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Eileen Fleck
Chief, Acute Care Policy & Planning
Maryland Health Care Commission
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Baltimore, Maryland 21215
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Dear Ms. Fleck:

Thanks to you and the Maryland Health Care Commission for the opportunity to comment on the draft of COMAR 10.24.17.

I have the following comments to offer regarding the State Health Plan for Facilities and Services: Specialized Cardiovascular Services (COMAR 10.24.17):

.04 A (1) (b) Please read the first sentence carefully – it is not correct as written. I assume a “by” is missing between “recommended” and “the CSAC”. This proposed regulation I find troubling from two points-of-view. First, the CAG did develop and explicitly define quality measures. The purpose of CSAC, in my understanding, is to implement those quality measures: meaning, use them to monitor and help MHCC manage quality. Second, there was no discussion about linking the CSAC’s work to CON applications. Given the highly charged nature of the CON application process, this association would seem to “politicize” CSAC’s efforts from the start, something the CAG certainly does not support. I cannot understand the reasoning behind or justification for this regulation and would strongly suggest its removal. Please keep the focus of the CSAC and Data Committee on the monitoring and management of program quality. This review system is, arguably, the single most important result of the CAG’s work.

.05 A (1) (a) Regarding Minimum Requirements for CON for Cardiac Surgery, the requirement to demonstrate the “ability to meet a projected volume of 250 cardiac surgery cases in the second full year of operation” seems arbitrary, not supported by data and incongruent with the 200 cardiac procedure volume described in the rest of the Regulations document. The CAG did not discuss this number. Furthermore, the requirement of 200 cases per year expressed in the very next statement is, in fact, *the* requirement. The vague, arbitrary and unsupported first statement should be eliminated in a document otherwise so careful about discussion of volume.

.05 (3) (b) While a laudatory goal, there is no method of which I am aware that one could project the effect of a new cardiac surgery program on an existing program in any way other than volume. In the absence of an actual methodology to assess the influence of a new program on an existing program's quality, this regulation is meaningless and unachievable. If there is a specific methodology for completing this task other than through volume change projections, it should have been or should be explicitly defined prior to creating a regulation like this. It was not discussed in the CAG in ways other than volume. This should be eliminated.

.06 B (2) Regarding elective PCI volume, I thought the requirement was to reach 200 cases by the second year. The regulation says three. I have no specific objection to this, but wanted to bring that to your attention.

Again, many thanks to you, Executive Director Steffen and the Commissioners for your continued good works. Your commitment to providing optimal access to the highest quality cardiovascular care to the citizens of Maryland is reflected in these proposed regulations and the careful and thoughtful efforts required to develop them.

Sincerely

A handwritten signature in black ink, appearing to read 'T A', with a long horizontal flourish extending to the right.

Thomas Aversano, M.D.