STATE OF MARYLAND

Craig Tanio, M.D.
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MARYLAND HEALTH CARE COMMISSION

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MEMORANDUM

TO: Commissioners, Maryland Health Care Commission

Anne Arundel Medical Center
University of Maryland Baltimore Washington Medical Center
Anne Arundel County
Anne Arundel County Department of Health
Dimensions Health Corporation d/b/a Prince George's Hospital Center
LifeBridge Health, Inc.
MedStar Union Memorial Hospital
MedStar Washington Hospital Center

FROM: Craig P. Tanio, M.D.
Commissioner/Reviewer

RE: Revised Recommended Decision
Cardiac Surgery Review for the Baltimore/Upper Shore Region
Docket Nos.: 15-02-2360 and 15-02-2361

DATE: March 3, 2017

Enclosed is my Revised Recommended Decision in the comparative review of two Certificate of Need applications proposing the introduction of cardiac surgery services in the Baltimore/Upper Shore health planning region established in COMAR 10.24.17 for regulatory oversight of cardiac surgery services. Based on my review of the entire record in this review, I recommend that the application of Anne Arundel Medical Center, Inc. ("AAMC") for a Certificate of Need to introduce cardiac surgery services be **APPROVED** with conditions. I also recommend that the application of the University of Maryland Baltimore Washington Medical Center, Inc. ("BWMC") to introduce cardiac surgery services be **DENIED**.

I recommend that, if the Commission adopts my Revised Recommended Decision as its decision, the following conditions be placed on the Certificate of Need issued to Anne Arundel Medical Center:

1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b);

2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center;

3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services; and

4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to the Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

This Revised Recommended Decision replaces a Recommended Decision that I released on December 30, 2016. I determined that some information used in my original Recommended Decision, information on Maryland residents obtaining cardiac surgery in Virginia in recent years and a record key for population estimates and projection information entered into the record on December 30, 2016, should have been provided to the parties with sufficient time for them to comment on this information prior to the Commission's consideration of my recommendation. For this reason, I delayed consideration of my earlier recommendation, originally scheduled for January 26, 2017, and provided time for comments on that information. During this delay, I also made additional changes in this Revised Recommended Decision. These changes did not materially alter my findings or conclusions or my recommendation.

I recommend that Anne Arundel Medical Center's application to establish cardiac surgery services be approved because it has the highest potential for establishment of a lower charge cardiac surgery program that will also be high performing. AAMC is the larger of the two applicant hospitals and has a larger service area base than BWMC from which to draw patients. Geographically, AAMC is better positioned than BWMC to draw from the two urban areas in which all but two of the programs serving Maryland residents are currently located: Baltimore City and County, with five programs; and Washington, D.C. and its two contiguous Maryland suburban jurisdictions, Montgomery and Prince George's Counties, with six programs. Anne Arundel Medical Center is also better positioned to have the greatest impact on reducing travel time for cardiac surgery services, given the access it affords to the population of

Maryland's Eastern Shore in the mid-Shore jurisdictions of Caroline, Kent, Queen Anne's, and Talbot Counties and also to the population of northern Calvert County.

I recommend that only one new cardiac surgery program be created at this time. As health care delivery technologies evolve, it is important that the health system reduce the costs of such technologies over time. It has also been an important health policy objective in Maryland to search for strategies to improve the cost-effectiveness of care in the hospital setting. Each of the proposed programs has potential for reducing the charges paid by patients and payers for cardiac surgery services and each applicant hospital, working in collaboration with its partner hospital or system affiliate, could develop a safe and clinically competent program. AAMC has entered into a collaborative relationship with Johns Hopkins Medicine and the cardiac surgery program at The Johns Hopkins Hospital in Baltimore to develop its proposed cardiac surgery program. BWMC has proposed development of its program in collaboration with the cardiac surgery program at the University of Maryland Medical Center in Baltimore and the University of Maryland Medical System, of which it is a member hospital. To help assure that the impact of moving surgery cases from high cost to lower cost settings does in fact reduce charges paid by patients and payers, I requested and received financial commitments from both applicants and their collaborating partners that neither would approach HSCRC in the future to seek an increase in rates due to shifts in cardiac surgery volumes. The financial commitments received by the MHCC create an important precedent.

I note that I considered the market feasibility and the impact of two new programs being developed at the same time. However, a new cardiac surgery program is required by COMAR 10.24.17, the Cardiac Surgery Chapter of the State Health Plan, to achieve a required minimum volume of adult cardiac surgery cases. The approval of two new cardiac surgery programs at the same time could risk the creation of two low volume, underperforming programs that could require ongoing corrective actions by the Commission, possibly leading to closure of one or both programs. I concluded that the most prudent approach is to recommend approval of only the stronger application, that of Anne Arundel Medical Center.

This recommendation does not preclude BWMC from coming back to the MHCC at a future time once there is concrete evidence of the impact on the movement of cardiac surgery volume from a high cost center to a lower cost center on cost, quality, and access. I recommend that, if the Commission adopts my Revised Recommended Decision as its decision, it request that staff collect such impact information and monitor the impact of AAMC's cardiac surgery on cost, quality, and access and report this impact to the Commission on an annual basis for the next four years.

REVIEW SCHEDULE AND FURTHER PROCEEDINGS

This matter will be placed on the agenda of a meeting of the Maryland Health Care Commission on March 23, 2017, beginning at 1:00 p.m., at 4160 Patterson Avenue in Baltimore. The Commission will issue a final decision based on the record of the proceeding.

As provided in COMAR 10.24.01.09B, each applicant and interested party may submit written exceptions to the enclosed Revised Recommended Decision. Written exceptions and argument must identify specifically those findings or conclusions to which exception is taken, citing the portions of the record on which each exception is based. Each applicant and interested party must submit 20 copies of its written exceptions. Copies of exceptions and responses to exceptions must be emailed to all parties by the due date and time, but the required copies may be filed with the Commission on the next business day.

I note that, because a participating entity does not have a right of judicial appeal, Commission regulations do not grant a participating entity the right to file exceptions to a Recommended Decision. I want to point out that a participating entity may, in accordance with COMAR 10.24.01.09C, request that the Chair of the Commission permit it to make an oral presentation to MHCC before action is taken on an application for Certificate of Need. If Anne Arundel County desires to speak before the Commission takes action on my Revised Recommended Decision, it should make such a request and file comments regarding the Revised Recommended Decision by the deadline for the filing of exceptions.

Oral argument on the exceptions during the exceptions hearing before the Commission is limited to 15 minutes per applicant and ten minutes per interested party, unless extended by the Chair of the Commission or the Chair's designated presiding officer. The schedule for the submission of exceptions and responses is as follows:

Submission of exceptions	March 10, 2017 No later than 4:30 pm
Submission of responses	March 16, 2017 No later than 4:30 pm
Exceptions hearing	March 23, 2017 1:00 pm

IN THE MATTER OF	*	**BEFORE THE**
	*	
BALTIMORE/UPPER SHORE	*	**MARYLAND HEALTH**
	*	
CARDIAC SURGERY REVIEW	*	**CARE COMMISSION**
	*	
Anne Arundel Medical Center	*	
Docket No. 15-02-2360	*	
	*	
University of Maryland	*	
Baltimore Washington Medical	*	
Center	*	
Docket No. 15-02-2361	*	

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Reviewer's Revised Recommended Decision

March 23, 2017

(Released March 3, 2017)

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I. INTRODUCTION

A. The Applicants

This is a comparative review of Certificate of Need ("CON") applications, for the establishment of new cardiac surgery programs, filed by Anne Arundel Medical Center, Inc. ("AAMC") and University of Maryland Baltimore Washington Medical Center, Inc. t/a University of Maryland Baltimore Washington Medical Center ("BWMC"). Both applicant hospitals are located in Anne Arundel County.

AAMC is a 370-bed independent, not-for-profit general hospital located at 2001 Medical Parkway, in Annapolis. It is the fourth largest general hospital in Maryland, based on FY 2016 average daily census. Its inpatient acute care services include medical/surgical, obstetric, and pediatric services.[1]

BWMC is a 293-bed, not-for-profit general hospital, located at 301 Hospital Drive, in Glen Burnie. It is one of eleven general hospitals affiliated with the University of Maryland Medical System ("UMMS"), and is the eighth largest general hospital in Maryland. Its inpatient services include medical/surgical, obstetric, pediatric, and acute psychiatric services.

B. The Projects

AAMC seeks to establish, in partnership with Johns Hopkins Medicine ("JHM"), a new cardiac surgery program at its hospital in Annapolis. As noted in its application, AAMC currently provides cardiology and vascular services, including screening and preventive programs, medical management of cardiac disease, diagnostic and interventional procedures, and endovascular procedures. AAMC states that its "ability to provide a continuum of basic through advanced cardiac services for the population it serves is compromised by its restriction from offering cardiac surgery," and that a cardiac surgery program "is necessary to improve safe access to a full range of care for its patients with heart disease." (DI #3AA, p. 12). It proposes to develop the cardiac surgery program with "the support and expertise of JHM's recognized cardiac surgery team" and projects that the program will be "among the least expensive" programs in Maryland." (DI #3AA, p. 12).

BWMC also seeks to establish a new cardiac surgery program at its hospital in Glen Burnie. Currently, the University of Maryland Cardiac Surgery Services Program provides cardiac surgery at two locations: the University of Maryland Medical Center ("UMMC") in Baltimore City and the University of Maryland St. Joseph Medical Center ("UMSJ") in Towson. BWMC describes its proposed cardiac program as "a third location for the existing University of Maryland (UM) Cardiac Surgery Services Program." Cardiac surgeons and staff who provide cardiac surgery at UMMC will perform surgery at BWMC. Like AAMC, BWMC also claims that development of its program will result in "lower cost to patients and payers," noting that "relative to other cardiac surgery programs, the proposed project will have lower variable costs because the costs will be shared with UMMC's existing costs." (DI #2BW p. 4).

[1]AAMC also has a pending CON application (Docket No. 16-02-2375), seeking to introduce acute psychiatric inpatient services on separate premises from the existing hospital.

BWMC states that since the time of its exploration of the eventual affiliation with UMMS,[2] it has examined the possibility of developing a cardiac surgery program primarily to serve patients in its service area. The proposed program is described by BWMC as a clinical benefit of its affiliation with UMMS for local residents. Other examples cited by BWMC as analogous include: the Tate Cancer Center at BWMC (affiliated with the UM Marlene and Stewart Greenebaum Cancer Center); The University of Maryland Center for Diabetes and Endocrinology at BWMC; the obstetrical services program at BWMC (affiliated with the UM Center for Advanced Fetal Care); and the primary and elective angioplasty services (affiliated with the UM Comprehensive Heart Center). (DI #2BW, p. 4).

Each applicant hospital has surgical facilities suitable for major surgery and the cost to upgrade the existing facilities to accommodate a new cardiac surgery program is not estimated to require large expenditures.[3] AAMC plans to upgrade two operating rooms ("ORs") and surgical intensive care rooms and purchase equipment needed to initiate the service. The estimated cost of the project is $2.5 million. BWMC estimates that only $1.26 million of equipment expenditures will be necessary to make the hospital capable for providing cardiac surgery. Both hospitals have upgraded their surgical facilities in the last ten to fifteen years.

C. Revised Recommended Decision

I recommend that the Maryland Health Care Commission issue a Certificate of Need to Anne Arundel Medical Center, Inc. to introduce cardiac surgical services, through an affiliation with Johns Hopkins Medicine. AAMC will need to meet the performance requirements applicable to this CON approval and document that it has developed a cardiac surgery program in conformance with the plan contained in its CON application, Docket No. 15-02-2361, in order to obtain first use approval and initiate the service. I recommend that the CON be issued with the following conditions:

1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.

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[2] The former North Arundel Hospital joined the University of Maryland Medical System in 2000 and was renamed Baltimore Washington Medical Center in 2005. In 2012, it became known as University of Maryland Baltimore Washington Medical Center.

[3] For context, the capital expenditure threshold, which is part of the scope of hospital CON regulation, is currently just under $12 million, indexed for inflation.
http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_update_20160502.pdf

3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.

4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

I recommend that the Maryland Health Care Commission deny the application of Baltimore Washington Medical Center, Inc. for a Certificate of Need to introduce cardiac surgical services. While lower charges for cardiac surgery could be obtained through implementation of this program, and UMMS and BWMC have made a strong case that they could develop a quality program, my consideration of all the applicable standards and criteria leads me to recommend approval of only the stronger application in this review.

II. PROCEDURAL HISTORY

A. Record of the Review

On February 20, 2015, AAMC and BWMC filed separate applications for a CON to establish cardiac surgery programs at their respective hospitals.[4] (DI #3AA; DI #2BW). Following submission of these applications, MHCC staff sent each applicant a request for additional information to complete each application. (DI #7AA; DI # 10AA; DI #11AA; DI #5BW; DI #7BW). On June 4, 2015, MHCC staff notified the applicants that the applications would be docketed on June 26, 2015. (DI #14AA; DI #11BW).

On July 23, 2015, the Anne Arundel County Health Department sought interested party status and filed comments on both applications. (DI #27GF). On July 27, 2015, pursuant to COMAR 10.24.01.08F, BWMC sought interested party status and filed comments on AAMC's application. (DI #29GF). On the same day, and pursuant to COMAR 10.24.01.08F, AAMC sought interested party status and filed comments on BWMC's application. (DI #28GF). Also on July 27, 2015, MedStar Union Memorial Hospital and MedStar Washington Hospital Center (collectively, "MedStar Hospitals") and LifeBridge Health, Inc. ("LifeBridge") sought interested party status and filed comments on both applications, and Dimensions Health Corporation ("Dimensions") d/b/a Prince George's Hospital Center ("PGHC") sought interested party status and filed comments on AAMC's application. (DI #30GF; DI #33GF; DI #34GF).

On December 15, 2014, CareFirst BlueCross BlueShield ("CareFirst") submitted a letter to MHCC staff expressing support for AAMC's application. On July 27, 2015, CareFirst reiterated its support for the AAMC application. (DI #35GF).

[4] A detailed procedural history of this review is included as Appendix 1: Record of the Review.

On July 21, 2015, pursuant to COMAR 10.24.01.01B(30) and 10.24.01.08F(2), Anne Arundel County sought participating entity status in the review of both applications. (DI #26GF).

On July 15, 2015, pursuant to COMAR 10.24.01.01B(30) and 10.24.01.08F(2), the City of Annapolis sought participating entity status in the review of both applications. (DI #25GF).

On August 10, 2015, pursuant to COMAR 10.24.01.08E, BWMC filed a modification to its CON application.[5] (DI #17BW). On August 25, 2015 AAMC filed comments on BWMC's modified application. (DI #46GF). On September 28, 2015, BWMC filed a response to AAMC's comments on the modified application. (DI #53GF).

Pursuant to COMAR 10.24.01.09A(1)(b), I was appointed to serve as Reviewer of each application on a comparative basis. On December 8, 2015, I issued a ruling on interested party status. (DI #55GF). Pursuant to COMAR 10.24.01.01B(20), I granted both AAMC and BWMC interested party status. Pursuant to COMAR 10.24.01.08F and COMAR 10.24.01.01B(2) and (20), I also granted interested party status to each hospital seeking such status because each is authorized to provide the same service as that proposed by each applicant in the same planning region used for purposes of determining need under the State Health Plan or in a contiguous planning region. (DI #55GF). Pursuant to COMAR 10.24.01.01.B(2), I also granted interested party status to the Anne Arundel County Department of Health because it is a local health department in the jurisdiction in which the proposed service is to be offered. (DI #55GF). Pursuant to COMAR 10.24.01.01B(3) and COMAR 10.24.01.08F(2), Ben Steffen, Executive Director of the MHCC, granted participating entity status to Anne Arundel County and denied participating entity status to the City of Annapolis. (DI #56GF).

On July 15, 2016, I requested that Health Services Cost Review Commission (HSCRC) staff review each applicant's financial projections and comment on the financial feasibility of each hospital's proposal and the reasonableness of each hospital's assumptions. (DI #64GF). By letter dated August 24, 2016, HSCRC staff provided comments in response to my request. (DI #68GF).

On October 5, 2016, I issued a request to each applicant, and each applicant's partner/collaborating hospital, to provide certain binding commitments regarding matters raised by HSCRC's review of the applicants' financial projections. (DI #69GF). I also requested that AAMC revise its revenue projections to conform to HSCRC's previously stated approach to correctly modeling revenue gains from market shifts of Maryland residents between hospitals. (DI #69GF).

By letter dated October 17, 2016, BWMC and UMMC made the requested binding commitments not to seek adjustments in their global budget revenue agreements aimed at off-setting any revenue loss associated with the shift of cardiac surgery cases from UMMC to BWMC. (DI #76GF). Likewise, on the same date, AAMC and JHH made the requested binding commitments. (DI #75GF). AAMC also provided revised pro forma schedules of revenues and expenses. (DI #75GF). I struck these schedules from the record of the review by letter ruling dated

[5]The modified application committed BWMC and UMMC to accept 50% revenue variability for cardiac surgery cases shifted from UMMC to BWMC. (DI #17BW).

October 21, 2016, by which I also notified the parties that I would hold a project status conference in the review. (DI #77GF).

On October 28, 2016, pursuant to COMAR 10.24.01.09A(2), I held a project status conference to address aspects of AAMC's application that were potentially inconsistent with the applicable standards and review criteria. (DI #89GF; DI #90GF). Specifically, I requested that AAMC modify its application by filing revised revenue and expense projections conforming with HSCRC's current policy on changes in hospital volume resulting from shifts in market share and how those shifts would affect global budget revenue. (DI #89GF; DI #90GF).

On November 7, 2016, as a result of the project status conference, AAMC filed a modification to its CON application, in which it revised its original revenue projections. (DI #22AA). On November 14, 2016, BWMC, Dimensions, and the MedStar Hospitals filed comments on AAMC's modified application. (DI #93GF; DI #94GF; DI #96GF).

On December 30, 2016, I issued a ruling to open the record and enter zip code area population estimate and projection data sets from Nielsen Claritas and hospital audited financial statements (DI #97GF). On the same day I released a Memorandum and Recommended Decision in this review, recommending that the application of AAMC for a CON to introduce cardiac surgery services be approved with conditions, and recommending that BWMC's application to introduce cardiac surgery services be denied. (DI #98GF)

On January 11, 2017, AAMC filed a response to the Recommended Decision. (DI #99GF) On the same day, BWMC, Dimensions, and MedStar Hospitals filed exceptions to the Recommended Decision. (DI #s 100-102) On January 19, 2017, AAMC filed a response to the exceptions filed by BWMC, Dimensions, and MedStar Hospitals. (DI #103)

Seven days after it filed exceptions to the Recommended Decision, BWMC filed a motion to strike the Recommended Decision and the data entered into the record on that day. (DI #104GF) In its motion, BWMC argued that the Recommended Decision should be stricken because it erroneously relied on "newly disclosed and undisclosed facts." (DI #104GF, p.2). BWMC specifically stated that the 2015 and 2020 population projections, District of Columbia hospital discharge data, and CY 2020 cardiac surgery use rates were missing from the record, as well as other unknown data that was not "readily apparent." (DI #104GF, pp. 2-4). It also argued that the Recommended Decision used an invalid alternative model to analyze minimum volume without fully disclosing the assumptions or methodology underlying the model. (DI #104GF, pp.4-5). Finally, BWMC argued that reliance on the newly disclosed and undisclosed data violated the Administrative Procedures Act, Md. Code, State Government, § 10-201 et seq. (DI #104GF, pp. 5-7).

On January 23, 2017, I denied BWMC's motion to strike the Recommended Decision and the data entered into the record on that day. (DI #105GF) In my ruling I noted that, while I denied the motion, it would be inappropriate for the Commission to consider the Recommended Decision at its scheduled January 26, 2017 public meeting. (DI #105GF, p. 1). I made this determination based on the discovery that data from the Virginia Health Information ("VHI") discharge data set, as well as the record layout for the previously provided 2020 Nielsen population projections, were

inadvertently omitted from the record. (DI #105GF, p. 2). I also noted that, contrary to BWMC's argument, I had already admitted both the HSCRC and the District of Columbia hospital discharge data and provided notice to the parties regarding admission of this data in the record in a letter to the parties dated October 5, 2016. (DI #105GF, pp. 2-3). I requested that the parties file comments on the VHI data and the 2020 Nielsen population projections by February 1, 2017. (DI #105GF, p. 5). I also stated that any party that required additional time to respond to those two data elements should advise me of such by January 24, 2017, with a detailed explanation of the reason additional time is required. (DI #105GF, p. 5). I granted the parties five business days to respond to any comments filed on the data admitted on December 30, 2016. (DI #105GF, p. 5). Finally, I stated that it was "likely that I will issue a revised Recommended Decision that considers comments and makes corrections or clarifications to the December 30, 2016 Recommended Decision that I believe are appropriate." (DI #105GF, p. 5).

