IN THE MATTER OF	*	**BEFORE THE MARYLAND STATE**
MARK G. MIDEI, M.D.	*	**BOARD OF PHYSICIANS**
Respondent	*	**Case Numbers: 2009-0364**
		2009-0803
License Number: D30042	*	**2010-0036**

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CHARGES UNDER THE MARYLAND MEDICAL PRACTICE ACT

The Maryland State Board of Physicians (the "Board") hereby charges Mark G. Midei, M.D. (the "Respondent") (D.O.B. 06/24/1957), License Number D30042, under the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 14-401 *et seq.* (2009 Repl.Vol.).

The pertinent provisions of the Act under H.O. § 14-404(a) provide as follows:

§ 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.

GENERAL ALLEGATIONS OF FACT[1]

The Board bases its charges on the following facts that the Board has reason to believe are true:

1. At all times relevant hereto, the Respondent, who is board-certified in cardiology, was and is licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on October 18, 1983. His license will expire on September 30, 2011.

2. At all times relevant hereto, the Respondent was the Director of the Cardiac Catheterization Laboratory at St. Joseph Medical Center ("SJMC") in Towson, Maryland, a position he had held as of January 1, 1995. While functioning in that capacity, the Respondent was a member of Mid-Atlantic Cardiologist Associates until January 21, 2008, when he was hired by SJMC.

3. In November 2008, the Board received the first of several complaints that the Respondent was performing cardiac stent procedures in the absence of medical necessity and sufficient clinical indications.

4. A stent is a cylindrical metal mesh tube or scaffolding that is placed in a coronary artery or arteries where there is a severe blockage or "lesion," the purpose of which is to keep the artery open and relieve symptoms or ischemia in the treatment of severe coronary artery disease. The physician places a stent during a percutaneous coronary intervention ("PCI") procedure, typically after having performed a diagnostic coronary angiogram to assess

[1]The statements of the Respondent's conduct with respect to the patients identified herein are intended to provide the Respondent with notice of the alleged charges. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent.

the coronary arterial circulation.

5. At all times relevant to the complaints, the 2005 American College of Cardiology/American Heart Association ("ACC/AHA") Guidelines were in effect. The Guidelines provided that PCI was indicated in patients with significant coronary stenosis (narrowing of the artery), which the Guidelines defined as greater than 50% diameter stenosis. PCI was not recommended for patients with less than 50% stenosis.[2]

6. PCI and the placement of coronary stents is not risk-free. The cardiac catheterization itself carries a 1% - 5% risk of complications that ranges from bleeding to a stroke or heart attack. Once a stent is placed, there is additional risk of stent thrombosis, which happens rarely (1%) but carries a 40-50 % chance of mortality. Accordingly, patients in whom stents are placed must undergo continued anti-platelet therapy with Plavix (clopidogrel) and aspirin to protect them against this. Placement of coronary stents in patients in whom sufficient clinical indications are not present exposes them to needless risk of harm.

Procedural History

7. On November 10, 2008, the Board received the first of 2 anonymous complaints regarding the Respondent from an individual ("Complainant") who identified him/herself as an SJMC employee. The Complainant alleged that the Respondent was committing "medical fraud" by placing stents in coronary arteries with insignificant blockages. The Complainant provided a list of

[2] The 2009 ACC/AHA Guidelines are more stringent; PCI is not indicated unless the stenosis is greater than 70%.

medical record numbers and dates of 36 stent procedures performed by the Respondent from July 2008 through early November 2008 for which the Complainant alleged there were insufficient blockages to justify the procedure. The complaint was designated as Board Case Number 2009-0364.

8. On April 24, 2009, the Board received a second letter from the Complainant regarding the Respondent's continued performance of medically unnecessary stent procedures. The Complainant listed 41 such procedures performed by the Respondent from mid-November 2008 through mid-February 2009. This complaint was designated as Board Case Number 2009-0803.

9. On July 21, 2009, the Board received an Adverse Action Report from SJMC notifying the Board that the Respondent's privileges had been summarily suspended based on the findings of an SJMC investigation that had revealed, *inter alia,* that the Respondent "displayed a repeated pattern of placing stents in patients based on [the Respondent's] overestimation of the degree of stenosis in the cardiac catheterization reports, and without clinical indication of the need for percutaneous intervention." This matter was designated as Board Case Number 2010-0036.

