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October 21, 2013

Eileen Fleck
Chief, Acute Care Policy & Planning
Maryland Health Care Commission
41060 Patterson Avenue
Baltimore, MD 21215

RE: COMAR 10.24.17 State Health Plan for Facilities and Services: Specialized Cardiovascular Services

Dear Ms. Fleck:

On behalf of our 66 member hospitals, the Maryland Hospital Association (MHA) appreciates the opportunity to provide informal comments on the draft regulatory changes to 10.24.17 State Health Plan for Facilities and Services: Specialized Cardiovascular Services. MHA commends the Maryland Health Care Commission (Commission) staff for their work in support of the Clinical Advisory Group on Cardiac and PCI Services (CAG), charged with providing guidance to the Commission for a new regulatory framework for the oversight of percutaneous coronary intervention (PCI) services and cardiac surgery. The CAG represented the broad range of clinical and administrative expertise and perspective necessary for such a challenging task. Their recommendations were thorough and deliberate.

The mission of Maryland's hospitals is to provide safe, high quality care, and MHA is committed to working with the Commission and others on regulatory processes that support this objective. MHA appreciates the work of the Commission in implementing HB 1141 from the 2012 session and efforts to engage the stakeholder community in this work. However, we believe the charge contained in HB 1141 has been broadly interpreted in the draft regulations; most notably with regard to the future of the certificate of need (CON) program.

Under .04A(1) of the draft, applications for new cardiac surgery programs will not be considered until the Commission makes a finding that the rate setting system is "adequately stable" for an evaluation of a new program. No standards are provided for this determination, nor is there any detail on the process by which it will be made, which suggests a moratorium on new programs. If this is to be a constraint, greater clarity is needed before implementation.

While we acknowledge the conditions of Maryland's modernized waiver application have never been tried or tested, we believe the Commission needs to be mindful of the work of the Health Services Cost Review Commission (HSCRC). The HSCRC is establishing an implementation process including formation of an Advisory Committee and several workgroups, any of which

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may be charged with considering how capital investments and CON may or may not need to evolve. Until that time, we would urge the Commission to refrain from making determinations about the stability of the rate setting system.

The CAG recommendations reflect changes in the scientific consensus regarding PCI at non-surgical hospitals, and also take into account current findings regarding quality of care in cardiac surgery and related services. The CAG provided scientific and clinical practice perspectives, gave input on appropriate peer review practices, and also spoke to regulatory experience in other states. For these reasons, we are requesting clarification on several inconsistencies with the recommendations of the Clinical Advisory Group as listed below, which have raised concern among some of our members.

- **Minimum volume requirement for new programs (.05A(1)):** The CAG recommended minimum volume of 200 cases by the end of the second year of operation. The draft would require an applicant to demonstrate the ability to perform 250 cases.
- **Impact on Non-Maryland Programs (.05A(2)):** The CAG recommended limiting the review of the impact of a new program on existing programs to programs in the State of Maryland. The draft appears to require an applicant to demonstrate lack of impact on providers outside the State of Maryland.
- **Charge of Cardiac Services Advisory Committee and Timing of Consideration of New Programs (.04A(1)):** The draft would defer any consideration of new programs until there has been at least a year of reporting under quality standards to be recommended by a yet-to-be established Cardiac Services Advisory Committee (CSAC). The CAG recommended the formation of an expert standing committee to provide advice on the implementation of the new Chapter and on a hospital's plan of correction when it fails to meet those requirements, but did not specifically charge this group with development of quality measures. The CAG developed quality criteria for cardiac surgery programs which are contained in the draft chapter. Further, the one-year time frame was not discussed within CAG deliberations.

Given these inconsistencies and the policy implications related to the modernized waiver, MHA will continue to process the impact of these issues among our membership and will seek to provide specific recommendations during the formal comment period.

Again, thank you for the opportunity to informally comment on the draft regulatory changes. If you have any questions, I can be reached at 410-540-5069.

Sincerely,



Nicole Dempsey Stallings
Assistant Vice President, Quality Policy & Advocacy