On January 24, 2017, BWMC filed a request for a two week extension of time to file comments on the data (VHI data and 2020 Nielsen population projections) that were the subject of my January 23, 2017 ruling. (DI #106GF). BWMC requested the extension because it had not obtained all of the District of Columbia discharge data nor the historical population data that was in the record because "it had not anticipated that it would be used to develop a new minimum forecast model . . . ." (DI #106GF, p. 1). BWMC reiterated its position that the forecast model used in the Recommended Decision was an invalid method to determine minimum volume, and that it would therefore continue to object to the admission of any data used in the model on relevance grounds. (DI #106GF, pp. 1-2). BWMC also noted that it would continue to object to the entry of any data into the record unless parties are provided an opportunity to comment on the data prior to a decision to enter it into the record. (DI #106GF, p. 2).

On January 25, 2017, I denied BWMC's request for additional time to file comments, noting that I was surprised and disappointed that BWMC had ignored or disregarded the notice I gave on October 5, 2016, that I intended to use the information from the HSCRC and District of Columbia hospital discharge databases in this review. (DI #108GF, pp. 1-2). Accordingly, I gave the parties until February 3, 2017 to file comments on the data that was the subject of my January 23, 2017 ruling. (DI #108GF, p. 2).

On February 3, 2017, both AAMC and BWMC filed comments on my January 23, 2017 ruling. (DI #s 112GF and 113GF). BWMC argued that the data from the VHI database should not have been admitted into the record for any purpose because it lacks sufficient information (how the term "cardiac surgery" is defined in the VHI database) to be reliable. (DI #112GF, pp. 7-8). BWMC also argued that the HSCRC and District of Columbia hospital discharge data, as well as the 2020 Nielsen population projection data, should not be admitted for the purpose of using the forecast model to assess minimum volume because it is not relevant to that analysis. (DI #112GF, pp. 1-3).

On February 13, 2017, Dimensions filed a response to AAMC's comments on my January 23, 2017 ruling. (DI #116GF). Dimensions argued that that the forecast model used in the Recommended Decision was flawed, and that the failure to allow the parties an opportunity to respond to the data utilized in the model before that data was entered into the record, required that both the data and the model be stricken. (DI #116GF, pp. 1-4).

On February 21, 2017, Dimensions filed a Motion for Recusal and to Strike the Recommended Decision that I released on December 30, 2016. (DI #117GF). In its motion, Dimensions argued that I should recuse myself from this case because my "relationship" with my former wife (a medical cardiologist at Johns Hopkins Medicine), as well as what it characterized as my part-time position Johns Hopkins General Internal Medicine, presents the appearance of impropriety and an apparent conflict of interest. (DI #117GF). On February 24, 2017, AAMC filed an opposition to Dimensions' motion, arguing that the motion was both untimely and unsupported by facts. (DI #119GF). On March 2, 2017, I denied Dimensions' motion. (DI #120GF). In my ruling, I affirmed that neither my ex-wife's employment, nor my part-time, unpaid faculty position at the Division of General Internal Medicine in the Johns Hopkins School of Medicine has in any way impacted my ability to render an impartial decision in this contested case. (DI # 120GF).

On March 3, 2017, I released a memorandum and my Revised Recommended Decision in this review, recommending that the Commission approve, with conditions, the application of AAMC for a CON to establish cardiac surgery services, and recommending that that the Commission deny BWMC's application to establish cardiac surgery services. (DI #122GF).

B. Interested Parties in the Review

Three hospital organizations, in addition to the two applicant hospitals, are interested parties in this review: Dimensions, LifeBridge, and the two MedStar Hospitals. Dimensions opposes the AAMC project. LifeBridge and the MedStar Hospitals oppose both applications. AAMC opposes the BWMC project and BWMC opposes the AAMC project.

Dimensions owns and operates PGHC. PGHC is a provider of cardiac surgery that has never operated with high case volume. In the past three years, it has worked with UMMS to grow its program and has had some success while not yet reaching maintenance of the case volume target (200 cases per annum) set out in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Coronary Intervention Services Chapter ("Cardiac Surgery Chapter") of the State Health Plan for Facilities and Services ("SHP" or "State Health Plan"). UMMS is poised to incorporate Dimensions into its hospital system and Dimensions has been approved by MHCC to relocate PGHC to Largo and replace it with a new general hospital to be known as Prince George's Regional Medical Center ("PGRMC"). Cardiac surgery has been approved as a service for PGRMC. Dimensions' opposition to the AAMC project is based on its contention that a new program at AAMC will doom its rebuilding effort in cardiac surgery. (DI #30GF; DI #93GF).

LifeBridge operates a cardiac surgery program at Sinai Hospital of Baltimore, located in northern Baltimore City. It believes that additional cardiac surgery programs are not needed in Maryland and that any such additional program(s) would threaten the ability of existing programs to either build or maintain appropriate volume. (DI #33GF).

The MedStar Hospitals, operate cardiac surgery programs (MedStar Union Memorial in Baltimore City and MedStar Washington Hospital Center in Washington, D.C.). The MedStar

Hospitals oppose both projects as unneeded, poorly planned, infeasible, less cost-effective than maintaining the current supply of programs, and lacking in sustainability. (DI #34GF; DI #95GF).

The Anne Arundel County Department of Health is also an interested party in this comparative review. County Health Officer, Jinlene Chan, M.D., M.P.H, expresses the Health Department's support for a cardiac surgery program in Anne Arundel County but does not explicitly favor one application over the other. (DI #27GF). Dr. Chan noted that Anne Arundel County has no cardiac surgery programs, despite a population of over 555,000. She also stated that the closest available cardiac surgery programs (Baltimore or District of Columbia) require a minimum travel time of 30 to 45 minutes for Anne Arundel County residents. Dr. Chan urged MHCC to approve a cardiac surgery program in Anne Arundel County, for these reasons.

C. Participating Entity in the Review

Anne Arundel County is a participating entity in this comparative review. The County's comments, expressed in a letter from its County Executive, Steven R. Schuh, support having a cardiac surgery program in Anne Arundel County. Like the County Health Department, the County did not favor one application over the other, but noted a general absence of a cardiac surgery program in the County and stated that the travel time to programs in other jurisdictions has "created unnecessary risks and hardships for . . . County residents." Specifically, the County cited a 2014 study showing a correlation between travel time and mortality and noting that when patients and their families are burdened by travel time, it may adversely affect their health status, compliance and well-being.[6] The County "strongly urge[ed] the Commission to expand the cardiac surgery programs available to Anne Arundel County residents." (DI #26GF).

D. Community Comments

On July 15, 2015, Mayor Michael Pantelides, on behalf of the City of Annapolis, filed a request for participating entity status and provided comments on the proposed applications. On December 8, 2015, Executive Director Steffen denied the City's request for participating entity status, noting that it did not meet the qualifications for that status found in COMAR 10.24.01.01B(30). He stated that the City's comments are part of the official record of this comparative review. The City supports the introduction of a cardiac surgery program in Anne Arundel County, and specifically favors AAMC's proposal over BWMC's proposal. With respect to the general need for such a program within the County, the City noted the problems associated with long travel times to other jurisdictions for cardiac surgery services. With respect to its preference for AAMC's proposal, the City stated that AAMC is "best positioned to meet this need," and that the proposal provides "superior cost savings to patients and to the employer health plans that often finance their care." The City also noted that a program located at AAMC will create greater access to care for a greater number of people (including Eastern Shore and Southern Maryland residents) than a program located at BWMC, just six miles to the south of UMMC. (DI #25GF).

[6] Chou S., *et al.*, "Travel Distance and Health Outcomes for Scheduled Surgery," Medical Care 52:3 (2014) (cited at DI #26GF).

CareFirst filed comments stating its preference for AAMC's proposed cardiac surgery program. In urging the Commission to approve the application, CareFirst stated its view that AAMC's cardiac surgery program would meet the objectives of: (1) the federal Centers for Medicare and Medicaid Services' Triple Aim; (2) the Patient Centered Medical Home Program; and (3) the Maryland All-Payer Model. In addition, CareFirst stated that AAMC's proposed project "represents the most cost effective alternative for Maryland's health care system." CareFirst also stated that AAMC's average projected payment rate for cardiac surgery will be nearly 40% lower than the estimated payment rate at Washington Hospital Center for a comparable case mix and nearly 50% lower than the average payment rate at Johns Hopkins Hospital and University of Maryland Medical Center for a comparable case mix. (DI #26GF).

The AAMC CON application contained 296 letters of support from the following groups: elected officials – 14 letters; payers – two letters; community organizations – 16 letters; Board members and business leaders – 30 letters; patients – 171 letters; and physicians and CRNPs – 63 letters. Additionally, AAMC's application included Resolutions in support of its proposed project by the AAMC Board of Trustees and the AAMC Foundation Board of Directors, as well as three letters of support from the leadership of Johns Hopkins Medicine. (DI #3AA, App. 3). The BWMC CON application contained 115 letters of support from the following groups: business and industry leaders – seven letters; community service organizations – four letters; education – one letter; County government – 16 letters; State government – nine letters; health - UMMS affiliated – 30 letters; health – non-UMMS affiliated – 23 letters; individuals – 21 letters; and religious institutions – four letters. (DI #2BW, Exh. 33).

III. BACKGROUND

A. Delivery of Cardiac Surgery Services

Cardiac surgery means surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery. COMAR 10.24.17.09. The Cardiac Surgery Chapter of the State Health Plan divides Maryland into four regions for purposes of forecasting demand for cardiac surgery and regulating the supply of cardiac surgery programs. COMAR 10.24.17.03. These regions were established based upon patient catchment areas for the State's existing programs in 2014.[7] Anne Arundel County is part of the Baltimore/Upper Shore Region, which includes the jurisdictions of Baltimore City, and Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties. This large region contains half of the State's cardiac surgery programs and just under half (49.8%) of the State's total population.[8]

The five Baltimore/Upper Shore cardiac surgery hospitals serviced approximately 74% of the adult cardiac surgery volume experienced by Maryland's ten cardiac surgery programs in CY 2015. Four of the five centers are in Baltimore City, the second largest jurisdiction in the region[9]

[7]Jurisdictions were included in each region based on where most of the cardiac surgery patients in each jurisdiction used cardiac surgery services. See COMAR 10.24.17.03, p. 7.
[8]U.S. Bureau of the Census Estimated Population, July 1, 2015.
[9]Baltimore City had a 2015 estimated population of 621,849. (U.S. Bureau of the Census Estimated Population, July 1, 2015).

and the fifth center is in Baltimore County, the region's largest jurisdiction.[10] Anne Arundel County has the region's third largest population.[11] The region's existing cardiac surgery hospitals are members of four multi-hospital systems that collectively served 58% of the State's total demand for adult inpatient medical/surgical hospitalization in 2015. UMMS has two centers in the region, UMMC and UMSJ. Johns Hopkins Health (The Johns Hopkins Hospital), MedStar (Union Memorial Hospital), and LifeBridge (Sinai Hospital of Baltimore) each operate a single program in this region.

Each applicant in this review seeks to establish an additional cardiac surgery program in the region. Anne Arundel County is in the Baltimore/Upper Shore Region because most of its adult cardiac surgery patients use the cardiac surgery facilities in the Baltimore area.

Table 1 inventories the current and proposed Maryland and District of Columbia cardiac surgery programs by region, hospital system (if applicable), and hospital. Chart 1, which immediately follows Table 1, shows that adult cardiac surgery case volume performed at Maryland hospitals increased strongly in the 1990s, a 74% increase between 1990 and the peak case volume year of 2000. Case volumes declined approximately 30% between 2000 and 2011, a recent inflection year, in that case volume has steadily increased since 2011, an increase of approximately 13% over the four-year period of 2011 to 2015. Percutaneous coronary intervention ("PCI"), commonly referred to as "angioplasty," is a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. (See COMAR 10.24.17.09) Thus, it is an alternative to coronary artery bypass surgery, the most common form of cardiac surgery, in the treatment of some coronary artery disease cases. PCI case volume rose in the first decade of this century, but the volume of PCI cases in Maryland also saw substantial decline beginning approximately ten years ago.

[10]Baltimore County had a 2015 estimated population of 831,138. (U.S. Bureau of the Census Estimated Population, July 1, 2015).
[11]Anne Arundel County had a 2015 estimated population of 564,125. . (U.S. Bureau of the Census Estimated Population, July 1, 2015).

Table 1: Regional Profile of Adult Cardiac Surgery Center Hospitals, Maryland and District of Columbia Current (2016) and *Proposed Programs*

Hospital System/Hospital	City/Jurisdiction	Adult Cardiac Surgery Cases CY 2015
BALTIMORE/UPPER SHORE REGION		
Johns Hopkins Health System		
The Johns Hopkins Hospital	Baltimore City	1,262
LifeBridge Health		
Sinai Hospital of Baltimore	Baltimore City	409
MedStar Health		
MedStar Union Memorial Hospital	Baltimore City	626
University of Maryland (UM) Medical System		
UM Medical Center	Baltimore City	1,000
UM St. Joseph Medical Center	Towson/Baltimore County	454
UM Baltimore Washington Medical Center	***Glen Burnie/Anne Arundel***	-
Anne Arundel Medical Center*	***Annapolis/Anne Arundel***	-
METROPOLITAN WASHINGTON REGION		
Adventist HealthCare		
Washington Adventist Hospital	Takoma Park/Montgomery	285
Dimensions Health System		
Prince George's Hospital Center**	Cheverly/Prince George's	105
Johns Hopkins Health System		
Suburban Hospital	Bethesda/Montgomery	212
MedStar Health		
MedStar Washington Hospital Center***	District of Columbia	1,694
George Washington University Hospital***	District of Columbia	193
Howard University Hospital***	District of Columbia	19
LOWER SHORE REGION		
Peninsula Regional Medical Center	Salisbury/Wicomico	433
WESTERN MARYLAND REGION		
Western Maryland Reg. Med. Center	Cumberland/Allegany	174

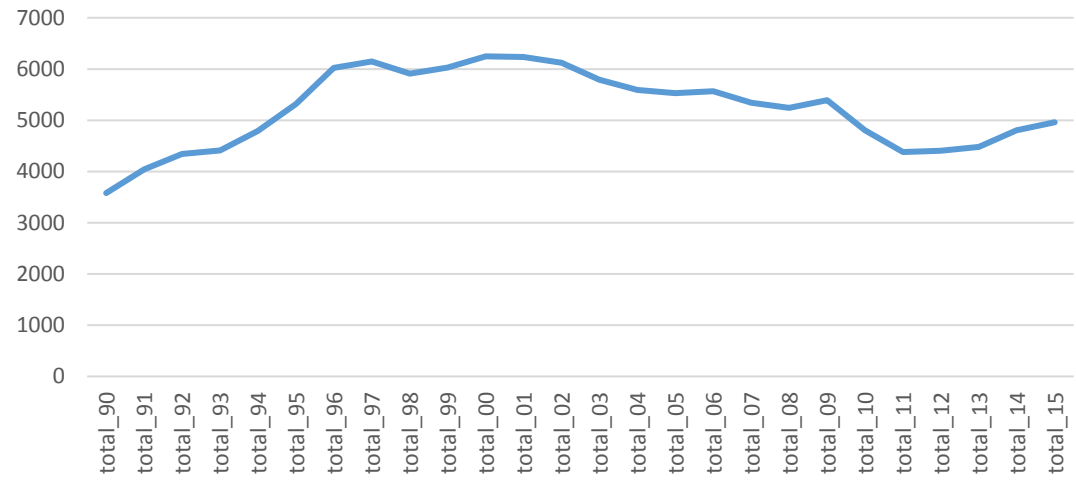
*Proposed as a partner of Johns Hopkins Medicine in provision of cardiac surgery but not part of the Johns Hopkins Health system of hospitals.

**This hospital has been authorized to relocate to Largo. UMMS has entered into an agreement to acquire Dimensions Health System.

***Case volume shown for MedStar WHC is for FY 2015 from: http://www.medstarwashington.org/our-hospital/facts-and-figures/#q={}. Cases shown for George Washington University and Howard University Hospitals are for CY 2014.

Data Source: HSCRC Discharge Database and D.C. Discharge Database.

Chart 1: Trend in Adult Cardiac Surgery Discharges for Maryland Hospitals, CY 1990-2015



Source: HSCRC Discharge Database

Table 2 below shows case volume at Maryland hospitals for total adult cardiac surgery from 2011 to 2015, the recent period of growth in case volume. As can be seen, the two academic medical center programs in Baltimore, Johns Hopkins and UMMC, have experienced a major share of this growth, with case volume increasing 26.7% over this period. In contrast, case volume at the other three community hospital programs in the Baltimore/Upper Shore region, Union Memorial, UMSJ, and Sinai, saw growth of 12.5% during the same time frame, with growth limited to the latter two programs. The three Maryland programs in the District of Columbia suburbs saw a slight decline, -2.6%, between 2011 and 2015 despite the revival of case numbers at Prince George's Hospital Center, because of reductions in the caseload at Washington Adventist and little change at Suburban. Peninsula Regional experienced little change over this period and Western Maryland Regional saw a decline in case volume of over 20% during this period.

Table 2: Adult Cardiac Surgery Cases, Maryland Hospitals CY 2011-CY 2015

Hospital	2011	2012	2013	2014	2015
Johns Hopkins	969	1,026	1,142	1,182	1,262
University of Maryland	817	851	923	984	1,000
Union Memorial	688	575	588	636	626
UM St. Joseph's	339	285	296	448	454
Peninsula Regional	426	378	431	431	433
Sinai	296	317	345	382	409
Washington Adventist	398	463	374	301	285
Suburban	205	279	205	244	212
Western Maryland	224	215	169	170	174
Prince George's	15	18	8	29	105
TOTAL	4,377	4,407	4,481	4,807	4,960

Note: Adult is defined as aged 15 or older. ICD-9 codes are used to define cardiac surgery in COMAR 10.24.17 (current version) for CY 2011 through the third quarter of CY 2015. The case counts for the last quarter of CY 2015 are based on the same definition, but only ICD-10 codes are used in discharge abstracts for this period, so a crosswalk developed by the Centers for Medicare and Medicaid services of ICD-10 to ICD-9 codes was used to count cases. This crosswalk has not been officially adopted in State regulations.

Sources: HSCRC Discharge Database, CY 2011-2015; CMS 2016 General Equivalence Mappings-Procedure Codes and Guide.

The Cardiac Surgery Chapter, at COMAR 10.24.17.08, includes a methodology for forecasting adult cardiac surgery case volume. The most recently published forecast (February 6, 2015) is for a target year of 2019 and used the definition of cardiac surgery found in the version of COMAR 10.24.17 that became effective on August 17, 2014.[12] The methodology relies on the use rate trend for adult cardiac surgery observed over the most recent six-year period for which data is available to predict future case volume or, in the case of these most recently published projections, the six-year period of 2008 through 2013. This trend was negative during this applicable time period for the February 2015 forecast and assumed a future of declining population use. The published forecast projected that adult cardiac surgery case volume for the Baltimore/Upper Shore region would decline approximately 12% between 2014 and 2019. The trend in cardiac surgery case volume between 2011 and 2015 (Table 2, *supra*) indicates that an update of the demand forecast for a target year of 2021 would be based on an increasing use rate trend, given that case volume is growing faster than the adult population.

B. Population of the Baltimore/Upper Shore Region

As shown in Table 3, below, the Baltimore/Upper Shore region is projected to contain just under half of the State's population and is projected to be growing at a slower pace (7.7% between 2015 and 2030) than the statewide population over the same period (10% growth). The region's population is slightly older than the State's as a whole, with a projected elderly population (65+) of 14.5% compared to Maryland's 14 percent.

Table 3: Projected Population, Total and Elderly Population, 2015 and 2030
Baltimore/Upper Shore Health Planning Region and Maryland

Jurisdiction	2015		2030	
	Total Population	65+ Population	Total Population	65+ Population
Anne Arundel	559,603	77,775	606,700	120,986
Baltimore City	624,997	75,158	651,100	92,086
Baltimore County	832,048	132,756	862,200	183,032
Carroll	168,549	26,479	183,250	45,889
Harford	252,000	37,506	273,147	60,609
Howard	309,048	39,148	357,103	72,332
Western Shore	*2,746,245*	*388,622*	*2,993,500*	*574,934*
Caroline	33,900	5,040	40,450	8,111
Cecil	103,602	14,478	125,250	25,826
Kent	20,600	5,079	22,600	8,038
Queen Anne's	50,150	8,705	60,348	14,894
Talbot	39,100	10,518	42,902	15,011
Eastern Shore	*247,352*	*43,820*	*291,550*	*71,880*
TOTAL REGION	2,993,597	432,642	3,225,050	646,814
MARYLAND	6,010,141	838,974	6,612,191	1,300,012

Source: Maryland Dept. of Planning, 2014 Population Projection Series.

[12] *Maryland Register*, Vol. 42, Issue 3 (February 6, 2015).

