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By Email and Regular Mail

Eileen Fleck  
Chief, Acute Care Policy and Planning  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore MD 21215

October 21, 2013

Re: Draft Regulations For Informal Comment; State Health Plan for Facilities  
and Services: Specialized Cardiovascular Services COMAR 10.24.17 (Draft Plan)

Dear Ms. Fleck:

This letter serves as Johns Hopkins Medicine's comments on the recently released draft regulations on Specialized Cardiovascular Services as noted above.

We applaud the efforts of the Maryland Health Care Commission and the Clinical Advisory Group in its implementation of House Bill 1141 (Chapter 418), passed in 2012. The broad policy objectives stated under .03 Issues and Policies are laudable and consistent with our policies and practices to provide all patient care in a safe, effective and appropriate manner. We also strongly believe in equity of access to care for all Marylanders, transparent, rigorous, and consistent quality reviews and performance evaluations among the programs, and continuous quality improvement efforts throughout the system. To this end, there are several provisions in the Draft Plan which we believe require reconsideration. We therefore submit the following comments for your consideration:

A. .03 Issues and Policies

We agree with Policy 4 that cardiac surgery and PCI services should be financially and geographically accessible. However, we note that the access discussion found in the draft chapter at pages 9 through 10 only discusses PCI services. This should be amended to also include a discussion of the importance of geographic access to cardiac surgery services.

We also note that on page 6, the draft chapter has amended the health planning regions to include Cecil, Kent, Queen Anne's, Caroline, and Talbot Counties in the newly named "Baltimore Upper Shore" planning region. Although it may be reasonable to include these "Upper Shore" counties in a more Baltimore-based planning region, presumably based on utilization patterns and geographic proximity, we would suggest that the plan provide more rationale and discussion as to the basis for defining and sizing service areas in support of the goal of assuring appropriate access to care for Maryland residents.

B. .04 Program Policies

We support the statement in section .04A(1)(c) that the hospital rate setting system must evaluate the future costs and benefits of any new cardiac surgery program in Maryland. However, such a policy – and eventual finding by the Commission – should be considered as part of the certificate of need review process regarding the financial viability of any new project, and not act to prohibit the filing of a certificate of need application.

C. .05 Review Standards

Regarding section .05A(2), we note that it is unprecedented to require an applicant to show that a new program will not cause any loss in volume at an underperforming program with an “overlapping” service area. We do not support this affirmative shifting of burden from a planning perspective. It is unfair and not necessary.

We also note the exclusion from the draft chapter at .05A(7) of a preference standard for a program that includes a research, education, and training component. We strongly disagree with the removal of this preference standard, and urge that the Commission reinstate it in its next version of the draft chapter. The furtherance of research, education and training should always be a preferred result of any new health care program in our State.

D. .07A Certificate of Ongoing Performance Cardiac Surgery (4) Quality (b) and (c)

The purpose for hospitals to perform an external review of 5% of cardiac surgery cases is not clear, and does not specify for what the reviewer would be looking. Random case reviews generally are not effective in reasonably assessing quality, nor do they assess appropriateness of care. Alternatively, review of programs can be targeted based on their STS data. STS observed mortality to expected mortality is a very clear metric for quality and provides an objective, easily reportable metric that is a surrogate for quality. We believe the STS data base is the gold standard by which all cardiac surgery programs should be evaluated.

Similarly, the requirement for random review of 10 or 10% of cases, whichever is greater, for each cardiac surgeon is very vague and fails to point the reviewer at a measureable outcome. If the goal is to measure quality and appropriateness of care, the methodology is not likely to serve the intended purpose in surgery. Further, it will result in a low yield and will add significant costs. Random case reviews have been proven to be inefficient, ineffective and costly. Consider the fact that last year there were some 3900 cardiac surgery cases in Maryland; reviewing nearly 400 cases would present a significant burden and drain on resources. One cardiac surgeon at our institution alone performs approximately 350 cases annually, with only 50 of those being straightforward Coronary Artery Bypass Grafts (CABGs). If the goal is to identify those procedures which are not appropriate, it is very unlikely that a random review will identify such cases. Nor is a random review the most effective means to identify quality concerns. Alternatively, auditing the STS data would be more useful, would provide quantitative information, and would verify the efficacy of the STS database.

We recognize and agree with the need for uniformity among the cardiac surgeons and programs, especially as it relates to quality review. However we strongly believe that the focus should be on outcomes through the use of the STS data. That methodology would be the best use of resources to assure quality.

Finally, we formally incorporate into this comment letter those comments made by Dr. Thomas Aversano, Associate Professor of Medicine, Johns Hopkins University, in his letter to the MHCC dated October 19, 2013.

Thank you for the opportunity to comment on this critically important draft chapter of the Maryland State Health Plan.

Sincerely,

A handwritten signature in black ink, appearing to read "Anne Langley", with a long horizontal flourish extending to the right.

Anne Langley