10. Thereafter, the Board initiated an investigation of the Respondent's performance of stent procedures at SJMC. The Board's investigation included obtaining from the Respondent a response regarding his placement of stents in specified patients under his care. The patient records and the Respondent's response were then referred to a peer review entity for review

of the Respondent's practice. The results of the peer review are set forth below:

Patient-Specific Allegations

Patient A[3]

11. Patient A, a female born in 1946, was referred to the Respondent by her cardiologist on August 22, 2008 for elective cardiac catheterization.

12. Patient A's past medical history included a strong family history of premature coronary artery disease ("CAD"). Patient A had a 10-year history of chest pain occurring with exertion and relieved with rest.

13. Prior to her referral to the Respondent, on May 14, 2008, Patient A had undergone a nuclear stress test which revealed no myocardial ischemia.[4] On August 12, 2008, Patient A's treating cardiologist had ordered her to undergo a computed tomography ("CT") angiogram. The CT angiogram revealed, *inter alia,* a mildly elevated coronary calcium score (277) and 80% calcified stenosis of the left anterior descending coronary artery ("LAD"). Patient A also underwent an electrocardiography ("EKG"), the results of which were normal.

14. Patient A's medical therapy at the time included aspirin, Nexium and sublingual nitroglycerin ("SL NTG").

15. Patient A's cardiologist noted in his referral that Patient A had "no further symptoms" at the time of the referral.

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[3] Patient names are confidential. The Respondent may obtain the names from the Administrative Prosecutor.

[4] Patient A performed at 91% maximum age-related heart rate ("MAPHR"), with 10.1 metabolic equivalents ("METS"). These results generally indicate the physiologic adequacy of the stress test .

16. On August 29, 2008, the Respondent performed a coronary angiogram. In his procedure note, the Respondent listed "unstable angina" and "positive exercise test in the anterior distribution" among the procedural indications.

17. In the Respondent's catheterization report ("cath report"), the Respondent documented that the angiogram revealed a normal left main coronary artery, a calcified mid-LAD with 80% stenosis and insignificant disease of the left circumflex and right coronary artery ("RCA").

18. Based on the Respondent's findings, he performed PCI on Patient A's LAD with direct stenting[5] using a drug-eluting stent ("DES")[6] The Respondent administered intra-arterial heparin for procedural anticoagulation.

19. Review of the coronary angiogram performed by the Respondent reveals at most a 40% – 50% calcified mid-LAD stenosis, not 80% as reported by the Respondent. The angiogram did not reveal any evidence of a flow-limited lesion or plaque rupture in the LAD or any other of the coronary arteries that may have resulted in unstable angina, as had been documented by the Respondent.

20. To perform PCI safely, a patient's blood must first be anti-coagulated, or "thinned" before introducing a device into the coronary artery to avoid thrombosis or clotting of the artery. In this case, as in all the cases reviewed, the Respondent failed to document the effect of anti-coagulation when using unfractionated heparin; specifically, he failed to obtain and document Patient

[5] In "direct stenting" the stent is threaded through the lesion over a guidewire and expanded without having first pre-dilated the lesion with a balloon.

[6] A drug-eluting stent is a coronary stent which is coated with an anti-proliferative medication that is released into the surrounding tissues to prevent re-blockage of the stented segment from neointima formation and restenosis.

A's activated clotting time ("ACT") prior to performing PCI with unfractionated heparin.

21. The Respondent violated the Act for reasons including, but not limited to the following:

    a. 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;

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

    c. 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;

    d. The Respondent failed to consider that a trial of more optimal medication therapy would be a more appropriate form of treatment for Patient A rather than placement of the stent; and

    e. 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.

Patient B

22. Patient B, a male born in 1930, developed profound weakness and shortness of breath on September 10, 2008 after moving some boxes. Patient B's medical history included rheumatoid arthritis, bladder cancer, gastroesophageal reflux disease ("GERD"), hypertension and dyslipidemia.