IV. REVIEW AND ANALYSIS

I note that the record in this review is voluminous. In my analysis of the applicable criteria and standards, I have sought to create a single document that can be used to gain a meaningful overview and discussion of the issues and questions raised in the review, as well as my findings and conclusions on the applications presented. The record requires a great deal of summarization to create a manageable overview and results in some repetition, which I have tried to minimize wherever possible. The substantive filings may be accessed at the following links:[13]
for AAMC, http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con_aamc.aspx; and,
for BWMC: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con_bwmc.aspx.

A. The State Health Plan

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(a) State Health Plan. An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The Cardiac Surgery Chapter, COMAR 10.24.17, is the chapter of the State Health Plan that is used in CON review of projects involving cardiac surgery and PCI services, two services specifically regulated under Maryland's CON law. The Cardiac Surgery Chapter was comprehensively updated in 2014 and this is the first time it has been used in a review of applications seeking to establish cardiac surgery services.

COMAR 10.24.17.04 Commission Program Policies.

A. Consideration of New Programs.

(1) Cardiac surgery.

(a) A Certificate of Need is required to establish cardiac surgery services.

(b) A hospital shall have a current population-based budget agreement, a total patient revenue agreement, or a modified charge per episode agreement with the Health Services Cost Review Commission before a hospital's CON application to establish a cardiac surgery program will be docketed.

(c) A hospital shall have provided both primary and elective PCI services for at least three years before filing an application for a CON to establish cardiac surgery services.

(d) A new cardiac surgery program will only be considered in a health planning region if the most recently approved program in the health planning region has been in operation for at least three years.

(e) A review schedule for receipt of letters of intent and applications seeking a CON to establish cardiac surgery services will be published in the Maryland Register for each health planning region where the condition in Paragraph .04A(1)(d) is met. Publication of a review schedule does not indicate that the Commission has determined an additional provider of cardiac services is needed in a region.

[13]The MHCC's general webpage for access to CON applications is found at:
http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con.aspx

Applicants' Responses

Each applicant documented that it met the qualifying criteria in subparagraphs (b) and (c) of this policy. (DI #3AA, pp. 69-74; DI #2BW, pp. 15-16, 62).

Reviewer's Analysis and Findings

The qualifications in this policy for consideration of a new cardiac surgery program are met by each applicant. Because all hospitals with cardiac surgery services in the Baltimore Upper Shore Region have been providing these services for more than three years, the requirement in subparagraph (d) is met.

AAMC and BWMC have each successfully provided both primary and non-primary PCI services for more than three years, as required by paragraph (c) of this standard.

As required by paragraph (b), each hospital has a global budget agreement with the Health Services Cost Review Commission.[14] HSCRC provides for adjustment of these budgets over time. HSCRC's methodology contains a demographic adjustment factor that uses changes estimated or projected for individual hospital service area populations as a basis for adjusting a hospital's revenue base. The budgets can also be adjusted for shifts in market share among hospitals and other factors.

I find that each applicant meets the requirements of this policy.

.05 Certificate of Need Review Standards for Cardiac Surgery Programs.
An applicant for a Certificate of Need to establish or relocate cardiac surgery services shall address and meet the applicable general standards in COMAR 10.24.10.04(A), in addition to the applicable standards in this chapter.

Each applicant responded with information to demonstrate compliance with these general standards. These are basic threshold requirements for availability of information on charges, quality of care, and charity care policies applicable to all CON applications filed by general hospitals. (DI #3AA, pp. 32-37; DI #2BW, pp. 36-42, Exh. 14-22).

Information on charges provided on the applicant hospitals' websites at the time of application completeness review was found to be compliant with the general standard. For AAMC, this charge information can be accessed through the following links:

http://www.aahs.org/patients-visitors/Charges/inpatient.pdf
http://www.aahs.org/patients-visitors/Charges/ancillary.pdf
http://www.aahs.org/patients-visitors/Charges/ot.pdf
http://www.aahs.org/patients-visitors/Charges/outpatient.pdf

[14] Each hospital has a total patient revenue agreement with HSCRC, which we shall refer to using the more commonly used term, the global budget agreement.

http://www.aahs.org/patients-visitors/Charges/pt.pdf
http://www.aahs.org/patients-visitors/Charges/rad.pdf

For BWMC, this charge information can be accessed through the following link:

http://www.mybwmc.org/sites/default/files/related_uploads/EstimatedCharges.pdf

Both hospitals provided copies of their charity care policies that comply with the requirements of the charity care policy general standard. The policies provide for timely determinations of probable eligibility for financial assistance and the required modes of notification of the charity care policy. (DI #3AA, pp. 34-35 and Exhibits 2 and 5(c) and DI #2BW, pp. 38-41 and Exhibits 16-19)

In FY 2013, AAMC provided a level of charity care, defined as the percentage of total operating expenses, falling within the bottom quartile of all Maryland hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report. It reported "community benefit charity care" equivalent to $5.69 million, or 1.1% of total operating expenses in FY 2014. (HSCRC Community Benefit Report for FY 2014) For this reason, AAMC was required to demonstrate that its level of charity care is appropriate to the needs of its service area population. (DI #3AA, p. 34)

AAMC stated that, on the basis of median income levels, its patient population is more affluent than that of the state. It also cited AAMC initiatives aimed at enrolling low-income patients eligible for Medicaid coverage as a basis for lower demand for financial assistance by its service area population. It describes its charity care policy as "generous," with eligibility for 100% charity care available to households at or below 200% of the U.S. Poverty Line and a sliding fee scale for households providing discounted care for households between 200% and 330% of the U.S. Poverty Line. It also cites a valuation of $36.1 million in total "community benefit" for FY 2014, stating that this was in the top third of Maryland hospitals. Finally, it noted that, under Maryland's rate setting system, AAMC contributes a proportionate share of funding to support uncompensated care across the state's entire hospital system. (DI #3AA, p. 35).

Both hospitals documented licensure in good standing, Joint Commission accreditation, and compliance with Medicare and Medicaid conditions of participation. (DI #3AA, p. 36 and DI #2BW, p. 42).

AAMC noted that it ranked at or above the state and/or national averages on 33 of 43 applicable performance measures posted on the Centers for Medicare and Medicaid Services Hospital Compare platform as of December 18, 2014 and that it had the second highest patient satisfaction ranking from this same source. It conceded poor relative performance on two emergency department throughput measures and described the actions it has initiated to improve performance in this area. (DI #3AA, p. 36-37).

BWMC noted that MHCC's re-designed Maryland Hospital Performance Evaluation Guide does not provide a "readily apparent" ability to assess quartile performance on the quality measures. It provided an Exhibit listing 18 measures for which it calculated BWMC performance as falling within the bottom quartile for all Maryland hospitals in FYE September 30, 2013. The

exhibit described the activities being taken by BWMC to improve performance on these measures. (DI #2BW, p. 42 and Exhibit 22).

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC states that AAMC failed to comply with the general standard for quality at COMAR 10.24.10.04(A)(3)(b) because it did not disclose any quality measures in the most recent update of the Maryland Hospital Performance Evaluation Guide for which the hospital's score was within the bottom quartile of all hospitals' reported performance and that also fell below a 90% level of compliance with the quality measure. (DI #29GF, p. 32).

BWMC notes that MHCC has implemented a new and significantly re-designed Hospital Performance Evaluation Guide in which quality measure performance within the bottom quartile of all hospitals is not readily apparent. It also notes that AAMC discussed its performance relative to data reported on the Centers for Medicare and Medicaid Services Hospital Compare website.

Comments on BWMC Application

No party provided comments on BWMC's compliance with COMAR 10.24.10, the applicable general standards for cardiac surgery programs.

Applicant's Response to Comments

Anne Arundel Medical Center

In response, AAMC notes that the Maryland Hospital Performance Evaluation Guide relies heavily on Hospital Compare data and states that it has "adequately documented its quality improvement processes as a hospital" and that its performance under the CMS Hospital Compare metrics are excellent, with only one unfavorable metric (emergency department turnaround time) for which it provided an action plan. (DI #45GF, pp. 34-35). It notes that BWMC has acknowledged that the new version of the Performance Guide does not make quartile performance readily apparent.

Reviewer's Analysis and Findings

For some time, Commission staff and Reviewers have noted that COMAR 10.24.10.04(A)(3)(b), the provision in the Surgical Services Chapter referenced in this Cardiac Surgery standard, which is now a seven-year old standard, does not reflect more recent changes in the Maryland Hospital Performance Evaluation Guide. Commission staff noted that the Commission's current quality reports "focus[] on two priority areas: (1) patient experience, as reported by the Centers for Medicare and Medicaid Services … in its Hospital Consumer Assessment of Healthcare Providers and Systems … survey; and (2) healthcare associated

infections, as tracked by CDC's National Healthcare Safety Network …."[15] Staff noted that this standard will be amended in the future to make it relevant to current hospital performance reporting. (*Id.*).

For this reason, I find that each applicant has adequately addressed the currently relevant components of the standard in COMAR 10.24.10.04A and demonstrated that it actively addressed needed improvement in aspects of its performance that are indicated as subpar in measurements by the referenced sources.

A. Cardiac Surgery Standards.

(1) Minimum Volume Standard.
An applicant proposing establishment or relocation of cardiac surgery services shall document that the proposed cardiac surgery program will meet the following standards:

> ***(a) For an adult cardiac surgery program, demonstrate the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation; the program shall attain a minimum annual volume of 200 cardiac surgery cases by the end of the second year of operation.***
> ***(b) For a pediatric cardiac surgery program, demonstrate the ability to meet a projected minimum case volume of 130 cardiac surgery cases per year; the program shall attain a minimum annual volume of 130 cases by the end of the second year of operation.***
> ***(c) For a program performing both adult and pediatric cardiac surgery, demonstrate the ability to meet a projected minimum of 50 pediatric cardiac surgery cases per year, and 200 adult cardiac surgery cases per year; the program shall attain a minimum annual volume of each type of cardiac surgery cases by the end of the second year of operation.***
> ***(d) The applicant's demonstration of compliance with the Minimum Volume and Impact standards of this chapter shall address the most recent published utilization projection of cardiac surgery cases in Regulation .08 for the health planning region in which the applicant hospital is located and any other health planning regions from which it projects drawing 20 percent of more of its patients. The applicant shall demonstrate that its volume projections and impact analysis are consistent with the projection in Regulation .08 or, alternatively, demonstrate why the methods and assumptions employed in the Regulation .08 projections are not reasonable as a basis for forecasting case volume.***

Applicants' Responses

Anne Arundel Medical Center

AAMC projects that its cardiac surgery program will perform 241 adult cardiac surgery cases in the first year of operation (FY 2017), 337 in its second year, and 387 cases in its third year of operation. It projects that most of this volume (approximately 92-93%) will originate in its defined service area, consisting of Anne Arundel County, four Eastern Shore Counties (Caroline, Kent, Queen Anne's, and Talbot), and portions of northern Calvert County and eastern Prince

[15] Staff Report, Matter of Calvert County Memorial Hospital (Docket No. 15-04-2370), p. 12 (November 17, 2016).

George's County.[16] It cites a projected increase in the adult population from 895,000 to 913,000 for this service area during the 2017 to 2019 period projected as the first three years of AAMC's cardiac surgery program operation. AAMC projects achieving a market share of 25% of adult cardiac surgery cases in its defined service area in the first year of operation and projects that it will ramp up to a 40% market share by the third year of operation. (DI #3AA, p. 77).

AAMC describes its projections as resting on consideration of four major factors: (1) cardiac surgery need of inpatients and outpatients currently treated at AAMC; (2) volume shifts from the Johns Hopkins Hospital ("JHH") cardiac surgery program to AAMC as a function of the collaborative AAMC/JHM cardiac surgery program at AAMC; (3) cardiology market share growth at AAMC and referral redirection anticipated with a new program at AAMC; and (4) cardiac surgery use rates for the service area population. (DI #3AA, p. 78).

AAMC states that its approach to case volume projection began with consideration of existing clinician relationships and existing inpatient and outpatient hospital volume. (DI #3AA, p. 78). It notes that physicians from AAMC discussed the proposed program with six cardiology practices[17] affiliated with AAMC to document the referral base for cardiac surgery represented by these practices and to estimate the percentage of cases these cardiologists would refer to its new cardiac surgery program. AAMC concluded that its existing base of affiliated cardiologists would generate a volume of cardiac surgery cases in excess of 200 cases per year, even if use rates decline as assumed in the published volume projections.

From its clinician-based analysis of the six cardiology practices, AAMC arrived at a base volume estimate of 422 total cardiac surgical referrals for 2014. Assuming that this 2014 base volume will decline because of the Cardiac Surgery Chapter's assumption of a declining population use rate, AAMC calculated base volume projections for 2017-2019 of 406 cases, 395 cases, and 393 cases, respectively. AAMC assumes that it could capture 67% percent of the base volume projected for the first year of operation, 2017, yielding 272 cases in that year, and 79% in the following two years, yielding 312 cases in Years 2 and 3 of operation. (DI #3AA, p. 79).

AAMC states that it reviewed its hospital records to determine inpatient and outpatient referrals and direct transfers to other hospitals for cardiac surgery. This included all patients transferred for cardiovascular bypass surgery and valve surgery, and a portion of patients transferred specifically for evaluation for cardiac surgery. AAMC assumed that 50% of patients transferred for evaluation for cardiac surgery actually received cardiac surgery. It also reviewed the number of outpatients undergoing cardiac catheterization in the AAMC catheterization lab who were subsequently referred for cardiac surgery or surgical evaluation. This review yielded what the hospital calls the "existing cardiac surgery patient base" at AAMC, a total of 237 cardiac care patients at AAMC who were transferred from or referred from AAMC and, based on AAMC's assumption, received surgery. This included 162 direct hospital-to-hospital transfers from AAMC and 75 outpatients referred for cardiac surgery following a cardiac catheterization at AAMC. The

[16] These five counties are located in the Baltimore/Upper Shore Region. Calvert and Prince George's Counties are in the Metropolitan Washington Region because the cardiac surgery programs in that region handle most of the demand for cardiac surgery that originates in those jurisdictions.

[17] AAMC Cardiology Specialists, Annapolis Cardiology Consultants, LLC, Chesapeake Cardiac Care, P.A, Bay Cardiology, Chestertown Cardiology, and Cardiology Associates. (DI #3AA, p. 79).

hospital assumed 80% of the patient base would have remained at AAMC for cardiac surgery if the hospital had offered this service, yielding a total of 188 estimated AAMC cardiac surgery cases. (DI #3AA, p. 80).

AAMC assumes, based on consultation with JHH surgical leadership and AAMC clinicians, that half of the cardiac surgery patients in its service area who are now served at JHH will shift to AAMC if it develops a cardiac surgery program. The applicant describes its partnership with JH Medicine's cardiac surgery program as a collaboration in which "patients at AAMC will be offered access to JHM surgeons at the patient's own regional hospital, continuity of care under local cardiologists, and AAMC's high quality of care." (DI #3AA, p. 80). AAMC states that 163 service area residents received cardiac surgery at JHH in 2013, yielding 82 cases based on the assumed 50% shift to AAMC. AAMC states that it adjusted this estimate to account for the numbers already developed from the review of transferred patients previously described and determined that 37 of these patients were already documented in its transfer analysis, yielding a net addition of 45 cases. (DI #3AA, p. 81). AAMC projects an ability to capture a 40% market share of cardiac surgery originating in its service area by the third year of its cardiac surgery program's operation. It states that its

> expectation is based on AAMC's historical performance as a provider of specialty services and its geographic location. AAMC is particularly well positioned to serve residents of Anne Arundel and the midshore [Eastern Shore] counties currently isolated from local cardiac surgery hospitals. (DI #3AA, p. 81).

AAMC points out that it currently enjoys a 40% service area market share for its joint replacement program and a 32% service area market share for its bariatric surgery program. It believes it will achieve comparable results for cardiac surgery, given the lack of local providers for this service and its established "dominance [as a] provider of cardiac services for Anne Arundel County residents." (DI #3AA, p. 82). AAMC also looks to its PCI patient origin as a basis for projecting that an AAMC cardiac surgery program will attract cases from outside its service area equivalent to eight percent of its total cardiac surgery cases.

AAMC notes that it used the above-discussed analyses to develop its projected ramp-up from 241 to 387 cardiac surgery cases during its first three years of operation. In discussing the reasonableness of its market share target, AAMC again references: (1) its base of hospital transfers and hospital referrals; (2) the market share it has achieved in general for adults and in specialty programs, including PCI services, where it commands a nearly 20% market share in the defined service area; and (3) the volume shifts expected from JHH through AAMC's collaboration with JH Medicine. AAMC notes that it has recently affiliated with physician practices in Kent County. AAMC states that its proposed program will be the "only cardiac surgery provider within a 60 minute drive for thousands of area residents." (DI #3AA, p. 83). AAMC anticipates further expansion of its caseload for PCI and general cardiology and believes that "payer-provider contracts that channel books of business to high quality, low cost providers" support its market share assumptions. (DI #3AA, p. 83).

Baltimore Washington Medical Center

BWMC projects case volumes for six years, FY 2016 to 2021, on the basis of its defined service area and expected shifts in cardiac surgery caseload from existing hospitals. With respect to its service area, BWMC includes: (1) a local five zip code area primary service area ("PSA"), consisting of Glen Burnie, Pasadena, Severn, and Brooklyn zip code areas); (2) an eight zip code area secondary service area ("SSA"), consisting of north and central Anne Arundel zip code areas; (3) a 47 zip code area tertiary service area ("TSA"), labeled as the "Upper Shore areas;"[18] and (4) a 22 zip code area quaternary service area ("QSA"), primarily Anne Arundel County zip code areas and some Prince George's County areas, described as the "other service area." (DI #2BW, Exh. 4). In the sixth forecast year of operation, 2021, BWMC projects that 84 cases (31% of total) will originate in its PSA, 48 cases (18%) will be residents of its SSA, 50 cases (19%) will originate in the TSA's Upper Shore areas, and 87 cases (32%) will originate in the QSA's other service area. (DI #2BW, Exh. 23).

BWMC concludes that it will perform cardiac surgeries that would otherwise be performed at the University of Maryland Medical Center, at other Maryland hospitals, or at District of Columbia hospitals. It assumes that, in the first six years, most cases will represent a shift in caseload from the University of Maryland Medical Center. In the first partial year of operation of its cardiac surgery program, BWMC projects 84 cases, classifying 76% of these cases (64) as cases that would otherwise be performed at UMMC. By Year 2, the first full year of operation, it forecasts 204 cases, with 71% (145 cases) shifting from UMMC. By 2021, BWMC predicts a caseload of 270 cases, with only 56% (150 cases of this load) identified as shifting from UMMC. Cases shifting from Maryland hospitals other than UMMC are assumed to account for a growing proportion of total cases over time, increasing from 15% (12 cases) to 27% of total cases (74 cases) between 2016 and 2021. BWMC predicts that cases will shift to it from District of Columbia hospitals, with eight in 2016 (six percent of total cases) to 46 cases by 2021 (17% of total cases). BWMC employs a case severity adjustment in its model to reflect that BWMC will not be the cardiac surgery program of choice for some cases in its service area. (DI #2BW, Exh. 23).

BWMC projects that its service area will generate 616 cardiac surgery cases in FY 2016. It addresses the most recent published MHCC utilization projection of cardiac surgery cases by predicting this service area caseload will decline to 545 cases by 2021. It assumes that 30% of the UMMC caseload originating in its service area will shift to BWMC in the first year of operation and that this will quickly rise to 80% and stabilize at that level by Year 4. It assumes that 5% of the other Maryland hospital cases originating in BWMC's service area will initially shift to BWMC and that this will increase to 33% by 2021. BWMC assumes that the cardiac surgery cases will shift to it from District of Columbia hospitals on a similar trajectory over the first six years, from 5% to 33%. (DI #2BW, Exh. 23).

[18] All of the general hospitals operating in the "Mid-Shore" area of the Eastern Shore are UMMS hospitals. This area consists of Caroline, Dorchester, Kent, Queen Anne's, and Talbot Counties.

BWMC states that it took a second step to verify and corroborate the reliability of its model by gathering estimates of referred cases from five supportive cardiology practices,[19] noting that this approach yields an estimate of 312 referred cardiac cases, which supports its forecast model. (DI #2BW, p. 45).

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC states that AAMC has not documented that it will be able to achieve the minimum case volume because it "relies on undocumented statements and aspirational assumptions." (DI #29GF, p. 6). It criticizes AAMC's forecasting approach for not discounting for severity of illness[20] and patient preference and questions AAMC's expectation that it will receive referrals for cardiac surgery from Cardiology Associates, a practice that is owned by MedStar. More generally, it claims the review of cardiology practices as referral sources by AAMC relies on "unsupported assertions that are insufficient to comply with this standard" and reviews the documentation provided by AAMC for this aspect of its analysis, finding that a more rigorous consideration of "documented referrals," fully eliminating Cardiology Associates as a referral source, would yield approximately a 38% smaller estimate of patient referrals. (DI #29GF, p. 7)

Beyond its critique with respect to discounting for case severity, BWMC also questions AAMC's assumption that 100% of referred patients will have surgery, noting that patients may ultimately be determined to be too clinically unstable for surgery or may die before surgery can be performed. It also notes that the elective nature of most cardiac surgery allows patients to consider and exercise preferences that lead them to obtain care from other providers for a wide variety of reasons.

