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March 10, 2015

Paula S. Widerlite, Chief Strategy Officer
Anne Arundel Medical Center
2001 Medical Parkway
Annapolis, Maryland 21401

Re: Anne Arundel Medical Center Proposal to Change the Type and Scope of Health Care Services Offered to Include Cardiac Surgery – Matter No. 15-02-2360

VIA E-MAIL AND REGULAR MAIL

Dear Ms. Widerlite:

Staff of the Maryland Health Care Commission ("MHCC") has reviewed the Certificate of Need application filed on February 20, 2015. We have the following questions and requests for additional information concerning this application. Please respond to this request, following the rules at COMAR 10.24.01.07. The application will be docketed if the response is complete.

PROJECT DESCRIPTION

1. The application, on p. 9, states: *AAMC must transfer more than 200 patients each year for cardiac surgical care, a number in excess of the minimum requirement for a program.* This statement is repeated on p. 17, and alluded to elsewhere ion the application. Does this mean literally transferred, in an ambulance or helicopter, or does it also include patients who are referred? Please document these numbers.

2. Please document and quantify the statement on p. 15 that: *The CPORT program at AAMC, providing angioplasty for acute MI, has some of the highest volumes and best outcomes in Maryland, with exemplary door to balloon times, excellent results and outstanding quality of care.* Show those results compared to the compare group.

3. The application states, on p. 18, that the service area defined for the proposed program extends beyond the HSCRC's GBR-defined service area. Please provide a list of zip codes in the defined service area, distinguishing between those that are in the GBR-defined service area and those that are not. (The listing in Appendix 2 seems to be the total presumed service area, greater than the GBR-defined service area.)

4. Given that existing room(s) will be turned over to use by a prospective cardiac surgery program, please demonstrate that existing OR use allows for this new program. What % of OR capacity is AAMC currently running at?

CONSISTENCY WITH GENERAL REVIEW CRITERIA (COMAR 10.24.01.08G(3))

a) The State Health Plan

COMAR 10.24.10.04 A. - ACUTE HOSPITAL SERVICES standards

Charity Care Policy

5. Please describe how – other than postings in the hospital -- public notice of information regarding the hospital's charity care policy are distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis.

6. The *Patient Financial Services – Hospital Financial Assistance, Charity Care, Billing & Collection Policy* alludes to a Financial Assistance Policy as being posted on the AAMC website.
   a. Is there a separate Financial Assistance Policy? It seems instead to be wrapped into the *Patient Financial Services – Hospital Financial Assistance, Charity Care, Billing & Collection Policy* ?
   b. If there is a separate policy please submit a copy and provide direction to where it is located on the web site.

COMAR 10.24.17 Cardiac surgery standards

Minimum Volume

7. On p. 78 the following statement is made: *Findings: AAMC's current base of affiliated cardiologists generates the volume to support a cardiac surgery program of greater than 200 cases, even after the projected use rate factor has been applied.* Please explain what is meant by the phrase: *even after the projected use rate factor has been applied.*

8. On p. 80 of the application there is a reference to AAMC's review of the records of all inpatient and outpatient direct transfers arranged from AAMC to other hospitals for cardiac surgery. It states that the review included all patients transferred for cardiovascular bypass surgery and valve surgery, as well as a portion of patients transferred specifically for evaluation for cardiac surgery and that "clinicians assumed that 50% of those patients transferred for evaluation for cardiac surgery…received cardiac surgery."
    a. How many of these patients were definitively referred for cardiac surgery, and how many for evaluation?
    b. What was the basis for assuming that 50% of those referred for evaluation actually had cardiac surgery performed?