23. On October 6, 2008, while still experiencing weakness and shortness of breath, Patient B presented to his cardiologist who transferred him to Carroll Hospital Center ("CHC") based upon Patient B's abnormal EKG results (poor R wave progression), a mildly elevated troponin[7] level (0.117), a creatinine level that ranged from normal to mildly elevated (1.1) and a negative CPK.[8] Patient B's cardiologist, suspecting that Patient B had had a cardiac event, started him on a medication regimen of aspirin and Coreg.[9] Patient B had no reported chest pain.

24. While at CHC, Patient B was started on a statin, a beta-blocker, lisinopril[10] and was intravenously administered a full dose of low molecular weight heparin (Lovenox; dose80 mg.), an anti-coagulant used for the treatment of an acute coronary syndrome.

25. On October 7, 2008, Patient B was transferred to SJMC for cardiac catheterization by the Respondent. Patient B's last dose of Lovanox was administered prior to his discharge from CHC, at 10:23 a.m.

26. On October 7, 2008, the Respondent performed a coronary angiography. In his procedure note, the Respondent noted "unstable angina" and "elevated enzymes" among the indications for the procedure. He also noted that Patient B had chest pain, although this complaint was not noted elsewhere in the record.

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[7] Troponin is a diagnostic biochemical enzyme marker of necrosis (death) of cardiac muscle cells or heart muscle damage..

[8] CPK is the abbreviation for creatine phosphokinase, another enzyme found in the heart. An elevated level indicates heart muscle damage.

[9] Coreg is a beta-blocker used to treat hypertension and heart failure.

[10] Lisinopril is an ACE inhibitor used to treat hypertension and congestive heart failure.

27. In his cath report, the Respondent noted, *inter alia,* a normal left main coronary artery, 30% proximal and 80% mid LAD obstruction.

28. Based on his finding of 80% mid-LAD obstruction, the Respondent performed PCI with direct stenting using a drug-eluting stent (DES) and placed a second stent distal to the first stent for what may have been an edge dissection. The Respondent used 6000 units of intra-arterial heparin for procedural anticoagulation, which was administered to Patient B at 1:34 p.m.

29. Review of the angiogram performed by the Respondent revealed a "wrap around" LAD[11] with no more than a 50% mid-LAD calcified stenosis with TIMI III[12] flow present and no stigmata of plaque rupture, thrombus, flow-limiting stenosis or spontaneous dissection. Patient B's left ventricle ("LV") demonstrated preserved hyperdynamic function, suggesting that no prior or ongoing transmural infarction had had any permanent adverse effect on LV function.

30. The Respondent violated the Act for reasons including but not limited to the following:

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

    b. The Respondent documented symptoms that were not present elsewhere in Patient B's chart as clinical indications for stent placement;

[11] A "wrap around" LAD reaches not only the cardiac apex, but also a portion of the inferior wall of the heart.

[12] TIMI is the abbreviation for Thrombolysis In Myocardial Infarction (the dissolution of abnormal blood clots that damage blood vessels). The TIMI Grade Flow is a scoring system (from 0 to III) of the levels of coronary blood flow. TIMI III indicates complete perfusion/normal flow.

c. 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 his placement of the stent;

d. 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;

e. The Respondent failed to document Patient B's ACT.

f. Using two anti-coagulants simultaneously with both unfractionated heparin and low molecular weight heparin (Lovanox). Patient B had received essentially a double dosage of anti-coagulation on the same day: a full dose of Lovanox at CHC prior to discharge and 6000 units of inter-arterial heparin at 1:34 p.m. for the procedure prior to the PCI. The Respondent's administration of unfractionated heparin prior to performing PCI after he had already been fully anti-coagulated with low molecular weight heparin (Lovanox) put Patient B at a much higher risk for bleeding complications.

Patient C

31. Patient C, a male born in 1945, presented to SJMC Emergency Department ("ED") on September 10, 2008, complaining of chest pain. Patient C had previously undergone PCI in March 2007, at which time LAD and RCA stents had been placed; he reported that his chest pain felt "just like the pain before his stents."

32. Patient C underwent an EKG and laboratory studies while in the ED. His

EKG results were unremarkable and his cardiac enzymes were negative. Patient C did not complain of chest pain while in the ED.

33. Patient C's treating physician referred him to the Respondent for a coronary angiogram, noting Patient C's history of unstable angina.