BWMC argues that AAMC's analysis of inpatient transfers, outpatient transfers, and expected volume shift from JHH does not support AAMC's view that its existing patient base is sufficient to meet the minimum volume standard. It states that this component of AAMC's analysis does not provide "a meaningful way to evaluate the appropriateness of AAMC's surgery assumptions." (DI #29GF, p. 12). BWMC believes that application of the assumptions underlying the Commission's projections to the base numbers used in this component of AAMC's analysis would push the 2017 and 2018 projected caseload below 200 cases, to approximately 180 cases in each year. BWMC cites inconsistencies in AAMC's claims with respect to the shift of cases from JHH to AAMC. (DI #29GF, p. 11).

[19] The practices are: Arundel Heart Associates, P.A.; The Heart Center of Northern Anne Arundel County, P.A.; Chesapeake Cardiology at Shore Health; the UM School of Medicine Division of Cardiovascular Medicine; and Maryland Heart Associates, L.L.C.

[20] BWMC suggests that AAMC's projection of case volume should be discounted by 17%, noting that, in 2014, this proportion of all Maryland cardiac cases had a "Severity of Illness" rating of "Extreme" and that such cases should only be handled by an academic medical center. (DI #29GF, p. 9).

BWMC characterizes AAMC's market share assumptions as unrealistic and unsupported by AAMC's reference to the market share it achieved in its provision of PCI, joint replacement surgery, or bariatric surgery. According to BWMC, AAMC does not adequately explain why the cardiac surgery market share assumptions relate to these other services in a meaningful way. It notes that AAMC's "overall inpatient market share in the region (the defined AAMC service area) is only 24%" and, in general, concludes that AAMC has not adequately justified its likely ability to achieve higher market shares in cardiac surgery. (DI #29GF, p. 16). It cites "an overwhelming preference for UMMS-affiliated cardiac surgical programs" in the mid-Eastern Shore, specifically noting UMMS' near 60% market share, and dismissing AAMC's assumptions with respect to likely growth in AAMC market power in this region as resting on weak references to new physician affiliations in Kent County without supporting detail. (DI #29GF, pp. 15-16).

BWMC also criticizes AAMC's use of travel time in responding to this standard. It states that AAMC does not quantify its claim that an AAMC cardiac surgery program will be the only program within a 60-minute drive for thousands of area residents. BWMC states that

> it is unlikely that there are many residents in the proposed AAMC service area who do not live within 60 minutes of PGHC, MedStar Washington Hospital Center, UMMC, Johns Hopkins Hospital, Peninsula Regional Medical Center, or Christiana Hospital (in Delaware). (DI #29GF, p. 16).

It notes that AAMC did not provide detail on payer-provider contracts as a basis for its market share assumptions. (DI #29GF, p. 17).

BWMC states that AAMC failed to consider "the strength of PGHC and UMMS in AAMC's proposed cardiac surgery service area," noting that 58 cardiac discharges from PGHC over a recent six-month period originated in zip code areas that "overlap with AAMC's proposed cardiac surgery service area." (*Id.*). It also describes PGHC's cardiac surgery program as "rapidly reviving." (*Id.*).

Dimensions Comments

Dimensions does not address the minimum volume standard in its comments. It references AAMC's service area definition and market share assumptions only as part of its comment on the Impact standard, COMAR 10.24.17.05A(2).[21]

[21]Dimensions' comments relate to the impact of AAMC's proposed project on PGHC's cardiac surgery program, and it opposes AAMC's application on that basis. See my summary of Dimensions' comments regarding the impact standard, COMAR 10.24.17.05A(2), *infra*, pp. 39-40, and my summary of its comments on the impact criterion, COMAR 10.24.01.08G(3)(f), *infra*, p. 119.

Comments on BWMC Application

AAMC Comments

AAMC states that BWMC is unlikely to meet the minimum volume standard, claiming BWMC's analysis is based on faulty assumptions. AAMC states that BWMC's market share assumptions are arbitrary and too high, given BWMC's proximity to its Baltimore area competitors. AAMC faults BWMC for applying high market share assumptions to important zip code areas where travel time differences between BWMC and other hospitals are slight or even favor the other hospital. (DI #28, pp. 3-4). AAMC also notes that BWMC has little margin for error in its analysis and that marginally missing the mark in its assumptions could mean failure to reach 200 cases. (DI #28GF, p. 3).

According to AAMC, BWMC has not shown that it can generate a base of sufficient "existing, in-house demand," forcing it to over rely on an assumption that it will rapidly capture high levels of market share in its defined service area to meet the case target of this standard. (DI #28GF, p. 8). It contrasts the number of 2014 patients reported by BWMC to have received cardiac catheterization at BWMC and, in BWMC's words, "later required 'procedures that could have been performed at UM BWMC if cardiac surgery services were available." It contrasts this number, 97 patients, with what it reports as a comparable number for AAMC in 2014, 162 patients. (DI 28GF, p. 8).

AAMC notes that BWMC showed, in responding to completeness questions, that it had no credible basis for its assumption that it will have a 50% market share of the cardiac surgery market in its service area. (DI #28, p. 10). AAMC argues that beyond the UMMS-affiliated hospitals, BWMC has no referral pattern that supports application of its market share assumption for its entire service area and points to BWMC's low existing market share in peripheral regions of the service area such as Prince George's, southern Anne Arundel, and the Eastern Shore counties. (*Id.*).

According to AAMC, the likely increase in severity of cardiac surgery cases over time would threaten BWMC's ability to reach 200 cases because such cases will be excluded from a BWMC program. (DI # 28GF, pp. 10-12).

Comments on Both Applications

LifeBridge Comments

LifeBridge states that neither applicant established a need for an additional cardiac surgery program in Maryland, nor demonstrated that its proposed project is consistent with the SHP.[22] LifeBridge points to Suburban Hospital's experience as the State's newest cardiac surgery program as a cautionary tale. It notes that Suburban Hospital projected reaching a caseload of 350 cases per annum but, in recent years, has never surpassed 250. (DI #33GF).

[22]LifeBridge's comment on the minimum volume standard more directly addresses the adverse impact that adding either of these new programs could have on existing programs and on case volume, with the potential for an adverse impact on the quality of cardiac surgery. For this reason, I am brief in my summary here.

MedStar Hospitals Comments

The MedStar Hospitals assert that each applicant uses faulty assumptions in its analysis of its ability to start a cardiac surgery program that will reach and maintain a caseload of at least 200 cases per annum. The MedStar Hospitals state that neither application addresses MHCC's projection of decline in cardiac surgery cases, and each makes assumptions with respect to its ability to "entice patients and effectuate market shifts." (DI #34GF, p. 22).

The MedStar Hospitals note that cardiac surgery case volume is declining as is inpatient case volume generally and that this trend is occurring both in Maryland and nationwide. (DI #34, p. 23). For this reason, they state that the CON review process "ought not myopically focus on whether an applicant has been somehow able, to devise a methodological calculation of volume expectations based on purported market share shift to squeeze above the 200 procedures 'entry requirement.'" (DI #34GF, p. 22).

The MedStar Hospitals assert that "there is no 'unmet need' for cardiac surgery services that existing providers cannot meet," linking this assertion to its observation that, because use of cardiac surgery is declining, existing cardiac surgery hospitals will have even more capacity to deliver this service. (DI #34GF, pp. 23-24). They also point out that letters from cardiologists are a "dubious source of support" for the proposed projects and "a risky planning model" in trying to project cardiac surgery volume since cardiac surgeons, not cardiologists, determine if surgery will be needed. (DI #34GF, p. 24).

The MedStar Hospitals claim that the applicants' assumptions that they will be able to shift market share are suspect. Taking significant market share from both Johns Hopkins and MedStar WHC, which AAMC projects, is not likely because these hospitals "operate well-established cardiac surgery programs set in well-developed systems of cardiac care delivery" providing "the full gamut of cardiac surgery services including the ability to treat very high risk surgical patients." This shift in market share "from MedStar WHC in particular is unlikely." (DI #34GF, pp. 24-25). The MedStar Hospitals note the experience of Suburban Hospital, which overestimated achievable volume and has not achieved a case volume far above 200 cases per annum during its first ten years. (DI #34GF, pp. 24-25).

The MedStar Hospitals state that the analogy drawn by AAMC between cardiac surgery and bariatric and joint replacement surgery" is not valid. They conclude that AAMC will "struggle to attain the expertise of existing high volume cardiac surgery providers." (DI #34GF, p. 26).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC organizes its response to the interested parties' comments using the framework of the four "distinct but interlocking methods" that it used in projecting case volumes. (DI #45GF). With respect to criticisms of its "internally-generated cases based on AAMC experience," it insists that its projection was valid. (DI #45GF, p. 5). AAMC points out that its forecast was based on

the actual number of patients already at the hospital, who selected AAMC, and who required surgery. AAMC states that its "unique base of internally-generated referrals is one reason why analogies by LifeBridge and MedStar between AAMC's volume projections and those of Suburban Hospital [are] inapt." (DI #45GF, p. 5). AAMC also notes that it assumed declining use rates in its projections and that Suburban did not. (DI #45GF, p. 5). It points to distance from existing cardiac surgery providers as another factor that distinguishes it from Suburban Hospital, noting that Suburban Hospital is located within 11 miles of three existing cardiac surgery programs. In contrast, AAMC is located more than 20 miles from PGHC, almost 30 miles from MedStar WHC and UMMC, more than 30 miles from JHH and Suburban, and almost 90 miles from Peninsula Regional Medical Center (in Salisbury, Maryland). (DI #45, pp. 5-6).

AAMC states that it properly documented its projection of case volume for its proposed cardiac surgery program. It notes that it reviewed records of all inpatient and outpatient transfers from AAMC to existing programs for cardiac surgery and that it "validly assumed that 50% of the patients referred for evaluation for cardiac surgery would ultimately receive that surgery." (DI #45GF, p. 6). It claims that this assumption "fit the experience of those AAMC cardiologists that make the majority of such referrals" and observes that the remainder includes patients who need surgery but are too unstable for surgery or die before surgery. On that basis, it states that "no further discount on those grounds is warranted." (DI #45GF, p. 6).

AAMC states that it "also validly assumed that 100% of the 95 patients specifically transferred for cardiac surgery received such surgery," (DI #45GF, p. 6) noting that "even if BWMC is correct that some discount of approximately 5% is appropriate for transferred patients who die prior to surgery (though AAMC records do not indicate this level of mortality), even this 5% discount would only result in the loss of approximately eight cases, as BWMC acknowledges." (DI #45GF, p. 7).

AAMC states that "BWMC has documented far fewer internally generated cases: in FY 2014, only about 97 BWMC cardiac catheterization patients needed surgery, whereas in the previous year, 234 patients of AAMC (inpatients, and outpatients requiring cardiac catheterization) required transfer to a hospital with a cardiac surgery program." (DI #45GF, p. 7). It notes that these are not the only source of patients, observing that "BWMC itself anticipates that adding a cardiac surgery program will attract patients who currently bypass it altogether and receive cardiac care from hospitals with existing programs." (DI #45GF, p. 7).

With respect to cases generated by AAMC's affiliation with Johns Hopkins, AAMC characterizes as conservative its estimate that approximately 50% of cases from its service area will shift from JHH to AAMC. It notes that "many of the patients who end up receiving surgery at JHH already choose AAMC for their cardiac care." (DI #45GF, p. 8).

AAMC defends its use of surveys of cardiology practices, pointing out that each of the six cardiology practices surveyed by AAMC expressed support for AAMC's program and that each has clinicians who have indicated their desire to use a program at AAMC. It states that BWMC mistakenly excluded two letters in its analysis that account for the gap BWMC identified. (DI #45GF, pp. 9-10). AAMC observes that "when projecting volume based on these representations from local cardiologists, AAMC adequately accounted for patient preference and acuity" and "the

decline in cases called for by the Commission's overall volume projections." It states that, "[i]n contrast, BWMC failed to account for patient preference or use rate decline, at least for those cases originating with the UM Division of Cardiovascular Medicine" (DI #45GF, p. 10).

AAMC states that it "did not estimate that it would perform cardiac surgery on all patients referred for such surgery by these cardiologists; rather, the cardiologists themselves estimated what proportion of such patients would actually receive referrals to AAMC for cardiac surgery" and notes that "these cardiologists understand the typical acuity of their own cases and presumably have a sense of patient preference; the Commission should not layer another level of discount upon these estimates." (DI #45GF, p. 10).

AAMC states that its market share assumptions for the Eastern Shore are reasonable, noting that "AAMC has a substantial market share in various surgical fields in that region, despite BWMC's claims to the contrary. Based on its decade-long relationship with Johns Hopkins, AAMC expects that relationship to increase AAMC's market share." (DI #45GF, pp. 11-12). With respect to the criticism offered by the MedStar Hospitals of AAMC's reference to its market share in other surgical specialties as indicative of its likely success with cardiac surgery, AAMC again notes its 40% market share for joint replacement surgery and its 32% market share for bariatric surgery, surgical specialties it identifies as "highly competitive" and "not subject to certificate of need." (DI #45GF, p. 12).

Baltimore Washington Medical Center

BWMC defends the projections it developed to demonstrate compliance with the minimum volume standard, stating that "AAMC's analysis of proximity of residents in Northern Anne Arundel County is incorrect and irrelevant." (DI #42GF, p. 4). Contrary to AAMC's assertion, BWMC notes that residents living in the five zip code areas (21225, 21090, 21226, 21227, and 21075) are not materially closer to UMMC than BWMC. Two are closer to BWMC and the differences of three to five minutes for the other three are "immaterial and irrelevant" and, thus, AAMCs challenges to BWMC's assumption about the number of cases it will receive from this area are not valid. (DI #42GF, pp. 4-5). BWMC notes that a larger percentage of patients originating in these five zip code areas obtain all their inpatient care at BWMC (10%) than the comparable percentage for UMMC (7%). BWMC has a greater cardiology market share of these areas than UMMC. (DI #42GF, pp. 5-6). BWMC concludes that the City of Annapolis was inaccurate in using travel time to support a preference for the AAMC application. BWMC states that its hospital campus, "measuring in a straight line, is 10.3 miles south of UMMC, and is a minimum of 13.5 miles from UMMC by car. (DI #GF42, p. 5, *citing* Google Maps). Also, on a straight line, BWMC is only 11.5 miles from the Annapolis city limits." (DI #GF42, p. 5).

The applicant states that it "appropriately discounted documented expected cardiologist referrals, and AAMC did not." (DI #42GF, p. 6). BWMC notes that AAMC questions BWMC's assumption of a 10% increase in cardiology referrals at The Heart Center of Northern Anne Arundel but claims that it documented 81 referrals from this practice and projected an additional eight cases, based on the addition of a cardiologist. But it notes that these eight cases are not critical to BWMC's ability to meet this standard. It states that AAMC has used similarly "undocumented" referrals in its case forecasting. (DI #42GF, p. 7).

BWMC states that it is inappropriate to compare the applications using different rates of decline in demand, as AAMC has done, because the projected decline will impact the proposed projects equally. AAMC's projected use rate decline is less than that in Commission projections for the two regions addressed in the AAMC forecast. (DI #42GF, pp. 8-9).

BWMC notes that AAMC's criticism that BWMC must account for severity of illness in its referrals applies equally to AAMC, since AAMC also expects to treat patients of about the same severity/acuity. (DI #42GF, p. 9).

Referencing AAMC's criticism of BWMC for not adjusting its cardiology referrals to account for patient and physician preference, BWMC claims that its analysis of referrals accounted for physician preference, accepting the physicians' indicated expectation of referring documented cases in BWMC's service area to BWMC. (DI #42GF, p. 9). BWMC notes that "there is nothing inconsistent with BWMC's assumption that physicians who estimate they expect to refer a certain number of cases to BWMC will likely do so. These referrals will overlap to some extent with the 80% shifting volume from UMMC, but will not overlap completely." (DI #42GF, p. 10).

BWMC responds to AAMC's criticism of BWMC's referral base analysis by claiming that it is not credible because the AAMC application recognizes the difference between surgery referral and cardiology referral data sets. (DI #42GF, pp. 10-11). Conceding that patients might go to hospitals other those recommended by their cardiologists, "BWMC does not believe this number is significant." (DI #42GF, p. 11). It notes that, "In order to compare BWMC and AAMC on a level basis, one must first account for physician preference in AAMC's documented referrals. Unlike BWMC, which documented the number of referrals a physician expected to make to BWMC, AAMC documented the total number of referrals a physician made, and then applied a percentage to those referrals based on the qualifying language of the cardiologist." (DI #42GF, p. 11). BWMC states that AAMC's discounting of BWMC cardiology referrals by the 70% market share shift expected from UMMC in FY 2017 is invalid and unsupported. BWMC asserts that it "has sufficient volume from documented referrals alone to support its application, while AAMC does not." (DI #42GF, pp. 11-12).

BWMC states that it can "document minimum volume based on inpatient transfers from the hospital, and AAMC cannot." (DI #42GF, p. 13). It states that "AAMC's existing in house demand is based on unsupported assumptions regarding the percentage of referred or transferred patients who actually had surgery, whereas BWMC's analysis is based on actual experience." It notes that it "replicated this analysis to identify an 'existing in-house demand,' as defined by AAMC, of 208 patients, as compared to AAMC's 224 patients." (DI #42GF, p. 14). BWMC claims that it "completed a detailed review of patient records to identify the actual treatment each patient received instead of assuming (as AAMC did) whether a patient had surgery. Of the 208 transferred patients, BWMC identified 103 confirmed surgeries; of the 50 outpatient referrals, BWMC confirmed 43 actual surgeries, totaling 146 actual confirmed cases." (DI #42GF, pp. 15-16). BWMC concludes that it "reasonably expects to achieve a market share in the cardiac surgery service area that is approximately equivalent to BWMC's current market share of 50% for cardiology in its HSCRC service area" and that its "market share projections are reasonable based on the strength of its membership in UMMS, which will provide numerous strengths and

advantages, including a powerful referral network throughout the proposed cardiac surgery service area." (DI #42GF, p. 17).

BWMC states that it "appropriately discounted for severity of illness." (DI #42GF, p. 17) It states that "AAMC's suggestion that BWMC's projections should account for an increased percentage of Extreme SOI (severity of illness) cases, which BWMC's proposed program will not accept, is without merit" claiming that "the health care system's increased emphasis on prevention and chronic disease management can also lead to reductions in extreme SOI. Without significant data, there is no basis to accept AAMC's mere speculation over BWMC's assumption based on actual experience." (DI #42GF, pp. 17-18).

Reviewer's Analysis and Findings

AAMC and BWMC each used similar and fairly conventional approaches to forecasting demand for cardiac surgery. BWMC did not appear to incorporate explicit market share assumptions in a conventional service area analysis approach, as AAMC did. Instead, it made assumptions about how the distribution of cases to existing cardiac surgery hospitals will change as BWMC enters the market and a proportion of cases from UMMC and other Maryland and District of Columbia hospitals shifts to BWMC, an approach that obviously implies certain market share assumptions. Both applicants forecast the ability to reach a level of cardiac surgery that would result in compliance with the standard.

Legitimate questions have been raised about the soundness and relevance of the information gathered by the applicants from physicians and the assumptions made by the applicant hospitals in their forecast models. My assessment is that both applicants took reasonable approaches to the development of forecasts but there is a basis for concluding that some assumptions about their likely cardiac surgery service areas and the market share levels they forecast, especially with respect to market share outside the collaborative framework that is proposed by both applicants to "steer" case volume to their new programs from affiliated hospitals, cannot be characterized as conservative. This shifting market share is accomplished through direct competition for cardiac surgery patients. I believe that the relatively stable annual case volume of 200 to 250 cases recently experienced by Suburban Hospital's cardiac surgery program is a relevant point of reference for soberly assessing what each proposed new market entrant can achieve. Finally, I am mindful that further declines in the use rate of cardiac surgery may lie ahead or demand may stabilize, leading to some growth in demand. Gradual decline in the use rate large enough to shrink nominal case volume has been incorporated into each applicant's projection and this may indeed play a role in pushing the applicant's choice of assumptions about how quickly and how much it can penetrate and move competitors' established referral patterns.

Based on my review of the applications, I constructed a simple alternative forecast model at the hospital service-area level, in order to provide a more direct comparison of the applicants' market potential. I do not intend this exercise as a rejection of each applicant's response to this standard. Rather, my intention is to provide a more balanced perspective, allowing for comparison of the applications on the basis of consistent assumptions, grounded in actual experience. The main attraction of this approach is that, first, it relies on established inpatient service areas, which both applicants obviously used to inform their service area definitions but only as one factor.

