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CORPORATE OFFICE

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Delivery via email
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Paul Parker
Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215-2299

RE: Written Comments regarding the State Health Plan for Facilities and Services:
Specialized Health Care Services-Cardiac Surgery and Percutaneous Coronary
Intervention Services

Dear Mr. Parker:

Thank you for the opportunity to comment on the permanent proposed regulations, State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services, COMAR 10.24.17 (hereinafter “PPR10.24.17”). These comments are offered on behalf of the hospitals within the University of Maryland Medical System (UMMS) including but not limited to University of Maryland Medical Center, Baltimore Washington Medical Center, and Upper Chesapeake Health System, each of which presently operates one or more cardiac services. The effort and attention which the Maryland Health Care Commission has put forth concerning the details in these regulations is very much appreciated. These comments are offered to make a good product even better.

Closure

The text in the section on Closure of Programs, Cardiac Surgery, PPR10.24.17.04B(1), pg. 15 is much improved. We have discussed making certain that a hospital has a chance to address the circumstances which might lead to closure before closure could occur and that evaluation for closure is only valid under the circumstances specified in PPR10.24.17 B(1)(a)(i) thru (iii), p. 15. UMMS suggests that clarifying language is needed to ensure that a hospital has had an opportunity to address the specific issues at hand in the proposed closure. For example:

(iv) a cardiac surgery program has been given an opportunity to address the deficiencies *identified pursuant to subsection B(1)(i) through (iii), above, following a focused review as described in subsection .07B(2), submit a plan of correction which addresses those deficiencies and the hospital has failed to adequately correct those deficiencies.*

(The proposed changes are indicated by italics).

Impact

Insofar as the array of cardiac services is inter-related and may be inter-dependent, UMMS recommends that an applicant for a new cardiac surgery program be required to demonstrate that other providers of cardiac “*services*”, versus “*surgery*”, in the health planning region or an adjacent health planning region will not be negatively affected. PPR10.2417.05A(2)(v), p. 18. Similarly, the mandate should be that a new cardiac surgery program must show that it will not “[c]ompromise the financial viability” of cardiac “*services*” versus solely cardiac “*surgery*” in the region or adjacent region.

Focused Reviews/Plan of Correction

The proposed regulations adequately delineates the process which follows a focused review when a program is deemed to fall short of one of more requirements for a Certificate of Ongoing Performance, PPR10.24.17.B(2), pps. 33–34, including the submission of a proposed plan of correction. However, the proposed regulations say only that “*an*” approved plan correction shall be timely and successfully completed. PPR10.24.17.07.B(2)(d), pg. 34. The Commission should ensure that the regulations refer to the relevant plan of correction, i.e. “*the*” plan of correction developed under PPR10.24.17.07.B(2)(c). The same concept should apply each time a reference is made to the consequences of failing to complete “*an*” approved plan of correction. See e.g., elective PCI, PPR10.24.17.07C(d), p.38 and primary PCI, PPR10.24.17.07D(d), p. 44.

Requisite physician resources are discussed in the sections on primary and elective PCI. PPR10.24.17.07D(7), pps. 48-49 and PPR10.24.17.07(6), pps. 40–41, respectively. If a physician fails to perform the requisite number of PCI procedures annually, the same opportunity to develop a plan of correction should exist. Elsewhere it is stipulated that a hospital “*shall*” develop a plan of correction. In these two physician resources sections, the term is “*may*” is used; “*shall*” would make these provisions appropriately, internally consist.

Data/STS

The proposed regulations would require hospitals with cardiac surgery programs to participate in the STS-ACSD and submit duplicate information to the MHCC. PPR10.24.17.07 B(3), pps. 34-35. Further “[e]ach cardiac surgery program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission.” UMMS agrees with the requirement that hospitals participate in STS-ACSD, as the STS process is robust and efficient. STS also compares cardiac surgery programs nationally on a multitude of factors and ultimately derives a composite STAR rating. UMMS would, however, strongly caution the MHCC against attempting to duplicate the STS-ACSD analysis, as it would be duplicative, time-consuming, and expensive for the MHCC to do so. Moreover, it appears that once substantial state resources are expended, there will be no additional benefit to the ultimate analysis of quality of the state’s cardiac surgery programs. The “costs” outweigh the value of supplying duplicate raw data and duplicating the STS analysis and reporting capabilities.

Auditor

UMMS appreciates that the Commission will seek outside, clinical expertise for focused reviews. PPR10.24.17.07B(2), pg. 33. However, UMMS suggests that the Commission include a definition of the term “auditor” to include the requisite qualifications and level of training an individual must have in order to serve as an auditor, specifically that an auditor must be a physician. UMMS also recommends that more than one auditor be included in each focused review, not just focused reviews where “quality” is at issue. Additionally, the definition should also incorporate the safeguard that a focused review of a cardiac surgery program may not be conducted by/with auditors who are direct competitors. A single individual may have a biased viewpoint point. In order to be most fair and equitable a team of clinicians of varying backgrounds should be carefully chosen to participate in each focused review.

Thank you again for the opportunity to comment on these important changes to the State Health Plan section on the cardiac services. Should you have any questions, please let us know.

Sincerely,



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Senior Vice President
Government & Regulatory Affairs