34. On September 10, 2008, the Respondent performed a coronary angiography on Patient C. In his cath report, the Respondent documented a normal left main coronary artery, an 80% obstruction past the previously stented site on the LAD with a widely patent stent, insignificant disease of the left circumflex artery and a dominant RCA with an 80% obstruction at the proximal stent margin with a widely patent stent.

35. Based on his findings, the Respondent performed a mid-LAD PCI and placed a DES. The Respondent also performed RCA PCI and placed two additional drug-eluting stents proximal to the original stent.

36. Review of the coronary angiogram performed by the Respondent failed to reveal an 80% obstruction to either the mid-LAD or RCA, as the Respondent had reported. Instead, review determined the LAD stenosis to be no more than 40%, and in the RCA at most a 50% stenosis proximal to the previously placed RCA stent. Notably, upon review, the previously placed stents were widely patent with no filling defect. There was no clear evidence of a flow-limiting lesion, thrombus or plaque rupture either within the LAD or the RCA or in any of the other coronary arteries that otherwise would have justified the Respondent's placement of stents.

37. The Respondent failed to document Patient C's ACT after administering

unfractionated heparin for procedural anti-coagulation.

38. The Respondent violated the Act for reasons including but not limited to the following:

    a. The Respondent exaggerated the degree of stenosis and used this as clinical justification for placement of the stents;

    b. The Respondent failed to consider alternate causes of Patient C's symptoms;

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

    d. 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;

    e. The Respondent failed to document Patient C's ACT after administering unfractionated heparin.

Patient D

39. Patient D, a male born in 1941, had a past medical history that included: CAD; a strong family history of CAD; hypertension; hyperlipidemia and atypical chest pain for the prior 30 years. Patient D reported that his chest pain was resolved completely in a few minutes after taking Mylanta, an antacid. His medication regimen included aspirin, metoprolol, Lipitor, protonix and lorazepam.

40. In March 2007, Patient D had undergone cardiac catheterization at another

facility (performed by a physician other than the Respondent) that revealed mild LAD irregularities and a normal left circumflex artery and RCA.

41. On October 13, 2008, Patient D underwent an exercise myoview nuclear stress test[13] the results of which revealed "minimal mild ischemia noted in the RCA distribution." Patient D attained a workload of 81 % MAPHR and 8 METS during the stress test; he reported dizziness, but no chest pain at his peak exercise level. The results of an echocardiogram performed on that date were unremarkable.

42. On October 16, 2008, Patient D's cardiologist referred him to the Respondent for cardiac catheterization.

43. The Respondent listed "unstable angina" as one of the indications for the coronary angiography. In his clinical summary, the Respondent documented that Patient D had borderline disease with symptoms dating back 2 years who presented with recurrence of symptoms and anteroseptal ischemia upon stress testing.

44. The Respondent documented that the angiogram revealed a normal left main artery, 80% proximal obstruction of the LAD with a 50% obstruction at the junction of the mid and distal vessel.

45. Based on his findings, the Respondent performed PCI of Patient D's proximal LAD with direct stenting using a DES.

46. The Respondent administered 6000 units of intra-arterial unfractionated heparin during the procedure; he failed to document the ACT.

[13] This test uses a radioactive isotope to examine blood flow to the heart while the patient is at rest and exercising.

47. The Respondent obtained only 1 image of the intervention in which the stent was already deployed.

48. The Respondent violated the Act for reasons including but not limited to the following:

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

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

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

d. 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;

e. 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;

f. The Respondent failed to document Patient D's ACT after administering unfractionated heparin for procedural anti-coagulation.

Patient E

49. Patient E, a female born in 1938, presented to her cardiologist on July 7, 2008 with atypical chest pain and an abnormal EKG. Her past medical history included hypertension, GERD, hyperlipidemia and a family history of CAD.

50. On July 7, 2008, Patient E underwent a myoview nuclear stress test, attaining a workload of 90% and 7 METS. Patient E had no ischemic ST segment changes and a small mild reversible area of anterior ischemia with normal left ventriclar ("LV") function. Her EKG revealed non-specific T wave changes. Patient E's cardiologist added aspirin and a beta-blocker to her medication regimen and referred her to the Respondent for cardiac catheterization.

51. On July 16, 2008, the Respondent performed coronary angiography. He noted "unstable angina" and "positive stress test" as the indications for the procedure.

