report – Matthews Chacko, M.D.
14. St. Joseph Medical Center – Minutes of Ad Hoc Committee
15. April 15, 2010 SJMC Response to State of Maryland Office of Health Care Quality Statement of Deficiencies
16. Article: Your Heart and Blood Vessels
17. Anti-Anginal Therapeutic Strategy
18. ACC/AHA 2005 Guideline Update
19. Angiogram – example of significant blockage
20. July 20, 2010 Notice of Amended Charges Under the Maryland Medical Practice Act (amending and superseding June 7, 2010 Charges)
21. Report of William Walter O’Neill, M.D.
22. Article entitled “Clinical and angiographic outcome of patients with mild coronary lesions treated with balloon angioplasty or coronary stenting,” *European Heart Journal* (2003)
23. Article from *The Baltimore Sun* (online version) entitled “St. Joseph doing the right thing on stents,” September 7, 2010<sup>23</sup>

I admitted the following exhibits on behalf of the Respondent:

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<sup>23</sup> Counsel for the Respondent gave me a binder after his closing argument containing documents. The binder was not offered or admitted into evidence.

- Resp. Ex. 1 - *Grossman's Cardiac Catheterization, Angiography & Intervention* (7<sup>th</sup> Edition), pages 187-221
- Resp. Ex. 2 - Article from *The Baltimore Sun* (online version) entitled "Stents stir growing doubts, legal action," July 26, 2010
- Resp. Ex. 3 - Article from Angioplasty.org Interview Series entitled "Eric J. Topol, M.D."
- Resp. Ex. 4 - Article from *The Baltimore Sun* (online version) entitled "St. Joseph doing the right thing on stents," September 7, 2010 (same as S. Ex. 23)
- Resp. Ex. 5 - not offered (Report of William D. Knopf, M.D. admitted as Resp. Ex. 15)
- Resp. Ex. 6 - Report to Board by Laurence Kelly, M.D.
- Resp. Ex. 7 - Article entitled "Drug-Eluting Stents in the Treatment of Intermediate Lesions," *Journal of the American College of Cardiology*, Vol. 47, November 11, 2006
- Resp. Ex. 8 - Article from *The Washington Times* (online version) entitled "The 'ultra' artery test," August 13, 2008
- Resp. Ex. 9 - Excerpt from Centricity Cardiology CA 1000 V1.0 Reference Guide
- Resp. Ex. 10 - Article entitled "Accuracy of Individual and Panel Vision Interpretations of Coronary Arteriograms: Implications for Clinical Decisions," *Journal of the American College of Cardiology*, Vol. 16, No.1, July 1990
- Resp. Ex. 11 - *Curriculum Vitae* of William W. O'Neill, M.D.
- Resp. Ex. 12 - Excerpt from ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention, p. e7
- Resp. Ex. 13 - Excerpt from ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention, p. e40-41
- Resp. Ex. 14 - Report to Board by Michael Sung-Chieh Chen, M.D. (with copy of Resp. Ex. 6)
- Resp. Ex. 15 - Report and *Curriculum Vitae* of William D. Knopf, M.D.
- Resp. Ex. 16 - Report of William W. O'Neill, M.D. (same as S. Ex. 21)
- Resp. Ex. 17 - *Curriculum Vitae* of the Respondent
- Resp. Ex. 18 - Agreement and General Release, November 18, 2009
- Resp. Ex. 19 - not admitted

Resp. Ex. 20 - not admitted