COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 1470

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY RAUL L. VILCA, M.D., LICENSE 41816, 170 MIDDLEGROUND WAY, #3, LONDON, KENTUCKY 40744

AGREED ORDER

Come now the Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Inquiry Panel A, and Raul L. Vilca, M.D. ("the licensee"), and, based upon their mutual desire to fully and finally resolve this pending investigation without an evidentiary hearing, hereby ENTER INTO the following **AGREED ORDER**:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Agreed Order:

1. At all relevant times, Raul L. Vilca, M.D., was licensed by the Board to practice medicine in the Commonwealth of Kentucky.
2. The licensee's medical specialty is Interventional Cardiology.
3. On March 22, 2011, the Kentucky Board of Medical Licensure (hereafter "the Board") received an anonymous grievance alleging that the licensee and others were performing unnecessary stenting and angioplasty procedures
4. During the Board's investigation, the medical records were obtained for five patients who had been treated by the licensee. Those records and other available information were provided to a Board consultant for review. The consultant concluded that the licensee failed to conform to the standards of acceptable and prevailing medical practice within the Commonwealth in his diagnosis of 3 of those patients, his

treatment of 2 of those patients and his records for of those patients. The consultant found that the overall care was below minimum standards in 2 of the cases and borderline in a third. He found incompetence in one of the cases. He concluded, in part,

Patient A

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Patients who present with the intensity of illness of this patient have a prognosis that is guarded at best. On average, 40% of cardiogenic shock patients similar to this patient are dead in 30 days or less from the onset of their myocardial infarction. In a high risk patient like this, inability of the interventional cardiologist to recognize and appropriately treat both of two in-stent re-stenoses in contradistinction to an acute thrombotic destabilizing problem before addressing a problem that is by nature not acute, but chronic and often tedious and time consuming to rectify...This could have had a role in the ensuing downward spiral of uncontrollable hypotension, pulmonary edema and eventual death of this unfortunate patient. Finally, the inability of the operator to either diagnose or rule out wide open mitral insufficiency from the start with a technically adequate ventriculogram or with the data obtained by using a pulmonary artery catheter is also seemingly below minimum standards. This diagnosis eventually was made on the third day, but quite likely was present from the start and was not corrected by the emergency PCI procedure. Earlier surgery before the patient was terminally ill with multisystem failure and complications (renal failure, respiratory failure, distal aortic dissection from balloon pump, etc.) would have been lower risk.

... It is my opinion that incompetence was exhibited in the acute setting. It can only be speculation that a better outcome would have been possible had management been different in the acute setting. It does not seem likely that remedial education or training is necessary or likely to help. Impartial ongoing hospital based monitoring of adverse outcomes could be helpful, as well as objective peer reviews of cath lab complications. It may be necessary for the hospital to obtain outside reviews to eliminate "friendly" internal reviews. It may be necessary for the hospital to provide a means of anonymous input from nurses and technicians in acute settings for outside review. Random case monitoring might be recommended to the State Licensure Board where Dr. Vilca now practices for their consideration.

Patient B

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A patient transferred from another facility for invasive evaluation by multiple other physicians in most settings will end up with the invasive evaluation proceeding as planned by the interventionalist, here Dr. Vilca. Once the angiogram shows a significant lesion in a stent, the intervention becomes "standard of care." Dr. Vilca practices in a group. The "group" had earlier inappropriately placed this stent in a non-infarction artery post MI eventually caused this restenosis, but Dr. Vilca had no

role in previous care. It is the opinion of the reviewer that assigning this patient with diagnoses ACS/UA and Class III angina without any supporting criteria is inappropriate and likely done to justify an aggressive approach in the cath lab.

Patient C

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It was Dr. Vilca's decision to intervene in 2009 when grafts two and three failed and nearly failed respectively. Saphenous vein graft interventions are more likely to be complicated by procedural complications, by recurrent problems in the same lesion and by additional problems in the same graft at a different site. Highly symptomatic patients with an intact LIMA graft but failed SVG's are ruled "uncertain" for proceeding with PCI but "appropriate" for surgery according to current appropriate use criteria for revascularization. This calls into question the appropriateness of the decision to not even consider re-do CABG, but to do PCI instead. Alternatively, taking care of an immediate problem with a plan to do re-do surgery in the near future is a common appropriate strategy. Although it is not appropriate to apply these criteria retrospectively to cases before the criteria were published, it has never been acceptable to intervene on a non-infarct artery at the time of intervening on an infarct artery. This was done here, setting the state for acute thrombosis of both stents the next day after the patient went home. Since then, this graft has failed two additional times requiring added admissions, and interventions and one resuscitation from ventricular fibrillation during a procedure. It may well be that re-do surgery would have been a better strategy even though the LIMA graft was still patent, as suggested by appropriate use criteria.