52. The Respondent reported that the angiogram revealed, *inter alia,* a normal left main artery, insignificant disease of the LAD, a 40% circumflex marginal branch obstruction and an 80% proximal RCA obstruction.

53. Based on his findings, the Respondent performed PCI on Patient E's RCA with direct stenting using a DES.

54. The Respondent administered 6000 units of intra-arterial heparin for procedural anti-coagulation for the PCI. He failed to document Patient E's ACT.

55. Review of the angiogram revealed a 30 – 40% stenosis at the proximal bend

of the RCA; not 80% as reported by the Respondent. The lesion would not be expected to cause LAD territory ischemia or "unstable angina" as there was no evidence of plaque rupture or thrombus.

56. The Respondent violated the Act for reasons including but not limited to the following:

a. The Respondent exaggerated the degree of stenosis and used this as clinical justification for placement of the stent;

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

c. The Respondent placed a coronary stent in Patient E and needlessly exposed him 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).

d. The Respondent failed to document ACT after administering unfractionated heparin for procedural anti-coagulation.

SJMC's Independent Review of the Respondent's Practice

57. As stated above, SJMC had 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.

58. During the course of the SJMC investigation, a committee met with the Respondent to review his stent procedure cases. According to the report of the committee, the Respondent acknowledged that it was his practice to use the percentages of 70%, 80% and 90% as "surrogates" or "defaults" in all cases to designate a mild, moderate or significant level of stenosis, respectively. He expressed "a little bit of surprise" that he had an established pattern of overestimating the degree of stenosis by consistently using the default percentages. Indeed, when asked to review the cases reviewed by the SJMC committee, the Respondent found significantly lower percentages of stenosis than he had initially dictated at the time of the procedure. The Respondent asserted that he considered the patients' clinical symptoms when determining whether to place a stent. The committee reported however, that the Respondent repeatedly performed interventions based on his overestimation of stenosis and in the absence of sufficient clinical indications to support the need for PCI. These findings are consistent with those of the Board's peer reviewers.

59. By letter dated July 10, 2009, SJMC notified the Respondent that he was summarily suspended. In the letter, the following practice deficiencies were noted:

    a. Systematic failure to document in the pre-procedure evaluation objective findings of ischemia to justify an intervention;

    b. Failure to include clinical descriptions of the patients' symptoms sufficient to explain [the Respondent's] decision to intervene;

c. Decisions to treat a less significant lesion, instead of the likely culprit lesion;

d. Failure to confirm or qualitate lesion significance using well-accepted intra-procedural techniques, such as fractional flow reserve or intravascular ultrasound;

e. Failure to document the effect of anti-coagulation, and failure to obtain ACT prior to the start of the intervention;

f. Decision to perform "non-culprit" coronary interventions in the setting of an Acute Myocardial Infarction without clinical indications; and

g. Failure to obtain adequate angiographic views to properly assess lesion severity.

CONCLUSION

60. The Respondent's treatment of Patients A, B, C, D and E in whole or in part, unprofessional conduct in the practice of medicine, in violation of H.O. § 140404(a)(3)(ii), willfully making a false report or record in the practice of medicine, in violation of H.O. § 14-404(11), gross overutilization of health care services, in violation of H.O. § 14-404(a)(19), violations of the standard of quality care, in violation of H.O. § 14-404(a)(22) and failure to maintain adequate medical records, in violation of H.O. § 14-404(a)(40).

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, the Board finds that there are grounds for action under H.O. § 14-404(a)(3)(ii), (11), (19), (22) and/or (40), the Board may impose disciplinary sanctions against the Respondent's license, revocation, suspension, or reprimand and

may place the Respondent on probation, and/or may impose a monetary fine.

NOTICE OF CASE RESOLUTION CONFERENCE

A Case Resolution Conference has been scheduled for **Wednesday, August 4, 2010 at 10:00 a.m.** at the offices of the Board, 4201 Patterson Avenue, Baltimore, Maryland, 21215. The nature and purpose of the Case Resolution Conference and Pre-Hearing Conference are described in the attached letter to the Respondent. If this case is not resolved at the Case Resolution Conference, an evidentiary hearing will be scheduled.

6/7/10
Date

C. Irving Pinder, Jr.,
Executive Director
Maryland State Board of Physicians