Second, it uses observed cardiac market shares within an identically constructed service area for similar existing programs. My model's key moving parts are the population use rate, which is projected to be declining, consistent with the SHP regional forecast model at the time these applications were filed, and observed cardiac market share.

The volume projections in Table 5B, *supra*, p. 31, are based on the applicants' CY 2014 observed 85% relevance medical/surgical/gynecological/addictions ("MSGA") service areas. This is a group of zip code areas that contributed, ranked by highest to lowest frequency, 85% of MSGA discharges. These service areas are smaller, geographically, and have smaller populations than the service areas defined by the applicants in their CON applications. Using zip code population estimates and projections supplied by Nielsen Company, the AAMC-defined service area had an estimated adult population of about 843,000 in 2015, which is projected to increase to about 888,000 by 2020. The observed MSGA service area of AAMC has an estimated 2015 adult population of about 674,000, which is projected to increase to about 713,000 by 2020. BWMC defined a cardiac surgery service area with an estimated 2015 adult population of 642,000, projected to grow to 675,000 by 2020. The actual MSGA service area of BWMC has an estimated 2015 population of only 335,000, projected to increase to 352,000 by 2020. Overlap of the service areas is significant, using both the applicants' broader defined service areas and the observed MSGA service areas, although the observed service areas I have used as a balancing analysis have less overlap than is seen in the applicants' defined service areas, especially with respect to AAMC. About 65% of the population in the AAMC-defined service area was also included in the service area that BWMC defined for cardiac surgery and about 86% of the BWMC service area population was also in AAMC's defined catchment area. Overlap drops to 36% for AAMC and to 73% for BWMC, when looking at observed MSGA service areas. This MSGA service area overlap is nine Anne Arundel County zip code areas, as shown in the following table.

Table 4: Zip Code Areas in the 85% Relevance MSGA Service Area of Both AAMC and BWMC and 2015 Adult (15+) Estimated Population

Zip Code	Area	2015 Adult Population	2015 Elderly (65+) Population
21054	Gambrills	8,867	1,701
21060	Glen Burnie	26,059	4,714
21061	Glen Burnie	44,967	6,918
21108	Millersville	14,475	2,473
21113	Odenton	26,636	3,508
21114	Crofton	20,642	2,640
21122	Pasadena	51,344	8,341
21144	Severn	26,889	3,651
21146	Severna Park	22,825	4,852
TOTAL		242,704	38,798

Source: HSCRC Discharge Database for service area definition: Nielsen for population estimates.

In order to develop case projections for the applicant hospitals' 85% relevance MSGA service areas, I first updated regional cardiac surgery projections for statewide Maryland adult resident cardiac surgery utilization, using the forecast model in the Cardiac Surgery Chapter, COMAR 10.24.17 that was effective on August 17, 2014, with the following adaptations. I used Nielson population estimates and projections instead of jurisdictional population estimates and projections to conform to the zip code area-level of analysis necessary for hospital service areas. This provided consistency of data sources for the entire time period. I included adult cardiac

surgery discharges that originated in Maryland and received services at a hospital in Virginia. This update produced resident use rate trends by age group for regions through the year 2020. I used the definition of cardiac surgery found in the 2014 Cardiac Surgery Chapter.

I determined the number of cardiac surgery discharges from any hospital in Maryland, District of Columbia, and Virginia that originated from the 2014 85% relevance MSGA service area for 2009-2014, by the age groups used in the Cardiac Surgery Chapter regional forecast model and also obtained population estimates for the hospitals' 2014 85% relevance MSGA service areas for 2009 to 2014 and population projections for 2015 to 2020, by those same age groups. Again, the definition of cardiac surgery found in the Cardiac Surgery Chapter that I used was effective on August 17, 2014. Due to low volumes and extreme annual fluctuations in use rates observed at the zip code area level, I determined that using the data on a zip code-level was problematic. Therefore, I applied projected regional annual use rates from the statewide regional projections by age group, through 2020, to population projections in zip code areas in AAMC's and BWMC's 85% relevance MSGA service areas, by age group, based on the corresponding region of each zip code area, as shown in the following table.

Table 5A: Projected Cardiac Surgery Use Rates (Cases per Thousand Population) Based on Regional Use Rate Trend Analysis, 2009-2014

	Age Group	2015	2016	2017	2018	2019	2020
Baltimore-Upper Shore Region Zip Code Areas	15-44	0.1353	0.1366	0.1380	0.1394	0.1408	0.1423
	45-64	1.2238	1.1656	1.1102	1.0574	1.0071	0.9593
	65+	3.6336	3.4975	3.3664	3.2403	3.1189	3.0021
Washington Metro Region Zip Code Areas	15-44	0.0944	0.0919	0.0894	0.0870	0.0846	0.0824
	45-64	0.9575	0.9370	0.9052	0.8802	0.8558	0.8322
	65+	2.6177	2.4987	2.3850	2.2766	2.1731	2.0742

Sources: Cardiac surgery cases from HSCRC Discharge Database, D.C. Discharge Database, and Virginia Health Information (VHI) discharge dataset
Population data obtained from Nielsen. 2009 to 2014 population interpolated using 2000, 2010, and 2015 estimates supplied by vendor, assuming the same rate of change year to year ("straight line interpolation")

I calculated projected case volume in each zip code area using the Nielsen projections and projected annual regional use rates. I summed zip code level projections to project case volume for the 85% relevance MSGA service area for the applicant hospitals, as shown in Table 5B.

Table 5B: Cardiac Surgery Case Volume Projections for Applicant Hospitals' 85% Relevance MSGA Service Area

Hospital		Projected Cardiac Surgery Discharges from 85% Relevance MSGA Service Area					
		2015	2016	2017	2018	2019	2020
AAMC		714	703	694	685	676	668
BWMC		353	348	343	338	334	330

Sources: Cardiac surgery cases from HSCRC Discharge Database, D.C. Discharge Database, and VHI discharge dataset
Population data obtained from Nielsen. 2016 to 2017 population interpolated using 2015 estimates and 2020 projections supplied by vendor, assuming the same rate of change year to year ("straight line interpolation")

In order to gauge the effect of the overlap in MSGA service areas on forecasted case volume if both proposed cardiac surgery programs were established, I adjusted for overlap in the

service areas by prorating the total case projection proportional to the adult population projection of each zip code area to produce case projections at the zip code area level and allocating case counts for the nine Anne Arundel County zip codes appearing in each service area on the basis of an even (50:50) split of the cases to each hospital. I did not attempt to create a more complicated model adjusting market share for travel time, because the travel time differences are too small to expect this kind of consistent relationship and it is also useful to assume that use rates will tend to revert to the mean over time, so I did not model pockets of higher or lower use observed for these small areas over short periods of time.

Table 6 displays the service area cardiac surgery case base for 2017 and 2020 without adjustment for service area overlap, the base applicable to establishment of one or the other proposed project, but not both. These case projections are taken from Table 5B. Table 7 shows the adjustment for service area overlap. As can be seen, this adjustment has a much larger impact on BWMC's service area base, because it has a much smaller MSGA service area (15 zip code areas with a 2015 estimated adult population of 335,000) than on AAMC (39 zip code areas with a 2015 estimated adult population of 674,000). As previously noted, BWMC also has a much larger level of overlap with AAMC's service area (73%) than AAMC has with BWMC's service area (36%).

Table 6: Cardiac Surgery Case Volume Projections for Applicant Hospitals' 85% Relevance MSGA Service Area – No Adjustment for Overlap of MSGA Service Areas

Hospital	2017	2020
AAMC	694	668
BWMC	343	330

Source: HSCRC Discharge Database.

Table 7: Adjusted Cardiac Surgery Case Volume Projections for Applicant Hospitals' 85% Relevance MSGA Service Area – Adjusted for Overlap of MSGA Service Areas

Hospital	2017	2020
AAMC	569	548
BWMC	219	210

Source: HSCRC Discharge Database.

I assumed a normative cardiac surgery market share range of 18% to 20% for cardiac surgery cases originating in each hospital's MSGA service area, based on the recent cardiac surgery experience of three comparable non-urban community hospitals.[23] Tables 8 and 9, below, display this normative range (N1 and N2) and add a maximum range of 25%. This maximum range was chosen because it allows for a marker of "best case scenario" success in building a referral base that has some credibility based on the analyses provided by the applicants with respect to their uptake of service lines in their service areas and recognizes that there is only a limited sample of peer hospitals. Perfect comparability is not achievable. For example, AAMC would be a somewhat unique cardiac surgery site for Maryland. It has non-urban and exurban

[23] The cardiac surgery market share experience of Suburban, Washington Adventist, and UMSJ in their respective 85% relevance MSGA service areas was used to establish this range. They are all non-urban community hospitals, i.e., they are not located in the urban core jurisdictions of their regions, are not isolated hospitals serving less densely population and largely rural areas, and they are not academic medical centers. For these reasons, they are most like the applicant hospitals, among Maryland's existing cardiac surgery hospitals.

characteristics, and its size and the size of its service area set it apart from other existing hospitals. My maximum 25% range is substantially more conservative than the 40% market share projected by AAMC in Year 3 or the market share implied in the BWMC analysis.

Table 8, below, shows the single new program scenario. Thus, it is applicable to the establishment of one of the proposed programs but not to the establishment of both. It is not adjusted for market overlap. Table 9, below, illustrates the two new programs scenario. It takes the market overlap into account and, thus, predicts the number of cardiac surgery cases each hospital might be able to generate from its MSGA service area if both developed cardiac surgery programs at the same time and achieved market share comparable to similar community hospitals.

Table 8: Cardiac Surgery Case Volume Projections for Applicant Hospitals at Three Levels of Market Share – No Adjustment for Overlap of MSGA Service Area

Market Share Assumption	2017		2020	
	AAMC	BWMC	AAMC	BWMC
N1 – 18%	125	62	120	59
N2 -20%	139	69	134	66
Max – 25%	174	86	167	83

Source: Based on Table 6.

Table 9: Cardiac Surgery Case Volume Projections for Applicant Hospitals at Three Levels of Market Share – Adjusted for Overlap of MSGA Service Area

Market Share Assumption	2017		2020	
	AAMC	BWMC	AAMC	BWMC
N1 – 18%	102	39	99	38
N2 -20%	114	44	110	42
Max – 25%	142	55	137	53

Source: Based on Table 7.

The final step in developing my forecast using this MSGA service area model adjusts for the fact that any cardiac surgery hospital will draw some patients from beyond its established service area. On average, Maryland's cardiac surgery hospitals have only generated about 75% of their total cardiac surgery case volume from their 85% relevance MSGA service areas. The most comparable non-urban hospitals, used as a benchmark for service area market share, have only generated about 66% of their cardiac surgery volume from their MSGA service areas. Tables 10 and 11 show the 66% adjustment factor applied to the cardiac surgery case volume projections shown in Tables 8 and 9, without adjustment for service area overlap (the single new program scenario) and with adjustment for service area overlap (the two new program scenario).

Table 10: Cardiac Surgery Case Volume Projections for Applicant Hospitals at Three Levels of Market Share and Adjusted for Cases Originating Outside of Service Area – No Adjustment for Service Area Overlap

Market Share Assumption	2017		2020	
	AAMC	BWMC	AAMC	BWMC
N1 – 18%	189	94	182	89
N2 -20%	211	105	203	100
Max – 25%	264	130	253	126

Source: Based on Table 8.

Table 11: Cardiac Surgery Case Volume Projections for Applicant Hospitals at Three Levels of Market Share and Adjusted for Cases Originating Outside of Service Area – Adjusted for Service Area Overlap

Market Share Assumption	2017			2020	
	AAMC	BWMC		AAMC	BWMC
N1 – 18%	155	59		150	58
N2 -20%	173	67		167	64
Max – 25%	215	83		208	80

Source: Based on Table 9.

My projections indicate that AAMC, if authorized to establish a cardiac surgery program and, if able to penetrate the cardiac surgery market in its established MSGA service area at levels comparable to that of the most similar existing cardiac surgery hospitals, can project an ability to generate a case volume of 200 or more cardiac surgery cases per year. If it is highly successful, and can capture a 25% market share, it would be likely to generate a case volume of 200 to 215 cases, if developing a program at the same time as BWMC, and 250 to 260 cases, if authorized to develop a program without a competing program at BWMC. This service area market share of 25% is one that AAMC projected achieving in its larger defined service area in the first year of operation. But it also forecast an ability to capture 40% of the market by Year 3, an assumption that appears aggressive based on observed experience in Maryland.

My projections provide less support for BWMC's ability to attain a volume of 200 cardiac surgery cases per year. If BWMC initiated a cardiac surgery program with no other competitors in Anne Arundel County, the high range market share assumption of 25% only generates 126 cases from its MSGA service area. Because of the overlap of service by both BWMC and AAMC in core Anne Arundel County zip code areas, the approach I have taken for adjusting for service area overlap makes the prospects significantly less favorable for BWMC.

It is possible, of course, that this service area overlap would not create a barrier for both BWMC and AAMC reaching normative or slightly above normative levels of market share in their respective MSGA service areas. My baseline analysis did not account for the impact of collaborative initiatives to shift case volume to BWMC, from UMMC, and to AAMC from JHH. Both applicant hospitals have bases of support that could, theoretically, allow either hospital or both hospitals to achieve the minimum surgery case volume threshold included in the Cardiac Surgery Chapter of 200 cases by the second year of operation. Cardiac surgeons performed 1,000 cardiac surgery cases at UMMC in 2015. My alternative forecast model suggests that, because of the MSGA service area it has established, AAMC, the larger applicant hospital, is starting with baseline advantages compared to BWMC. AAMC would likely require less proactive support in shifting cases from JHH. AAMC states that it is positioned to successfully compete, on a direct basis, for the cardiologists and surgeons in its service area who now refer patients to both MedStar WHC and UMMC surgeons. Johns Hopkins has a large cardiac surgery program (performing over 1,200 cases in 2015) and may be able to facilitate a greater shift of Anne Arundel residents who seek cardiac surgery to a program at AAMC than the 50% assumption made in AAMC's application.

Even when this less than conservative scenario is applied to a single new program scenario that uses my high-end assumption of 25% market share, BWMC, with about 130 cases, still does not reach the required threshold of 200 cardiac surgery cases by the end of its second full year of operation. Using the other assumptions in my model, BWMC would need to achieve a 40% market

share within its MSGA service area to hit the 200 case per annum level, which is well above the normative levels I have assumed. This scenario would mean that BWMC and, if two programs were approved, perhaps AAMC, would need to shift more cases to their new programs from UMMC and JHH and, secondarily, other Baltimore area hospitals and WHC, as well as the smaller programs of the District of Columbia suburbs, Washington Adventist and PGHC. I conclude that cutting away the market share of those programs is probably more difficult than either applicant portrayed in its application.

I conclude that AAMC has presented information and analyses that demonstrate its ability to meet a projected volume of at least 200 adult cardiac surgery cases in its second full year of operation. I considered AAMC's analysis and tested its basic structure with more conservative service area and market share assumptions. AAMC's projection model addressed the most recent published MHCC utilization projection of cardiac surgery cases. For these reasons, I find that the AAMC proposed cardiac surgery program meets the requirements of this standard. I recommend that any CON issued to AAMC be issued with the following condition:

> If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

I conclude that BWMC has not presented information and analyses that demonstrate an ability to meet a projected volume of 200 adult cardiac surgery cases in the second full year of operation. I reached this conclusion after considering BWMC's analysis and testing its basic structure with more conservative service area and market share assumptions. That test indicates that BWMC, even in a single new program scenario and working with a high level of integration as a component of the UMMC Cardiac Surgery Division, would need to: far exceed the recently observed performance of the most similar non-urban cardiac surgery programs in Maryland; and quickly establish a strong position of some dominance as a provider of cardiac surgery in its service area. AAMC, which can more readily make a case for compliance with this standard on the basis of its own medical/surgical market power, if approved with BWMC, would certainly increase the chance that BWMC would fail to reach the required case volume.

For these reasons, I find that the BWMC proposed project does not meet the requirements of this standard.

(2) Impact

(a) A hospital that projects that cardiac surgery volume will shift from one or more existing cardiac surgery hospitals as a result of the relocation or establishment of cardiac surgery services shall quantify the shift in volume and the estimated financial impact on the cardiac surgery program of each such hospital.

(b) An applicant shall demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:

(i) Compromise the financial viability of cardiac surgery services at an affected hospital; or
(ii) Result in an existing cardiac surgery program with an annual volume of 200 or more cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 200 cardiac surgery cases; or
(iii) Result in an existing cardiac surgery program with an annual volume of 100 to 199 cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 100 cardiac surgery cases.

Applicants' Responses

Anne Arundel Medical Center

AAMC notes that its forecast model predicts that only three hospitals will experience an annual loss of more than ten cardiac surgery cases as a result of its proposed new program. It points out that those hospitals, Johns Hopkins Hospital, MedStar Washington Hospital Center, and UMMC, are the largest cardiac surgery hospitals in Maryland and District of Columbia AAMC concludes that its proposed program will not hinder the ability of any hospital with 200 or more cases to maintain a case volume well above 200 cases. It also projects that its program will not compromise the financial viability of programs currently operating with 200 or more cases. (DI #3AA, p. 87).

AAMC states that the impact of its program on the costs per case and the charges per case of any competing Maryland hospital will be small, less than a 0.1% increase in all cases, with no projected impact on any competing hospital's net income from operations. (DI #3AA, p. 88). AAMC notes that HSCRC's market adjustment policies were not "firmly established" but that HSCRC was likely to use market share adjustments to reflect the expected shift in case location. (DI #3AA, p. 89). It notes that a hospital with reduced cases will see its budgeted revenue reduced in an amount equivalent to 50% of the charges that the hospital would have made if it had retained the cases.

AAMC states that the use of a 50% multiplier in the market shift adjustments is intended to leave whole the hospital that loses cases to a new program. According to AAMC, the HSCRC policy is designed so that there will be no adverse financial impact on a Maryland hospital that loses patients to AAMC's cardiac surgery program. (DI #3AA, p. 90).

AAMC states that the existing Maryland cardiac surgery hospitals would be expected to have no reduction in their net income from services because the affected hospitals will appropriately manage the costs of their smaller cardiac surgery services. (DI #3AA, p. 90). It predicts that Washington Hospital Center will lose the most cases as a result of AAMC's cardiac surgery service. It notes that MedStar WHC is paid for Medicare cases in accordance with the Medicare Inpatient Prospective Payment System and that other payers provide comparable per-case payment rates to WHC, with diagnosis related groups used to establish the scale of rates.

Because District of Columbia hospital rates are not regulated as are Maryland hospital rates, AAMC expects that WHC will lose all the revenue associated with the cases shifted to AAMC and will need to reduce its variable cardiac surgery costs accordingly. (DI #3AA, p. 90).

AAMC states that, in the second year (FY 2018) of operation of its cardiac surgery services, the total loss of cases from both District of Columbia and Baltimore hospitals will total 337. Specifically, it predicts that WHC will lose an estimated 221 cases, JHH will lose 69, UMMC will lose 29, and that losses at other hospitals will be small, with fewer than 10 at any individual hospital. (DI #3AA, p. 92).

According to AAMC, its program will not cause any Maryland hospital that currently performs more than 200 cardiac surgery cases annually to experience a decline that would take its volume below 200 cardiac surgery cases annually. (DI #3AA, p. 92). AAMC also states that its program will not cause any Maryland hospital that performs between 100 and 199 cardiac surgery cases annually to decline to an annual case volume below 100 cases. (DI #3AA, pp. 93-94).

AAMC's key assumptions are: (1) AAMC will retain 80% of existing volume at AAMC that is currently transferred or referred to other hospitals for cardiac surgery; (2) the AAMC-JHM collaborative program will redirect 50% of AAMC's service area volume currently treated at JHH to AAMC by offering local access to a JHM surgeon and providing continuity of care through AAMC cardiologists; (3) AAMC will maintain and develop clinician relationships focused on cardiology practices that currently direct a significant percentage of cardiac surgery referrals to WHC; (4) additional volume projected to shift from hospitals other than JHH and WHC is assumed to mirror the distribution of AAMC's 2014 transfer cases, by hospital, based on the assumption that a comparable base of referring physicians will support the AAMC program as it grows; (5) AAMC will continue to draw eight percent of its cardiac volume from outside its defined service area; and (6) AAMC projects that out-of-area volume will correspond to the mix of cases from each hospital, as projected in the earlier categories. (DI #3AA, p. 91).

Baltimore Washington Medical Center

BWMC states that almost all of the volume shift that will result from the establishment of its program will come from UMMC. It states that, to a much lesser extent, some volume will shift to its program from Johns Hopkins Hospital, Union Memorial Hospital, Sinai Hospital, Peninsula Regional Medical Center, Washington Adventist Hospital, and UMSJ. It also states that its program's impact on any single cardiac surgery program will not cause the number of cases for that program to drop below the applicable annual volume thresholds. (DI #2BW, p. 46).