As stated previously, it seems apparent that these physicians in general and Dr. Vilca in particular are aware of the appropriate use criteria. Ongoing monitoring will likely be necessary going forward to guard against inappropriate practice activity in settings where questionable practices have been noted.

Patient D

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Review of this case is complicated by several factors. Part of the complexity is based on the total of over 1800 pages provided detailing care administered by Dr. Vilca's group from 1996 through 2012. The case selected for review is but a small part of the overall picture.

The appropriate use criteria for both diagnostic angiography and coronary intervention published by the ACC heavily depend on accurate assessments of patient symptoms as well as patient performance during provocative testing. In this case, neither of these informational sources is available to help. Here there is an old outdated office generated note accompanied by a checkbox H&P completed by a mid- level provider before the procedure that provides no information as to the characteristics of the patient's symptoms. After the diagnostic angiogram is done, two tight lesions are found that appear to need revascularization. However, the plan from the beginning had always been to do a peripheral angiogram, but again the

reviewer is unable to justify the necessity of preempting the coronary intervention with this (large volume dye requiring) angiogram due to the absence of historical information about the presence or absence of rest pain or tissue loss with regard to the peripheral artery disease. This seeming digression procedure adds 77 cc's of dye to a total of 277 for the entire case. Once dye load exceeds 100 cc's, there are legitimate concerns about dye induce renal problems that can be more dangerous for certain patients dependent upon individual patient characteristics, not detailed by the records here.

The borderline nature of the opinion is strongly influenced by the records as discussed above. It may well be the patient really had CCS III level symptoms, but if so it is considered appropriate to detail them before, not after the intervention. If the patient did not have the marked limitation of activity as required to be classified as Class III, and this box was checked in error or because it was the option felt most appropriate, this falsification of records would be more of a concern. Accredited institutions may also require that records meet minimum standards prerequisite to proceeding in the lab.

Patient E

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Appropriate use criteria for revascularization are heavily dependent upon patient symptomatology. In terms of ischemia type symptoms, this is usually expressed as per the Canadian Cardiovascular System ranking worsening symptoms from Class I → Class IV. In addition, performance on stress testing is a major factor with low intermediate and high risk grades based on parameters used in stress testing. If this patient had post MI angina documented on any record, that record was not available for my review. Similarly, if the patient has a post- MI stress test, that record is not available for my review. From these records, it seems that the decision to proceed is based on the visual assessment that the stenosis is tight enough that it needs to be addressed in the opinion of Dr. Vilca and a surgical consultant. If the patient was completely without symptoms following the first MI, taking minimal anti-anginal treatment (ie, single drug therapy with a beta blocker), he would have to have had high risk criteria on a stress test to have solid agreement that revascularization was indicated. After the LAD was stented, then stress testing was done to see about the other lesion in question. This time, the records are contradictory, stating twice in the office chart that the patient was asymptomatic, but alleging that the patient had "Class III" angina on the hospital chart. Class III symptoms are reflective of marked limitation to even normal activities. The office record certainly does not back that assessment. Eventually "intermediate risk" findings on the pharmacologic stress test are used as supportive reason to do a third angiogram.

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STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Agreed Order:

1. The licensee's medical license is subject to regulation and discipline by the Board.
2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(3) and (4). Accordingly, there are legal grounds for the parties to enter into this Agreed Order.
3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve this pending investigation without an evidentiary hearing by entering into an informal resolution such as this Agreed Order.

AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this pending investigation without an evidentiary hearing, the parties hereby ENTER INTO the following **AGREED ORDER:**

1. The license to practice medicine within the Commonwealth of Kentucky held by Raul L. Vilca, M.D., SHALL BE SUBJECT to this Agreed Order for a period of five (5) years from the date of filing of the Agreed Order.
2. During the effective period of this Agreed Order, the licensee's medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS:

a. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL make all necessary arrangements to enroll in the Documentation Seminar at the Center for Personalized Education for Physicians (CPEP), 7351 Lowry Boulevard, Suite 100, Denver, Colorado 80230 – 303/577-3232, for the earliest seminar at which CPEP has an opening. The licensee shall complete the Documentation Seminar at the time and date(s) scheduled, at his expense;

b. The licensee SHALL also take all necessary steps to enroll in the CPEP Personalized Implementation Program. The licensee shall complete the Personalized Implementation Program, at his expense, as directed by CPEP's staff.

c. The licensee SHALL provide the Board's staff with written verification that he has successfully completed CPEP's Documentation Seminar, promptly after completing the Seminar, and that he has enrolled in the 6-month Personalized Implementation Program;

d. The licensee SHALL provide the Board's staff with written verification that he has successfully completed the 6-month Personalized Implementation Program promptly after completing that program.

e. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP will provide a copy of any evaluations from the Documentation Seminar and Personalized Implementation Program to the Board's Legal Department promptly after their completion;

f. If the licensee should evaluate, diagnose or treat any patient within the Commonwealth of Kentucky during the effective period of this Agreed Order, he SHALL comply with each of the following conditions:

1. The licensee SHALL obtain an adequate history and physical evaluation for each patient that supports the diagnosis and any procedure performed;
2. The licensee SHALL include documentation in each patient's medical record that meets Medicare documentation standards for Level 4-5 before performing any invasive procedure, unless the patient requires emergency treatment. In the event the patient requires emergency treatment, the licensee may provide treatment appropriate to address the emergency, but must meet this documentation requirement promptly after completing the emergency procedure;
3. The licensee SHALL ONLY perform a diagnostic coronary angiography when the appropriate use criteria of 2012 J.Am. College of Cardiology Appropriate Use Criteria for Diagnostic Catheterization (5/9/12) are present and supported by the patient record;
4. The licensee SHALL ONLY perform a coronary revascularization when the appropriate use criteria of 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update, Vol. 59, No. 9, 2012 are present and supported by the patient record;
5. The licensee SHALL ONLY perform an invasive procedure on a patient when a stress test has been performed or over-read by another

nuclear cardiologist, unless the licensee can adequately justify upon the patient record that a stress test is medically inappropriate for the particular patient;

6. The licensee SHALL calculate the Duke Treadmill score for regular treadmill stress testing for each patient;
7. The licensee SHALL ONLY perform an invasive procedure where nuclear stress testing and echo cardiogram stress test level of risk for the specific patient are specific and recent;

g. The licensee SHALL permit the Board's agents to inspect, copy and/or obtain patient records, upon request, for review by the Board's agents and/or consultants;

h. The licensee SHALL reimburse the Board fully for the costs of each consultant review performed pursuant to this Agreed Order. Once the Board receives the invoice from the consultant(s) for each review, it will provide the licensee with a redacted copy of that invoice, omitting the consultant's identifying information. The licensee SHALL pay the costs noted on the invoice within thirty (30) days of the date on the Board's written notice. The licensee's failure to fully reimburse the Board within that time frame SHALL constitute a violation of this Agreed Order;

i. The licensee understands and agrees that at least one favorable consultant review must be completed, on terms determined by the Panel or its staff, before the Panel will consider a request to terminate this Agreed Order;

j. The licensee SHALL pay the costs of the investigation in the amount of $6,750.00 within twenty-four (24) months from the date of entry of this Agreed Order;

k. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.

3. The licensee expressly agrees that if he should violate any term or condition of this Agreed Order, the licensee's practice will constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an *ex parte* presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Agreed Order;

4. The licensee understands and agrees that any violation of the terms of this Agreed Order would provide a legal basis for additional disciplinary action, including

revocation, pursuant to KRS 311.595(13).

SO AGREED on this 22 day of March, 2013.

FOR THE LICENSEE:

RAUL L. VILCA, M.D.

COUNSEL FOR THE LICENSEE
(IF APPLICABLE)

FOR THE BOARD:

C. WILLIAM BRISCOE, M.D.
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