9. Please list the counties making up the "service area that incorporates 5 counties from within the Baltimore Upper Shore region, and segments from 2 counties of the Washington Metropolitan region." (p.85)

Impact

10. In the *The Effect of Location – Impact on Maryland Hospitals* section the conclusion is drawn that the existing cardiac surgery hospitals operating in Maryland would be expected to have no reduction in their net income from services as a result of cardiac surgery volume shifting to AAMC (p. 90) due to HSCRC policy that you state "is designed so that there will be no adverse financial impact on a Maryland hospital as a result of the hospital losing patients to AAMC's cardiac surgery program" because 50% of the revenue would stay with that hospital. Please react to MHCC staff's belief that -- even if hospitals losing volume were to retain 50% of the associated revenue as AAMC posits – their revenue losses would be significantly greater than the incremental cost (variable cost) of the lost volume.

Cost-Effectiveness

11. The response to this standard failed to treat part (c) of the standard, i.e.: ***An applicant shall provide an analysis of how the establishment of its proposed cardiac surgery program will alter the effectiveness of cardiac surgery services for cardiac surgery patients in its proposed service area, quantifying the change in effectiveness to the extent possible. The analysis of service effectiveness shall include, but need not be limited to, the quality of care, care outcomes, and access to and availability of cardiac surgery services.*** AAMC may feel that this analysis is included elsewhere in the application, but it would be useful to summarize it here.

Access

12. The application cites an article published in the Journal of Medical Care in 2014 which the application states: "documents that longer travel time to the hospital for cardiac surgery and subsequent care may have significant effects on clinical outcomes." The results encapsulated in the article's abstract state: "*We found that patients living near a CABG hospital with acceptable quality traveled significantly less and if they were high risk, had lower in-hospital mortality rates. Readmission rates in general are not affected by patients' travel distance.*" While it is difficult to find a definition of what was considered living near or far from a CABG hospital in this study, it seems, however, that the article was speaking about patients who lived hundreds of miles from one, not the "up to 40 minutes in normal traffic and even longer during heavy traffic" that the application states that Anne Arundel County patients must travel to a cardiac surgery program in Baltimore City (p.110). Please discuss.

13. The application references a program partnership with Johns Hopkins Medicine (JHM) that would be part of the proposed new cardiac surgery program that will leverage the assets of the JHM cardiac surgery program and extend existing resources from Baltimore to the Anne Arundel County region, thus providing residents of the proposed service area with improved access to JHM surgical staff, new treatment modalities, and clinical care protocols. Please discuss why such a partnership and its resulting benefits could not be established through an alliance that included shared clinics and care plans and protocols and electronic medical records without establishment of a second cardiac surgery site.

Need

14. The table in the middle of p.130 lacks a heading, making the point it is meant to illustrate unclear; please submit that table with headers.

15. The application projects the number of diagnostic cardiac catheterizations on AAMC patients that would be expected to result in cardiac surgery, using 11.4% as the proportion that would result in surgery, and calls that 11.4% "consistent with national practice patterns and clinical expectations." Please cite and quote the source of this information.

Preference in Comparative Review

14. Please provide a more concise description and summation of the case that AAMC built regarding cost effectiveness and the Medicare and All-Payer Waiver Tests, between pp. 166 and 172.

15. The application (p.165) cites the research, training, and education that JHM would bring to this project. Please explain how this would "meet a local or national need" that JHM would not otherwise be meeting. Also elaborate on how "the applicant's circumstances offer special advantages."

b) Need

16. Please explain the a) 16.7% increase in ER visits projected between FY14 and FY19, and b) the 37.4% increase in same day surgery over the same period. Please show historical volumes for each of these services, beginning with FY10.

d) Viability of the Proposal

17. What accounts for the negative $31,684,793 shown for non-operating income in **Tables G and H?**

Please submit six copies of the responses to completeness questions and the additional information requested in this letter within ten working days of receipt. Also submit the response electronically, in both Word and PDF format, to Ruby Potter (ruby.potter@maryland.gov).

All information supplementing the applicant must be signed by person(s) available for cross-examination on the facts set forth in the supplementary information, who shall sign a statement as follows: "I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief."

Should you have any questions regarding this matter, feel free to contact either me at (410) 764-5982.

Sincerely,

Kevin McDonald
Chief, Certificate of Need

cc: Jonathan Montgomery, Esq.
Thomas C. Dame, Esquire
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