BWMC's forecast model projects that, by the fifth year of operation of its cardiac surgery program, its annual impact in cases that would otherwise be handled by existing cardiac surgery programs will be 150 cases at UMMC, 46 cases at MedStar WHC, 34 cases at JHH, 17 cases at MedStar Union Memorial, and 11 cases at UMSJ. BWMC projects that three other hospitals will experience single-digit case losses. (DI #2BW, p. 47).

BWMC states that, as a result of its proposed cardiac surgery program, Maryland's rate payment methodology will react to the

> incremental shifts in volume [and] be net neutral to the affected hospital. Utilizing the 50% Variable Cost Factor, the expectation is that increases or decreases in revenue should offset variable cost increases and decreases. Therefore UM BWMC expects that existing cardiac surgery programs should not experience significant financial impact. (DI #6BW, p. 10).

The applicant states that it used UMMC's cost accounting system to estimate that the direct variable cost of cardiac surgery as a percentage of total cost at UMMC is 49.5%.[24] It estimates that BWMC will experience a variable cost factor of 55%. BWMC uses these estimates to project a dollar impact on the hospitals other than UMMC that are projected to lose cases to BWMC, as shown in Table 12. (DI #6BW, p. 11).

Table 12: BWMC: Impact of BWMC's Cardiac Surgery at Selected Hospitals in Second Year of Operation (FY 2017)

Hospital	Revenue Impact	Cost Impact	Net Impact
Johns Hopkins	$315,033	$311,163	($3,150)*
MedStar Union Memorial	$152,689	$167,958	$15,269
Sinai of Baltimore	$31,812	$34,993	$3,181
Peninsula Regional	$76,828	$84, 511	$7,683
Washington Adventist	$25,543	$28, 097	$2,554
UM St. Joseph	$111,376	$122,513	$11,138

Source: BWMC First Completeness Response. (DI #6BW, p. 11).
Notes: BWMC assumes the UMMC variable cost factor (49.5%) for JHH, an academic medical center, and a factor of 55% for the community hospitals.
*The correct cost, assuming the revenue and cost estimates are correct, would appear to be ($3,870).

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC states that AAMC did not adequately address the impact of its proposed cardiac surgery program on PGHC. It notes that AAMC's proposed program will have a negative impact on PGHC and, for this reason, does not comply with this standard. BWMC contends that AAMC's program will cause PGHC's volume to drop below 100 discharges and will decrease access for an underserved population. BWMC states that AAMC failed to consider the growing volume in cardiac surgery at PGHC. (DI #29GF, p. 18). BWMC notes that the service area defined by AAMC overlaps extensively (15 zip code areas) with the existing service area of PGHC. BWMC urges the Commission to consider significant adverse impact of AAMC's proposed program on PGHC, a cardiac surgery program that "deserves special protection because substantial resources

[24] BWMC explains that, "in the absence of actual service line data from other hospitals, [it] extrapolated using the experience of UMMC and [BWMC's] proposal … to estimate the costs on other facilities." (DI #6BW, p. 11).

have been invested to revitalize the cardiac surgery program at PGHC, the only such program in Prince George's County, an underserved jurisdiction." (DI #29GF, p. 19).

BWMC believes that AAMC understates the impact its program will have on other hospitals. It also notes that AAMC's assumption that hospital costs are 50% fixed and 50% variable is not realistic. It states that hospital experience shows it is difficult to control expenses in the face of declining volume. (DI #29GF, p. 19). BWMC says that an AAMC cardiac surgery program could have a potential adverse impact on existing providers reaching $10.1 million in FY 2018, assuming a market share adjustment to revenue equal to 50% of the $20.2 million, or a $60,221 estimated per-case average payment for all 337 relocated cases. (DI #29GF, p. 20).

BWMC states that AAMC's assumption that hospitals operate with a 50% variable cost structure is also inconsistent with AAMC's financial projections. It notes that AAMC projected that its total uninflated expenses from FYs 2017-18 and FYs 2018-19 would grow with 38.5% and 39.0% expense variability, respectively, for an average of 38.8% expense variability as case volumes grow. If these expense variability assumptions are used to determine AAMC's impact on other providers, based on BWMC's adverse impact projection of $10.1 million in overall revenue losses by affected hospitals (50% of $20.2 million), the AAMC program would still result in a negative impact of $2.3 million on other providers, if one assumes that the affected hospitals will only be able to achieve cost reductions of 39% or $7.8 million. (DI #29GF, p. 20).

BWMC notes that, in contrast, it relies primarily on volumes already in the UMMS system (66% of BWMC cases in Year 3) and revenue shifts within UMMS, which transfer at 100%. Thus, BWMC concludes that its expected impact under both the same 50% revenue variability and the 39% expense variability assumptions is about one fifth of AAMC's impact, or $469,000. (DI #29GF, p. 20).

Dimensions Comments

Dimensions states that the service area defined by AAMC for cardiac surgery includes nearly one half of the area of Prince George's County and northern and central Calvert County. It notes that these areas are within PGHC's service area, as defined by travel time, which is inconsistent with AAMC's projection that no cardiac surgery discharges will shift from PGHC to AAMC. PGHC points out that the low number of cases at PGHC in 2012 and 2013 are not an exception to the requirements of this standard. (DI #30GF, p. 8). It states that a cardiac surgery program at AAMC will be detrimental to PGHC's efforts to rebuild the program by shifting cases to AAMC that would otherwise use the PGHC program, noting that the efforts by UMMS and PGHC to rebuild the program have, to date, been successful. (DI #30GF, pp. 9-11). It notes that, in FY 2012, approximately 372 Prince George's County residents received cardiac surgery from MedStar WHC, George Washington University Hospital, and Washington Adventist Hospital, about 75% of the total county residents who obtained cardiac surgery in that year. PGHC points out that AAMC projects that 233 cases will be shifted from those hospitals to AAMC. (DI #30GF, pp. 11-12).

Dimensions further notes that AAMC failed to demonstrate that its cardiac surgery program will not compromise the financial viability of PGHC's cardiac surgery service. It states that PGHC has made a significant investment in rebuilding its cardiac surgery program, estimated

to have a fixed cost of $4.8 million. (DI #30GF, p. 14). BWMC also faulted AAMC for not addressing impact on PGHC under subparagraph (b)(iii) of the standard. While PGHC did not have 100 to 199 cases in 2012, 2013, or 2014, case volume achieved in the early months of 2015 indicate that PGHC will have 100 or more cardiac surgery cases in 2015. Dimensions states that the loss of 20 to 23 cardiac surgery cases would reduce PGHC's projected cardiac surgery case volume of 116 in 2016 to fewer than 100 cases, specifically, between 93 and 96 cases. (DI #30GF, p. 17).

Dimensions urges the Commission to consider the impact of AAMC's project on PGHC in the future, when considering this standard, even though PGHC does not perform 200 cases per annum. It projects that PGHC will perform 220 cases in FY 2022. If AAMC shifts 44 cases in the Prince George's County portion of the defined AAMC service area from PGHC, based on an assumption that AAMC will get 40% of the total cases from these 15 zip code areas, Dimensions projects that this will constitute an impact that drops an existing program from above 200 cases to below 200 cases (i.e., to 176 cases). (DI #30GF, pp. 18-20).

In June 2016, Dimensions filed supplemental comments, noting that PGHC had been successful in reaching an annual case volume of 100 cases in 2015. (DI #62GF). Dimensions renewed its opposition to AAMC's proposed program on the basis of its likely negative impact on PGHC's ability to continue to grow its cardiac surgery program and reach the target caseload in the Cardiac Surgery Chapter.

Comments on BWMC's Application

No comments were filed that specifically addressed BWMC's compliance with this standard.

Comments on Both Applications

LifeBridge Comments

LifeBridge points out that the Commission has projected declining cardiac surgery case volume in the coming years and that the State Health Plan does not indicate that access to the service is inappropriate or strained in a way that requires increasing surgical program supply to improve access. It summarizes the two "significant risks" associated with both projects as a failure to reach sufficiently high volumes to ensure high-quality outcomes" or "success" in diverting a substantial number of cases from existing hospitals, with consequent adverse effect on those programs. It suggests that the cardiac surgery programs at Suburban and PGHC might experience the type of impact that the standard indicates is unacceptable. (DI #33GF, p. 2).

MedStar Hospitals Comments

The MedStar Hospitals ask the Commission to consider their arguments regarding the cost effectiveness of the proposed new cardiac surgery programs in relation to this standard.[25] (DI #34GF, pp. 28-29).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC states that it used "a valid methodology to estimate the volume loss and associated financial impact upon other hospitals entailed by AAMC's proposed cardiac surgery program." (DI #45GF, p. 25). The applicant states that it is sensible to assume that cases that are currently transferred from AAMC to other hospitals will shift to AAMC. (DI #45GF, p. 25).

Regarding its impact on the cardiac surgery program at PGHC, AAMC states that its program will have no impact on PGHC because no AAMC inpatients or cardiac surgery outpatients were transferred to PGHC from AAMC. It notes that "PGHC only performed five cardiac surgery cases in CY 2013" and states that AAMC's use of 2013 PGHC data was appropriate. (DI #45GF, pp. 26-27) It says that the standards "plainly protect programs with *current* volume from *dropping* below a certain threshold. They do not protect programs with *projected* volume from *failing to rise* above the volume thresholds." (DI #45GF, pp. 27-28).

AAMC insists that its proposed program will not prevent PGHC from reaching 200 cases, even if the Commission used Dimensions' volume projections. It states that its proposed program "would take few enough cases from Prince George's County that PGHC could reach 200 cases on County volume alone, while still leaving cases for other hospitals which currently draw cases from the County." (DI #45GF, p. 28). AAMC points out that its projection shows that, in 2019, the AAMC program will only take 14% of cardiac surgery cases that originate in Prince George's County. AAMC also notes that PGHC does not appear to anticipate reaching an annualized volume of 200 or more cardiac surgery cases until FY 2022. (DI #45GF, p. 29). It states that the PGHC cardiac surgery program has been in existence for decades and that it maintained its

[25] As noted, the key point made by the MedStar Hospitals with respect to the impact standard is general. They do not specifically argue that either project will have the specific impact on existing programs that this standard deems to be salient. However, they believe a need for additional cardiac surgery programs has not been demonstrated and that distributing cardiac surgery case volume over a larger number of programs is contrary to what they consider an important underpinning of the Cardiac Surgery Chapter, i.e., that the number of cardiac surgery programs should be limited so that higher case volumes can be achieved, which is positive with respect to both quality and cost efficiency. Thus, they conclude that the proposed programs will have a negative impact on existing programs. I provide a more complete summary of the MedStar Hospitals' comments with respect to the costs and effectiveness of the proposed programs in the sections of this Revised Recommended Decision that directly address the project review standard and criterion concerning cost effectiveness. See my summary of MedStar's comments regarding the cost-effectiveness standard, COMAR 10.24.17.05A(4), *infra*, pp.60-61.

program when it performed 20 or fewer cases. (DI #45GF, p. 29). In addition, AAMC notes that Dimensions did not produce any financial information to controvert AAMC's application other than that PGHC states that it will need to offset $4.8 million of program fixed costs. (DI #45GF, p. 29). AAMC points out that PGHC is one of the most expensive hospitals in Maryland for cardiac surgery and that the proposed AAMC program will have among the lowest charges for cardiac surgery.

Regarding the interaction of the existing programs at UMMS and PGHC, AAMC notes that neither Dimensions nor UMMS has described how the programs at BWMC and PGHC (and its replacement PGRMC) will coexist. It states that, because PGHC/PGRMC and BWMC will rely on UMMS physicians, "the Commission should not assume that the programs at UMMC, BWMC, and PGHC would be impenetrable to each other based on the geographic location of the patient." AAMC suggests that the Commission should require UMMS, BWMC, and Dimensions to detail the interaction among the three programs. (DI #45GF, p. 30).

Responding to LifeBridge's comments, AAMC states that its proposed cardiac surgery program would not cause Suburban Hospital's program to decline below 200 cases. It notes that Suburban's program could drop below 200 cardiac surgery cases due to declining case volumes even without a cardiac surgery program at AAMC. (DI #45GF, p. 28, n. 119).

Baltimore Washington Medical Center

BWMC states that its proposed program will have little impact on existing cardiac surgery programs, noting that "only 30.7% (70 cases) of the total projected volume would come from non-UMMS hospitals." The applicant contrasts its source of cases with AAMC's project, which relies on shifting cardiac surgery volume from non-affiliated hospitals. (DI #42GF, p. 2).

Reviewer's Analysis and Findings

My review of the applications, interested party comments, and the applicants' responses to comments convinces me that each applicant has demonstrated compliance with the impact standard. It is not remotely likely that implementation of AAMC's proposed cardiac surgery program would result in dropping the annual case volume of MedStar WHC, JHH, or UMMC below 200 cases. These are large programs with large market share, which means that AAMC must seek to shift cases from these hospitals because that is where the case volume is currently concentrated. The other two Baltimore City and the single Baltimore County community hospital programs are not likely to be greatly affected by an AAMC program and have large enough case volumes that any marginal shifts will not be threatening in the manner outlined in this standard.

The Washington, D.C. area has six programs, including three Maryland hospital cardiac surgery programs and, other than MedStar WHC, their caseloads are less robust. Suburban Hospital has experienced a relatively steady volume of cases that has remained above the annual case target. The case volume of Washington Adventist Hospital ("WAH") fell substantially between 2012 and 2015, slipping below 300 cases. This hospital's service volumes have generally declined in recent years and the hospital is approved to develop a new hospital campus in Silver Spring. I expect that the replacement WAH will have a positive impact on the hospital's ability to

compete for surgeons and patients. Each of these programs has less room to lose cases than the Baltimore facilities. Suburban draws heavily on Montgomery County, its home jurisdiction, for patients. Montgomery County is not a jurisdiction within the natural catchment area of AAMC, based on observed patient origin patterns. WAH relies on Montgomery County for the greatest number of cardiac surgery patients and, secondarily, on Prince George's County. Thus, WAH would be competing with an Anne Arundel-based program, to some extent, and is already competing with Prince George's Hospital Center for Prince George's County market share. Based on historic patient origin patterns for these hospitals, and evidence in this review, I cannot find that an AAMC or BWMC program would result in these hospitals dropping below 200 cases.[26] Such a finding under this standard would require more evidence than is available in this review.

One Maryland hospital, PGHC, and one District of Columbia hospital, Howard University Hospital, experienced years of chronically low volume up to the time that the two applications under review were filed, well below 100 cases per year. For the last two years, with surgical support provided by UMMS, PGHC has built volume above the annual level of 100 cases and may be able to reach the 200 case target level within the next two years, if its recent pace can be maintained. Another District of Columbia hospital, George Washington University Hospital, has typically been a fairly low volume program, with annual caseloads between 150 and 200 cases. Like AAMC, these weaker programs need to build market share primarily at the expense of MedStar WHC, the dominant program in the region. It appears that PGHC, which is also developing a replacement hospital to be owned and operated by UMMS, may be successful in reaching an acceptable level of use. As with Suburban and WAH, the impact of AAMC on George Washington University is likely to be marginal and probably not strong enough to result in this program dropping below 100 cases. Howard University's cardiac surgery case volume is so low that this standard does not require the Commission to consider the impact of proposed new cardiac surgery services on this program.

Like the proposed program at AAMC, the proposed program at BWMC also satisfies the impact standard. JHH and UMMC, and the MedStar Washington Hospital Center all have high volume programs. As noted, the other Baltimore area programs that would be likely to see some shift of their case volume to a new program in north Anne Arundel County have recent caseloads that are sufficiently strong that no hospital is likely to drop below 200 cardiac surgery cases as a result of the implementation of a program either at BWMC or at both BWMC and AAMC, for that matter. It seems likely that the impact of a program at BWMC would be milder on District of Columbia area programs than would a program at AAMC.

The existing programs that are most likely to experience the largest shift in cases are MedStar WHC (1,576 adult cardiac surgery cases in 2014), UMMC (858 adult cardiac surgery cases in 2014), and JHH (1,077 adult cardiac surgery cases in 2014). Each of these programs is too large to be compromised financially by the likely level of case shift if either or both of the proposed programs are established. Of the other five community hospitals operating at a level of 200 or more cardiac surgery cases, the most vulnerable would be Suburban Hospital, because it averaged an annual cardiac surgery case volume of 238 cases between 2013 and 2015. However, I find that the service areas of the two applicant hospitals do not indicate the likelihood that a new

[26] If WAH had no Prince George's County cases in 2014, it would still have performed over 200 cardiac surgery cases.

program in Glen Burnie or Annapolis will draw a significant number of cases from Suburban or threaten its program's financial viability. The other cardiac surgery hospitals would have to experience very high levels of market shift, based on recent cardiac surgery caseloads, ranging from 25% (Washington Adventist) to 56% (UMSJ), to fall within the critical impact range of this standard. A large impact on George Washington University Hospital would be required to drop it below 100 cases. I find that it cannot be concluded that either one of the proposed programs, individually, or both programs, collectively, would result in a drop in caseload below 200 cases at MedStar Union Memorial, UMSJ, Sinai, or Washington Adventist or would compromise the financial viability of these programs. I also find that neither of the proposed programs, individually, or both programs, collectively, would result in a drop in caseload below 100 cases at George Washington University Hospital or would compromise the financial viability of this program.

With respect to the impact of AAMC's proposed program on the program at PGHC, the applicant states that the standard does not speak to the potential impact that a new program might have on the potential for a low volume program to reach acceptable case volume levels. AAMC cannot be faulted for not quantifying a case shift from PGHC to AAMC in its CON application, given that PGHC's case volume was so negligible during the time frame in which AAMC was preparing its application. In calendar year 2015, the HSCRC discharge database[27] indicates 105 cardiac surgery cases at PGHC. When the AAMC application was filed, this number was probably not available in the HSCRC data. The last calendar year available would have been 2014, with a reported 29 cases at PGHC.

The impact standard requires me to consider whether an existing program, such as PGHC, that is performing over 100 cardiac surgery cases annually and has an STS rating of two or more stars "for two of the three most recent rating cycles *prior to Commission action on an application*," will be caused to drop below an annual volume of 100 cardiac surgery cases. COMAR 10.24.17.05A(2)(b)(iii) (emphasis added). I note that, based on the wording of the standard, I accepted into the record Dimensions' June 24, 2016 filing updating its comments on AAMC's application. (DI #62GF). These comments showed that PGHC had recently reached an annual volume of 100 cases and has also been given a three-star STS rating. I have considered the impact of each of the proposed programs on PGHC. As discussed below, I find that the establishment of a cardiac surgery program at AAMC and/or at BWMC would not be likely to cause PGHC's annual volume to drop below 100 cases.

I note that, while a finding of non-compliance with this standard based on the potential impact of either proposed program on PGHC is not warranted, the issue of how either or both of these new programs will affect the ability of PGHC to rebuild its program is a legitimate concern. As noted below, I conclude that the markets that will be tapped for cases by PGHC and the strongest applicant, AAMC, are sufficiently large that both programs could reach the annual target volume of 200 cases without having an unacceptable impact on other programs, as defined by this standard. It is even conceivable that two Anne Arundel County programs could operate without clearly jeopardizing the ability of PGHC to reach and maintain an annual case volume of 200 cases, although this would make it much more difficult for all three programs (PGHC, AAMC, and BWMC) to achieve the target level.

[27] See Table 2, *supra*, p. 12.

In CY 2014, Anne Arundel County and the five jurisdictions contiguous to Anne Arundel (Baltimore City, Baltimore County, Calvert County, Howard County, and Prince George's County) generated 2,716 adult cardiac surgery cases that were performed at Maryland, District of Columbia, or Virginia hospitals.[28] A Maryland jurisdiction that is not contiguous to Anne Arundel but geographically close, Montgomery County, generated an additional 605 adult cases and the four Eastern Shore jurisdictions that are primarily served in the Baltimore/Upper Shore catchment area (Caroline, Kent, Queen Anne's, and Talbot counties) generated another 152 cases. This total of approximately 3,470 cardiac surgery cases is large enough to accommodate a proposed new cardiac surgery program at AAMC and continued growth of the PGHC program to acceptable use levels. PGHC has reported in 2016 that it is more than halfway to the 200-case level and only marginal further penetration of the Prince George's County market and that of surrounding areas will be required to reach a volume of 200 cases. (DI #62GF).

Within a few years, PGHC's cardiac surgery program is projected to be in a new hospital that will be more centrally located within Prince George's County, functioning as part of UMMS. This further reinforces the likelihood that PGHC can revive its cardiac surgery program to acceptable use levels. A new cardiac surgery program at AAMC and, to a lesser extent, a new program at BWMC, is likely to draw some cases from PGHC's service area and AAMC will be aggressively seeking to pull cases away from District of Columbia hospitals. But it is logical to assume that these will primarily be patients from the Annapolis area and other areas of Anne Arundel County that look to AAMC for their hospital care. It is also logical to assume that the cardiac surgery cases most likely to shift from District of Columbia hospitals to PGHC are residents of Prince George's County, most of whom will continue to be a primary market for PGHC and/or District of Columbia hospitals, with AAMC or BWMC functioning as second-order providers, given their greater distance and travel time from these patients.

