

Dear Ms. Fleck,

Thank you for producing a very comprehensive and well written draft COMAR 10.24.17 (I reviewed the corrected version of 10/2/2013)

I have the following comments, or questions for clarification:

1. I agree with Dr. Christopher Haas that in addition to angiographic images, documentation, such as the procedure report as well as relevant clinical notes and test reports be included in a review of a PCI procedure.

Also, I may add that the new updated ACC AUC (appropriate use criteria) terminology is as follows: appropriate, maybe appropriate, and rarely appropriate. (vs. the old terminology of appropriate, uncertain and inappropriate) The AUC criteria are guides, but do not include every possible clinical and patient characteristic scenario.

2. I think Policy 3 is very important, that is for the Hospitals to continue community outreach and education in order to help reduce the incidence of cardiovascular disease and improve outcomes for Maryland residents.

For example, a door-to-balloon time of 25 minutes will have little impact if the patient presents with an anterior myocardial infarction 5 hours after development of symptoms. We have all seen such cases....

I think the State should also consider a statewide public education program (and appropriate funding), reinforcing the concept of not delaying calling 911 or seeking medical attention when signs and symptoms of a heart attack occur.

3. With regard to the sections on Physician Resources, there is a concern that physicians fresh out of fellowship training, who are beginning to build their practices, may not immediately achieve a 50 or more annual case volume averaged over two years. On p. 20 (6) (b), "cases performed during fellowship training cannot be counted in calculating a physician's compliance with this standard" This clause is not repeated in subsequent PCI Physician Resources sections of the draft document.

I think it should be clarified whether physicians less than two years out of their fellowship can perform primary PCI at hospitals without (or with) on-site cardiac surgery. My view is that the hospitals should have the discretion to decide when such operators are qualified to take on independently primary PCI call. I think the interventional program directors and hospitals can evaluate such physicians by accounting for their experience in fellowship training, as well as some type of initial proctoring by more experienced interventional colleagues and mentors, to decide when it is appropriate for physicians less than two years out of fellowship to begin to participate in primary PCI call. Certainly these physicians can be subject to a more

focused individual review, in the same manner that those performing less than 50 cases a year, who may have been in practice for many years.

In other words, my impression is that the draft document does not specifically state that individual operator case volume is an absolute exclusion, but more of a threshold for a more focused review of individuals performing less than 50 cases/year averaged over two years. An operator who performs, let's say 40 PCI cases a year, and has acceptable outcomes, will not be excluded from practice by Maryland Regulations. Am I correct ?

Otherwise, if our regulations are or seem too restrictive, well-qualified newly trained interventional cardiologists may choose to avoid joining a practice in Maryland and go elsewhere.

4. With regard to a "leave of absence" it is understandable, particularly in instances of female interventional cardiologists who take time out from their career to bear and give birth to children, a more prolonged absence of any physician, due to illness or taking a sabbatical, or even "paternity" leave for males; should be accounted for. One should be clear what is the definition of a "leave of absence".

For example a 1-3 week vacation likely does not need to be reported as a "leave of absence". Likewise, requiring 10 proctored cases may be more than is necessary, perhaps a lower number such as 5 should be sufficient.

5. I agree that the target volume for primary PCI operators should be 11 STEMI cases per year (as per current guidelines), but again, this can not and should not be an absolute cutoff that would affect credentialing and participation in an on call primary PCI roster.

6. On p. 41, under the definition of *Elective PCI*, it **CAN include patient's suffering from an acute coronary syndrome (but not a STEMI)**. Acute coronary syndromes can include: clinical unstable angina, non-STEMI and STEMI. *Emergency PCI or "primary PCI"* is the treatment for STEMI or its equivalents (ie new LBBB or pure posterior MI).

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