Unquestionably, approval of either or both proposed programs would constrain the ultimate growth potential of all the Baltimore and District of Columbia area programs, especially the large programs at MedStar WHC, JHH, and UMMC. However, as noted, these programs will continue to be large programs even if PGHC achieves a maintenance volume of 200 or more cases and the two proposed programs are successfully developed to achieve similar use levels. Ultimately, the public policy issue presented is one of weighing the benefits of having a viable program at PGHC and additional programs in Maryland, in terms of access, cost reduction, and quality of care, against the marginal negative impact on these existing programs.

I find that each applicant proposed a cardiac surgery program that complies with the specific requirements of the impact standard. I have determined that public policy favors the establishment of the single new cardiac surgery program proposed at AAMC, which is likely to result in greater savings to the health care system through lower charges and better access for the relatively large population of Anne Arundel County and the population of the Eastern Shore. While a program at AAMC is likely to incrementally constrain the growth potential of the existing program at PGHC, as any competing program would be expected to do. I conclude that the market is sufficiently large to support both programs at a level of 200 cardiac surgery cases.

[28] HSCRC Discharge Database, D.C. Discharge Database, and VHI-filtered dataset using the Cardiac Surgery Chapter definition of cardiac surgery effective August 17, 2014

(3) Quality

(a) An applicant shall demonstrate its commitment to provide high quality health care. An applicant seeking to establish cardiac surgery services shall have utilization or peer review and control programs with regularly scheduled conferences to:

(i) Establish protocols that govern the referral, admission, and discharge of cardiac surgery patients;

(ii) Establish and review a list of indications and contraindications to govern selection of patients for cardiac surgery;

(iii) Establish a program to educate patients about treatment options;

(iv) Establish mechanisms for monitoring long-term outcomes of discharged patients.

(v) Review morbidity and mortality rates and other indicators of patient outcomes, and compliance with established processes of care as compared with regional or national averages;

(b) Prior to first use approval, an applicant shall provide documentation of (i)-(iv).

Applicants' Responses

Anne Arundel Medical Center

AAMC lists AAMC's awards and recognitions, which it identifies as evidence of its commitment to high quality health care: 2013 and 2014 Delmarva Foundation Excellence Awards for quality improvement; Magnet Recognition through the American Nurses Credentialing Center; 2012 Leapfrog Top Hospital Recognition; 2011 American College of Cardiology Foundation's NCDR ACTION Registry–GWTG Gold Performance Achievement Award; recognition by the Institute for Patient and Family-centered Care; and national accreditation and recognition for its Breast Center, Weight Loss Program, Chest Pain Program, Cancer Center, Stroke Center, Pathways Substance Abuse program, and other clinical programs. (DI #3AA, pp. 99-107).

AAMC also notes that the Maryland Institute of Emergency Medical Services System ("MIEMSS") designated it as a Cardiac Intervention Center and that the Society of Cardiovascular Patient Care designated it as a Chest Pain Center with PCI (percutaneous coronary intervention services). The hospital describes its quality improvement program as integrated and collaborative, functioning in each department with teams, reporting to a hierarchy of quality improvement bodies, including AAMC's Executive Quality Council, a Medical Staff Quality Review Committee, and the Board of Trustees Quality and Patient Safety Committee. (DI #3AA, p. 99).

AAMC states that quality improvement efforts regarding cardiac surgery services will be done in conjunction with JHH. Patient selection and operative procedures will be based on the American Heart Association/American College of Cardiology ("AHA/ACC") guidelines. Practices employed by the JH Medicine Division of Cardiac Surgery will also inform patient and procedure selection, and post-operative management.

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AAMC notes that it will participate in the database of the Society of Thoracic Surgeons ("STS"), with collection and submission of data reviewed by an AAMC Cardiac Surgery Advisory Committee. AAMC's cardiac surgery program will also participate in the Maryland Cardiac

Surgery Quality Initiative, a collaborative statewide program with the goals of: sharing data among Maryland cardiac surgery programs; identifying best practices; and improving outcomes in a cost-effective way.

AAMC described its existing quality-related committee, group, and meeting structure as summarized in Table 13.

Table 13: AAMC: Committees, Groups, Meetings at AAMC Touching on Cardiac Services Quality

Committee/Group	Functions	Meetings
Emergency Department-Cardiac Catheterization Lab Quality	Review & analyze specific patient cases for continuous quality improvement Evaluate, monitor and disseminate key quality outcome indicators Utilize evidence based practice such as the ACS guidelines to develop protocols & standard operating procedures for care of cardiac patients Educate & consult with health care providers at all levels regarding patient care Develop & implement quality improvement measures	Quarterly
Emergency Department – EMS Quality	Communicating outcomes of door to balloon metrics Updating EMS regarding certifications & requirements from certifications, outcomes of referrals, field activations & suggestions for improvements along with positive feedback Share STEMI, stroke & AMI core measures data & metrics with EMS Open forum discussions & formal educational offerings to improve capabilities of EMS team members	Quarterly
Cardiology Mortality & Morbidity - Elective and Primary PCI	Provide case conferences with ECG's and Cine films Review cases that did not meet system goals or resulted in adverse event or outcome. Discuss medical & interventional management	Monthly
Cardiology Conference	Provide AMA/CME through didactic & interactive meetings on f cardiovascular disease topics Open to all cardiology staff	Three times per month (when M & M not meeting)
Cardiology Advisory Council	Communicates status of division of Cardiology to the health system & considers future plans & goals for operations & capital	Quarterly
Interventional Cardiology	Support ongoing communication among interventional cardiologists Provide format for sharing quality performance metrics, process improvement and peer review with & by physicians Evaluate & track individual practitioners' quality & outcomes - a peer review process specific to PCI/interventional cardiology	Quarterly
Cardiac Operations Team	Address internal processes that impact requirements set forth by Society of Cardiovascular Patient Care in response to the Chest Pain Accreditation	Monthly
Cardiac Workgroup	Oversee care of STEMI & non-primary PCI patients to assure compliance with Maryland regulations Discuss operational overview, data, obstacles & updates related to process improvement for interventional cardiac patient	NA
Wayfinding	Provide consistent & clear information to guide individuals to their destination using criteria set forth in Cycle IV Chest Pain Accreditation Establish wayfinding on evidence-based design principles	Monthly
Heart and Vascular Unit Quality	Monitor: Intra-operative communication with family members Respiratory care Patient falls Inpatient first case OR delays Communication, teamwork & process improvement Interdisciplinary rounds Hand washing initiative Increased patient satisfaction and analyze for purpose of improving quality	NA

Observation Unit Quality	Issue Observation Unit Quality reports on: 4PTS (patient safety line) trends NDNQI indicators Core measures Unit-specific nurse regulatory praises Patient Satisfaction Survey results Nursing documentation and data	NA
MIEMSS Regional STEMI QA	Review STEMI processes, procedures, & metrics at regional level Enable MIEMSS to create standardized feedback template from all organizations involved in care of STEMI patients Work with area EMS to support education and quality	NA
Resuscitation	Critical Care team discussion of Code Blue and Rapid Response documentation & case reviews Oversee stroke rapid response calls & therapeutic hypothermia protocol. Review data focused on inpatients that develop chest pain Raise awareness for the in-house STEMI patient	Monthly

Source: (DI #3AA, pp. 101-104).

With respect to subparagraphs (a)(i) through (a)(v) of the quality standard, AAMC responded as follows.

(a)(i) Protocols governing referral, admission, and discharge of cardiac surgery patients

AAMC states that access to its program by referring physicians can take place through: (1) direct referrals through the cardiac surgery office; (2) call-ins to the AAMC operator connecting to an on call surgeon or, if not available, a cardiac surgery PA/NP; (3) direct contact with a specific cardiac surgeon; or (4) direct consultation with the NP/PA in-house during the day and immediately available at night. It notes that this information will be available on its website and printed on a laminated sheet with AAMC cardiac surgery information.

AAMC states that it will have standardized admission, discharge, and intra-hospital transfer processes for efficiency and safety. Patient safety will be optimized through use of "time out checklists" and through use of treatment protocols prior to beginning operations or initiating intra-hospital transfers. (DI #3AA, p. 105). It notes that the treatment protocols will be developed for common clinical scenarios. It says that the standardized discharge process will include discharge teaching, communication to referring physicians, follow up appointments, and that patients will leave AAMC with a "discharge book" containing information on care plans, medication, wound care, and activity instructions.

(a)(ii) Indications and contraindications governing patient

According to AAMC, all indications for surgery will be identified consistent with good clinical practice based upon AHA/ACC guidelines and the usual and customary practice of the JHM Division of Cardiac Surgery. (DI #3AA, p. 105).

(a)(iii) Patient education about treatment options

AAMC states that its team will provide initial surgical consultation for patients undergoing elective surgeries and to the patients' families, including diagnostic information, testing,

indications, alternatives, risks, and expected benefits. Mortality risk will be predicted using an STS algorithm and written material on these topics will be provided to the patient and also available on AAMC's website. Patient service coordinators will do pre-operative teaching and assist in planning for post-surgical care, discharge, and follow-up. A patient handbook, based on the current book currently in use at JHH will be provided to all patients and will be tailored to each patient's specific needs.

(a)(iv) Mechanisms for monitoring long-term outcomes

AAMC plans for each discharged cardiac surgery patient to leave the hospital with follow-up appointments scheduled with the patient's cardiologist and cardiac surgeon, as well as appointments for any required laboratory or radiology procedures. Each patient will be contacted by phone daily for the first three days following discharge and weekly until the post-operative visit. An AAMC/JHU employee will follow patients as required for the STS database, to which data for all AAMC cardiac surgery patients will be submitted, using existing JHU protocols.

(a)(v) Review morbidity and mortality rates and other indicators of patient outcomes/ compliance with established processes of care as compared with regional or national averages

AAMC states that it will have bi-weekly cardiac surgery Morbidity and Mortality ("M&M") conferences, with cardiac surgery staff participating in its Department of Surgery M&M program, including a separate monthly joint M&M conference with the JHU program. In weeks without a cardiac surgery M&M conference, the hospital will hold a quality improvement program meeting of AAMC clinicians. Joint quality improvement projects with JHH will be undertaken to address problems or areas of concern common to both hospital sites and to establish joint protocols. All patient deaths will trigger a detailed "Phase of Mortality" review. (DI #3AA, p. 107). Outcomes will be monitored through STS database participation.

Baltimore Washington Medical Center

BWMC states that it will implement utilization (or peer review and control) programs for cardiac surgery and will also participate in the quality assurance and performance improvement programs currently in place at UMMC. (DI #2BW, pp. 48-53).

In discussing its existing quality improvement programs and initiatives, BWMC notes that its Quality Improvement ("QI") Department administers a performance improvement program. This program involves data collection and analysis to measure improvement, evaluates problems, and monitors solutions. This department uses a "Plan, Do, Check, Act" model. (DI #2BW, Table 25). It consults with clinical and administrative staff with a mission to integrate performance measurement hospital-wide for quality improvement, develop systems and processes measurement of outcomes, use quality indicators and regional and national benchmarks, and foster a culture of safety and harm reduction.

BWMC's QI Department supports four peer review committees, including the surgical and medical committees. Its purpose is to review cases with unexpected outcomes and make recommendations to the Medical Staff Quality Improvement Committee, which consists of department chairs.

Quality of Cardiac Services:

BWMC notes that it has a Cardiology Interdisciplinary Collaborative Practice Team ("the Team"), which analyzes quality and process trends, makes recommendations for change, and develops initiatives supported by data and analysis. This Team meets monthly to: review performance of cardiac care measures; examine processes and protocols; identify areas for improvement; make recommendations for change; and evaluates the impact of changes. BWMC points to its focus on shortening door-to-balloon times as an example of the Team's work. BWMC describes its communications process regarding quality assurance, noting that it distributes case worksheets to departments involved in cardiac services and maintains internal dashboards that include core measure data.

The applicant states that it convenes clinical case review meetings weekly, examining techniques, equipment, degree of disease being treated, and other variables in the cases. BWMC uses these meetings as a teaching tool and invites all staff disciplines to participate.

BWMC also describes the process and staff used in data collection related to the National Cardiovascular Data Registry ("NCDR") and a Data Quality Report. It notes that this work is the foundation for looking at performance and outcomes in the delivery of cardiac services at BWMC, with a focus on interventional services. (DI #2BW, Table 25). BWMC notes that it was recognized in FY 2013 for its commitment to high quality care for heart attack patients through its receipt of the American College of Cardiology Foundation's NCDR ACTION Registry-GWTG Platinum Performance Achievement Award. Regarding its assurance of patient safety, BWMC describes standardized policies and procedures, electronic medical records, the convening of daily safety huddles, standardization of scrub colors, and "Great Catch" awards program for reporting events that could harm patients. (DI #2BW, Table 25).

BWMC addresses the patient experience of care by maintaining Standards of Service Excellence, which it developed to promote positive experiences and work culture. BWMC utilizes the Hospital Consumer Assessment of Healthcare Providers and Systems ("HCAHPS") survey to measure patients' perspectives on nine key topics and has chartered a Patient and Family Advisory Council to obtain advice on how to enhance patient and family-centered care. Additionally, it employs a full-time patient advocate and has a Patient Experience Oversight Committee that meets monthly to oversee activities aimed at improving the patient experience. The hospital reports that it actively solicits patient feedback and empowers every employee to facilitate "Service Recovery," to immediately acknowledge patient concerns and respond with "sensitivity, respect, and professionalism." (DI #2BW, Table 25).

It describes the existing Quality Assurance and Performance Improvement Plan of the UM Division of Cardiac Surgery, which focuses on: identifying opportunities for improvement; promoting best practices; facilitating patient safety; ensuring optimal clinical outcomes; patient, family, and staff satisfaction; and creating the safest care environment possible. The Quality Assurance and Performance Improvement Plan facilitates compliance with external regulations and directives, as well as with local, regional, and national regulatory and accreditation requirements.

BWMC states that the UM Division of Cardiac Surgery continually assesses, reviews, and monitors quality of care throughout the cardiac surgery care episode and is supported by a full-time dedicated Senior Nurse Quality Improvement Coordinator. At least bi-weekly, a multi-disciplinary forum reviews quality of care, established protocols and guidelines, and outcomes data to identify clinical and process improvement projects. It notes that dedicated performance improvement sub-groups are established on an as-needed basis. Routine elements such as readmissions, returns to the operating room, deaths, complications, and adverse events are tracked for rapid assessment, review, and intervention. (DI #2BW, p. 49).

BWMC provides an overview of the organizational and reporting structures used by UMMC for quality assurance and performance improvement. At a departmental level, it uses a "Quality Physician Champion" and "Senior Quality Improvement Nurse" leadership model (DI #2BW, p. 49). Bi-monthly quality meetings are convened to identify opportunities for quality improvement. Division leadership reports to a UM Comprehensive Heart Center Executive Committee and UMMC Performance Improvement Steering Committee with multi-disciplinary participation. This Steering Committee meets monthly with a long-term agenda for review of quality objectives and departmental quality improvement initiatives. It is supervised by the Medical Executive Committee and information on outcomes and initiatives are reported to the UMMC Executive Board's Quality Committee, the UMMS Executive Board and the UMMS Quality Division. This division, which is led by the UMMS Senior Vice President and Chief Medical Officer who also serves as the Chief Quality Officer, also prepares a monthly "Quality Briefing Newsletter" for UMMS. (DI #2BW, p. 50).

BWMC describes the way in which the UM Division of Cardiac Surgery reports, tracks, and reviews trends in the occurrence of adverse events. For all such events, root causes are identified, interventions are implemented, and action plans are generated and communicated to departmental Quality Improvement Teams and leadership. It states that blame-free reporting of all events is encouraged and reporting employees and those who spot problems and prevent adverse events or mitigate such events from producing worse outcomes are recognized and acknowledged. (DI #2BW, p. 51).

(a)(i) Protocols governing referral, admission, and discharge of cardiac surgery patients

BWMC states that its protocols for referral, admission and discharge will follow best practice guidelines and the established guidelines of UMMC. It describes the evaluation, diagnostic workup, and pre-operative instructional and educational components of its protocol for referral and admittance of patients for cardiac surgery. BWMC states that discharge planning begins on the scheduled day of surgery. It describes the information provided to patients and family members regarding patient evaluation, as well as post-surgery care planning and location. Patients discharged to home will have access to a home health nurse for three days after surgery. BWMC has a rehabilitation program for cardiac patients. Nurse practitioners and social workers will consult in the development of post-operative plans of care. (DI #2BW, p. 52).

(a)(ii) Indications and contraindications governing patient selection

The UM Division of Cardiac Surgery follows the Guidelines of the STS for appropriateness of care and this protocol will be used at BWMC. Physicians will use the STS risk calculator to assist in evaluation of a patient's risk profile for surgery. Indications and contraindications for surgery will be established by disease progression and symptomatology using best practice guidelines. (DI #2BW, p. 52).

(a)(iii) Patient education about treatment options

Each patient will receive education regarding treatment options at the time of the referral for cardiac surgery by the attending cardiac surgeon who will be performing the procedure, and by the cardiac surgery nurse practitioners who see the patient in clinic and once they have determined that the patient is an appropriate surgical candidate. Educational videos are available for patient viewing. The UM Comprehensive Heart Center website is also a source of patient education. This website contains information categorized by disease, links to helpful sites, patient stories, and cardiac surgeons' biographies. (DI #2BW, p. 53).

(a)(iv) Mechanisms for monitoring long-term outcomes

Post-procedure follow-up will be determined on an individual basis for each patient, based on the type of procedure and individual patient needs. All patients will be seen within two weeks of discharge, or sooner if required. For long-term monitoring, patients will be followed in accordance with STS guidelines post-operatively from date of procedure through discharge and post-discharge. Cardiac surgeons will partner with community cardiologists to improve the transfer of care back to the referring cardiologist. (DI #2BW, p. 53).

(a)(v) Review morbidity and mortality rates and other indicators of patient outcomes/compliance with established processes of care as compared with regional or national averages

The UM Division of Cardiac Surgery currently conducts Cardiac Surgery Monthly Morbidity and Mortality reviews. All patient clinical outcomes are tracked, trended, and followed on a quarterly and annual basis, and reviews are based upon nationally established STS benchmarks. Other sources for clinical benchmarking include the University Hospitals Consortium. The program will also participate in the Maryland Cardiac Surgery QI Collaborative. Individual Physician Scorecards are created and utilized for surgeon re-credentialing and privileging based on clinical outcome objectives.

Interested Party and Participating Entity Comments

Comments on AAMC Application

No party commented on AAMC's compliance with the quality standard.

Comments on BWMC Application

AAMC Comments

AAMC states that the quality assurance and performance improvement process outlined in the BWMC application "suffers from being overly entwined with UMMC's existing quality processes," and has the potential to muddle the lines of authority and accountability. (DI #28GF, p. 23). Specifically, it questions the adequacy of management resources at UMMC's Division of Quality and Safety to oversee BWMC quality assurance efforts. It questions the ability of the UM Division of Cardiac Surgery bi-monthly quality forum to adequately review BWMC's quality of care. It notes that this Division currently has its resources divided among three hospitals , UMMC, UMSJ, and PGHC, and that BWMC will be a fourth program if the CON is approved. It states the CON application suggests that BWMC "may lack sufficient independence from UMMC (and UMMC generally) to be effective." (DI #28GF, p. 24).

Comments on Both Applications

MedStar Hospitals Comments

The MedStar Hospitals made one general reference to the quality standard, noting that the Commission's clinical advisory group recommended that the "'regulation of cardiac surgery services should place greater emphasis on quality rather than on volume.'" (DI #34GF, p. 15, quoting COMAR 10.24.17.03: Issues and Policies, p. 9). They point out that an essential component of quality is cost-effectiveness and that the Issues and Policies section in the Cardiac Surgery Chapter states that "'[n]umerous research studies show a strong [inverse] relationship exists between the volume of cardiac surgery performed and patient mortality and surgical complications.'" (DI #34GF, p. 15, quoting COMAR 10.24.17.03: Issues and Policies, p. 8).

Applicants' Responses to Comments

Baltimore Washington Medical Center

BWMC states that, contrary to AAMC's comment, integration of the proposed BWMC cardiac surgery program with UMMS is a source of strength. BWMC notes that its proposed program would be part of a "world-renowned cardiac surgery program." It states that the "system approach to quality improvement drives a culture of continuous improvement." (DI #42GF, p. 31). It finds AAMC's comment ironic, given that AAMC describes its own quality assurance and performance improvement effort regarding cardiac surgery as one that will benefit from its collaborative partnership with JHH. (DI #42GF, p. 31, n. 16).

BWMC reiterates the benefits and advantages it gains by being within the UM Division of Cardiac Surgery, which it describes as adding to the quality assurance and performance improvement structure already in place at BWMC. It notes that BWMC will develop a local operating council to implement best practices identified at the systems level, a feature of all UMMS' cardiac surgery programs. (DI #42GF, p. 33).

BWMC states that AAMC incorrectly implies that the BWMC's Quality Assurance and Performance Improvement Plan would be managed by one nurse, based at UMMC. It states that BWMC's statement about participation in the same quality assurance performance improvements programs as UMMC only meant that BWMC would create the same UMMC initiatives at BWMC, while also participating in system and BWMC-specific initiatives. BWMC's performance improvement plan will be led by a number of team members. (DI #42GF, pp. 33-34). It also states that the UM Division of Cardiac Surgery's bimonthly quality forum will be able to review BWMC's protocols, guidelines, outcomes data, and clinical and process improvement projects, noting that many of the cases handled by BWMC will represent a shift of cases currently performed at UMMC, i.e., not actually case volume that will add to the workload of the forum. Finally, it notes that the bimonthly forum is just one of many quality improvement processes it has identified. (DI #42GF, p. 34).

Reviewer's Analysis and Findings

AAMC has demonstrated its commitment to provide high quality cardiac surgery services consistent with the specific requirements of this standard. AAMC has described an organizational structure and processes that align with the requirements of this standard, including peer review programs. It will use protocols for appropriate selection of patients, and will consider indications and contraindications in determining procedures that are appropriate for patients. It has described the manner in which patients will be educated about treatment options. The bodies charged with implementing quality assurance and performance improvement will meet regularly. AAMC will also use protocols for referral, admission, and discharge and follow-up of cardiac surgery patients. It will engage in reviews of outcomes for surgery patients, including morbidity and mortality rates used with appropriate benchmarking.

BWMC has also demonstrated its commitment to provide high quality cardiac surgery services consistent with the specific requirements of this standard. It has described an organizational structure and processes that align with the requirements of this standard, consistent with the specific elements of the standard as described in the previous paragraph. AAMC's comment that a cardiac surgery program at BWMC will not be independent enough of UMMC in its quality assurance and performance improvement processes and activities is not persuasive.

While there are differences in the outlines provided by the two hospitals, each has experience and a background that raise no concerns with respect to the capability of each applicant to provide high quality care. Furthermore, each hospital is collaborating with or functioning within a system that features a large cardiac surgery program based at an academic medical center. Each proposed collaboration will involve direct provision of cardiac surgery and collaboration with the academic medical center partner in quality assurance and performance improvement for cardiac surgery.

The MedStar Hospitals make a valid point with respect to the connection that is presumed to exist between the number of cases handled by a cardiac surgery program and outcomes. However, this point is directly addressed by the Minimum Volume standard, COMAR 10.24.17.05A(1), and the Need standard, COMAR 10.24.17.05A(6), both of which establish a threshold volume intended to address this volume/quality relationship. By contrast, this standard simply addresses the requirements that an applicant must meet to assure that it will be able to

provide cardiac surgery safely to patients for which this treatment option is appropriate, to measure its performance in providing cardiac surgery in meaningful ways, and to work to improve performance, quality, and safety where such improvement is needed.

I find that AAMC and BWMC have each met the requirements of the quality standard.

(4) Cost Effectiveness

An applicant proposing establishment or relocation of cardiac surgery services shall demonstrate that the benefits of its proposed cardiac surgery program to the health care system as a whole exceed the cost to the health care system.

> ***(a) An applicant that proposes new construction of one or more operating rooms, cardiac catheterization laboratories, or intensive care units, or any combination thereof, as necessary infrastructure for its proposed new cardiac surgery program shall document why existing resources at the applicant hospital cannot be used to accommodate the proposed cardiac surgery services.***
>
> ***(b) An applicant shall provide an analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care system will change as a result of the proposed cardiac surgery program, quantifying these changes to the extent possible.***
>
> ***(c) 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.***

Applicants' Responses

Anne Arundel Medical Center

In responding to this standard, AAMC initially notes that the project will not require construction of operating rooms or intensive care space. It states that its proposed program will shift cardiac surgery cases from MedStar WHC and Maryland hospitals that AAMC identifies as having higher charges for this service than AAMC will offer under the Maryland all-payor hospital rate model. AAMC notes that its analysis found that "the relocation of 337 cardiac surgery cases from Maryland and District of Columbia cardiac surgery hospitals to AAMC will reduce total aggregate hospital payments by slightly more than $8.2 million for those services." (DI #3AA, p. 109). AAMC states that the new program will "positively impact Maryland's performance under the Medicare performance test [because it will] achieve a net reduction of $7.7 million in 'total health care spend' for hospital services." (DI #8AA, p. 26).

AAMC defines effectiveness as "a combination of cost, quality, and patient experience factors to produce benefits in clinical outcomes, cost performance, and patient satisfaction." It identifies its proposed cardiac surgery program as yielding benefits in each of these areas. (DI #3AA, p. 24). AAMC states that its cardiac surgery program will reduce the need to transfer

patients for cardiac surgery. This, in turn, will: improve quality of care/patient satisfaction for patients and their families; reduce duplication and costs associated with hospital transfers; and remove delays/barriers to timely care. AAMC states that, "[i]ncreasingly, patients requiring transfer from AAMC to another hospital for cardiac surgery have been delayed [due] to lack of an intensive care bed or denied due to patient's insurance status." (DI #8AA, p. 24).

The applicant plans for its new program to maintain a single clinical management team, minimizing the risks/downsides associated with hospital transfers and supporting more effective care management. AAMC states that it will improve quality of care by improving continuity of care. (DI #8AA, p. 24). It notes that its cardiac surgery service will reduce travel time for an increasingly older and frailer patient population and for more than 800,000 adult residents in its service area. (DI #8AA, p. 25).

In its application modifications filed after the project status conference, AAMC noted that its proposed project will reduce the patient cost of cardiac surgery in its service area, projecting one of the lowest charges per case in Maryland, an estimated $37,501 charge per case. It notes that this aspect of its proposal has not changed as a result of the modification. (DI # 22AA, p. 6).

Baltimore Washington Medical Center

BWMC states that paragraph (a) of the cost effectiveness standard is not applicable because it is not proposing new construction of operating rooms, cardiac catheterization laboratories, or intensive care units. (DI #2BW, p. 54). With respect to paragraph (b), BWMC states that its program will significantly reduce the costs of cardiac surgery because its charges are "markedly lower than at UMMC, from which most of the proposed case volume will be derived." (DI #2BW, p. 54). It projects total savings to its service area of $2.4 million by the third year of operation based on a charge-per-case analysis. Approximately 89% of this savings is projected to come from 151 cases that BWMC projects would otherwise be performed at UMMC at a projected charge of $66,211 per case, compared with BWMC's projected charge of $51,952. BWMC projects that its charges for cardiac surgery will be lower than the charges at five of six hospitals identified as experiencing a likely shift of cases to BWMC, if a program is developed. (DI #2BW, pp. 54-55). It also states that the personal and societal cost savings will result due to reductions in travel costs and disruption of work time for patients and families.

With respect to paragraph (c), BWMC states that it will maintain the highest quality of care in its cardiac surgery program, which will "benefit from the UMMS system-wide collaborative initiatives to improve quality performance." It states that "improving clinical performance at the enterprise level" is a strategic priority of UMMS, led by physicians and organized by clinical specialty. The goal is "a high performing network of providers delivering high quality, coordinated patient care." (DI #2BW, p. 56). BWMC cites the following specific cardiac surgery initiatives: blood conservation; reduction of prolonged intubation occurrences; reduction of 30-day mortality; continued reduction of surgical site infections; reducing complications – observed over expected; reduction of 30-day readmissions; and reduction of overall cost of care. (DI #2BW, p. 56).

BWMC modified its CON application on August 10, 2015, committing BWMC and UMMC to accept 50% revenue variability for cardiac surgery cases shifted from UMMC to BWMC. It noted that it and UMMC were not required to do this under the UMMS GBR agreement with HSCRC that permits revenue to be redistributed among UMMS affiliated hospitals without applying a revenue variability factor. (DI #17BW). According to BWMC, this commitment will improve the cost effectiveness of its proposed cardiac surgery program. BWMC presents two different calculations of projected cardiac surgery charges per case, a "rate center methodology" and a "traditional charge per case methodology" to calculate systems savings. It anticipates that the way in which HSCRC's market shift adjustment methodology is constructed will mean that the traditional charge-per-case methodology will be used to determine allowable revenue to be added to BWMC's GBR cap. However, it expects the rate center methodology will be used to determine the charges to be billed to payers. It uses this model to project that BWMC will realize a net GBR increase of $4.6 million in FY 2018 through the provision of cardiac surgery and existing cardiac surgery hospitals affected by the new BWMC program will experience a $6.5 million reduction in their cardiac surgery revenue, all incorporating the 50% variable cost factor, a net reduction in hospital charges in Maryland of $1.9 million and, specifically for Medicare, a projected payment reduction of approximately $690,000. BWMC states that its analysis shows that its proposed project is cost effective and is consistent with Maryland's All Payer Model Agreement with the Centers for Medicare and Medicaid Innovation.

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC claims that AAMC's "low charge per case results in part from maintaining certain outpatient services as rate-regulated, which is not a cost-effective practice." (DI #29GF, p. 21). It states that the proposed AAMC program "appears efficient [because] it has a broad base of rate-regulated outpatient services to which it can allocate its overhead costs." (DI #29GF, p. 21). In contrast, BWMC and other hospitals that have moved "certain outpatient services to an unregulated setting," have reduced the regulated outpatient services to which overhead costs can be allocated. Providing these outpatient services in a regulated setting, as AAMC plans, can result in "higher charges to payers and patients, and is not the most cost effective way to deliver health care services." (DI #29GF, pp. 21-22).

According to BWMC, the AAMC project will have a negative $5.8 million impact on the All-Payer Test of the All Payer Model Agreement because AAMC anticipates shifting cardiac surgery cases from District of Columbia hospitals. It states that this will have an "unfavorable impact on the requirement that Maryland maintain an annual limit on the all-payer total hospital revenue growth," projected by BWMC to be in excess of $5.8 million in AAMC's first two years of operation. (DI #29GF, p. 22).

BWMC commented on the revised financial projections filed by AAMC on November 7, 2016,[29] in response to requests I made at a project status conference.[30] BWMC criticizes AAMC's reliance on shifting cardiac surgery cases from District of Columbia hospitals and the savings related to that shift, which BWMC finds to be greatly overstated. (DI #94GF, p. 22). It also notes that some of the District of Columbia market shift may have already occurred or will soon occur as the PGHC program is revived. (DI #94GF, p. 22). BWMC points out that AAMC has provided no documentation to support its view that it is likely to obtain cases from Cardiology Associates, a practice owned by MedStar Health that currently refers cases to MedStar's Washington Hospital Center, an interested party in this review. (DI #94GF, pp. 22-23). BWMC states that the District of Columbia case shift projected by AAMC is undermined "by the experience of Suburban Hospital, a program developed in affiliation with JH Medicine, like the AAMC proposed program, and notes that HSCRC alluded to the Suburban experience as "instructive." (DI #94GF, p. 23).

Comments on BWMC Application

AAMC Comments

AAMC contrasts BWMC's proposed project with its own proposal, noting BWMC's much higher charge-per-case projection (approximately $52,000 at BWMC compared with $37,500 at AAMC) and states that the BWMC project will have little or no systems savings, with market shift savings involving UMMC and BWMC going "directly into UMMS pocket." (DI #28GF, pp. 12-13).

AAMC claims that BWMC's analysis that shows systems savings of $2.4 million is incorrect because it did not "apply the 50% volume cost factor" to its charges or the charges of other Maryland hospitals. AAMC's analysis of BWMC's proposal yields a savings estimate of only $129,000 with respect to Maryland hospitals and a net increase in spending for cardiac surgery of over $650,000 as a result of the 30 cases that BWMC projects will shift from District of Columbia hospitals. Furthermore, AAMC claims that BWMC's $2.4 million system savings figure was incorrectly calculated irrespective of the overstatement error, because it was based on multiplying hospital charges per revenue center by the relative value units per revenue center per case for BWMC's case mix. AAMC states that, under the GBR system, a hospital's allowable charge per case may be less than this product. AAMC states that the product of case mix-adjusted discharges and charge per case mix-adjusted discharge is the correct approach to calculating allowable charges. (DI #28GF, pp. 13-14).

Commenting on BWMC's August 2015 modification of its application, AAMC reiterated its focus on the greater cost savings of AAMC's proposed program ($7.7 million is AAMC's projection) compared to BWMC's proposed program ($3.5 million is cited by AAMC). (DI #46GF, p. 6). AAMC notes that it expects to draw most of its cases from District of Columbia hospitals as a major factor in this savings differential because District of Columbia hospitals will not retain any of the revenue lost when cases shift to AAMC. It points out that BWMC is primarily anticipating a shift from Maryland hospitals, which will retain half the revenue they would have received if the cases had not shifted.

[29] DI #22AA.

[30] My project status summary is found at DI #90GF.

AAMC also states that BWMC misapplied the rate center methodology in projecting AAMC's cardiac surgery charge per case, and thus understated the superior savings that AAMC says is associated with its project. (DI #46GF, p. 7).

Comments on Both Applications

MedStar Hospitals Comments

The MedStar Hospitals state that neither applicant demonstrated that its proposed project is more cost effective than providing the service through alternative existing facilities. They state that "maintaining the status quo" with respect to the supply of cardiac surgery programs is more cost effective, "since there is no need for any additional services, the cost to the health care system to add these new services is of no 'benefit'" and the new programs would only add cost. (DI #34GF, p. 14).

The MedStar Hospitals note that meeting higher levels of demand, if they occur, through higher use of existing facilities would be far less costly than creating a new program. Using "existing high-volume providers would clearly be more cost-efficient." According to the MedStar Hospitals, the programs proposed in these applications would "add cost to the system of existing providers, duplicate existing services, and stifle the opportunity of existing providers to achieve cost efficiencies in a shrinking market environment." (DI #34GF, p. 14). They state that the Cardiac Surgery Chapter has a policy that

> 'the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base. This approach promotes both high quality care and an efficient scale of operation.'
> (DI #34GF, pp. 14-15, *quoting* COMAR 10.24.17.03: Issues and Policies, p. 6).

Their view is that both projects would create "low, selective volume, cardiac surgery services … not intend[ed] to treat high-risk patients [and] would likely siphon lower risk patients away from existing providers, which may affect the existing providers' cost-efficiency." (DI #34GF, p. 15). Low volume programs such as those proposed would have difficulty in achieving efficiencies. They cite a 2010 article that "indicates that health system costs could be reduced by $171 million annually if all patients who underwent CABG at low volume providers had instead chosen higher volume hospitals." (DI #34GF, p. 15, *citing* Auerbach *et al*., "Case-volume, quality of care, and care efficiency in coronary artery bypass surgery," Archives of Internal Medicine, 2010 Jul 26 170(14): 1202-1208) ("Auerbach Study"). The MedStar Hospitals

> specifically … posit that AAMC would be focusing on simpler, less costly cardiac surgery patients. The high-cost patients would remain at the few existing providers with those capabilities, affecting their cost-efficiencies if they lose an undue proportion of patient volume for lower complexity procedures. There are no cost savings for the system, or for patients under this paradigm.
> (DI #34GF, p. 29).

The MedStar Hospitals state that their District of Columbia and Baltimore cardiac surgery programs operate within a high volume system of care and are more likely to be cost-effective and have capacity to handle additional cases. They note that the Commission's clinical advisory group recommended that the "'regulation of cardiac surgery services should place greater emphasis on quality rather than on volume.'" (DI #34GF, p. 15, *quoting* COMAR 10.24.17.03: Issues and Policies, p. 9). They state that cost effectiveness is an essential element of quality and argue that the cost savings claimed by the applicants should be disregarded because there has been no showing of need for either project and, thus, spending on these programs is unnecessary. (DI #34GF, p. 15) They state that both applicants overestimate revenue and underestimate costs, primarily by not projecting sufficient staffing levels. (DI #34GF, pp. 18-20).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC states that BWMC and other interested parties have "not dented AAMC's case" for cost effectiveness. AAMC insists that its lower cost per case-mix-adjusted discharge, which is lower than BWMC's and hospitals with cardiac surgery, derives from AAMC's efficiency and commitment to cost effectiveness and is not derived from "spreading overhead costs to overused rate-regulated outpatient services, as claimed by BWMC." (DI #34GF, p. 22). It states that the ratio of inpatient-to-outpatient hospital revenue is irrelevant. AAMC notes that HSCRC has adjusted the relative charge per case mix-adjusted discharge of Maryland hospitals to account for relevant differences between hospitals (such as payer mix and medical education costs) and that Medicare similarly derives a hospital's "Standard Rate" under the Inpatient Prospective Payment System. It points out that the level of a hospital's outpatient services is not used for this adjustment. It states that AAMC's efficiency is confirmed by overhead expense per licensed bed, noting that BWMC has overhead costs per bed that are 12.5% higher. (DI #45GF, p. 22).

AAMC reiterates its position that its proposed program will help Maryland meet the "Medicare Expenditure Test" under the All-Payer Model Agreement between Maryland and the federal government, commonly called the "Medicare Waiver."[31] It notes that this test is the more difficult of the two in the Agreement because HSCRC cannot control hospital expenditures incurred by Maryland patients in non-Maryland hospitals (importantly, e.g., District of Columbia hospitals) or the national rate of growth in Medicare hospital expenditures. (DI #8AA, p. 32 and DI #45GF, p. 23). AAMC believes that a shift in cardiac surgery cases from MedStar WHC to AAMC will result in "substantial savings for patients and payers" (DI #45GF, p. 23) and points to MedStar's failure to actually compare cardiac surgery charges at its WHC program with AAMC's projected charges as evidence that savings will be achieved, with a consequent positive impact on

[31] Under the All Payer Model Agreement between Maryland and the federal government, Maryland has the ability to set hospital rates for all payers, including Medicare, subject to the state's ability to pass two tests aimed at hospital cost containment during the five-year period of the agreement (2014-2018). The "All-Payer Test" requires Maryland to regulate hospital revenue at Maryland hospitals so that they do not grow at a rate exceeding 3.58% per year during the five-year Agreement period. The "Medicare Expenditure Test" requires Maryland to reduce total Medicare hospital expenditures per Medicare beneficiary, over the five-year period, by at least $330 million when compared to what those expenditures would be if they grew at the same rate as Medicare's total hospital expenditures per beneficiary nationally. (DI #8AA, p. 32).

Maryland's ability to meet the Medicare Expenditure Test. (DI #45GF, p. 23) It notes that, with respect to the All Payer Test, Maryland's experience has been so strongly positive that the additional savings associated with its proposed cardiac surgery program, are not relevant with respect to the state's ability to meet this test. (DI #45GF, p. 23)

AAMC contends that the MedStar Hospitals' reliance on the Auerbach Study is misplaced. It states that the study's findings are irrelevant to this review because of the volume of cases that AAMC will perform, noting that the study

> found savings would occur if the lowest volume hospitals (112 cases per year on average) shifted cases to higher volume hospitals. But it showed little savings would result from a shift of patients from the third highest or second highest volume hospitals to the highest volume hospitals (644 cases on average).
> (DI #45GF, p. 23).

AAMC notes that the MedStar Hospitals do not compare the charges for cardiac surgery at MedStar Washington Hospital Center to AAMC's projected charges, suggesting that this means AAMC's cost saving analysis is correct. It also states that the MedStar Hospitals' argument with respect to duplication of program costs means that "a new competitor could never generate cost savings" and rejects this "logic." (DI #45GF, pp. 23-24).

Baltimore Washington Medical Center

BWMC points to its August 2015 modification as showing that it would not charge materially more than AAMC for each cardiac surgery case, about 2.5% by BWMC's calculation. It explains that the applicants used different approaches for estimating costs, with BWMC using the 'rate center' approach and AAMC using the traditional 'charge per case' approach. It states that the charges are similar when the same approach is used for each applicant. (DI #42GF, p. 19). It contends that CareFirst's and the City of Annapolis' support for AAMC's proposed project were made in reliance on "AAMC's inaccurate comparison of cost effectiveness … identifying AAMC as a more cost effective provider." (DI #42GF, p. 19).

Reviewer's Analysis and Findings

AAMC defines the benefits of its proposed project as lower charges for cardiac surgery and improved availability and access to this service for its service area population. It has provided relevant information on how it will strive to establish a program that will maintain high standards of quality performance, collaborating with The Johns Hopkins Hospital cardiac surgery program as a partner in the project and points to its track record in the provision of quality medical and surgical care. AAMC projects that its proposed cardiac surgery program will reduce expenses for cardiac surgery in Maryland.

BWMC also defines the benefits of its proposed program as lower charges for cardiac surgery and improved availability and access to this service for its service area population. It states that its new program, when integrated with that of UMMC, will permit a more efficient operating model for the delivery of cardiac surgery within UMMS, resulting in overall savings in the delivery of cardiac surgery at the health system level. BWMC maintains that it can, through the combined

resources and experience of UMMS, UMMC, and BWMC, develop a cardiac surgery program of high quality.

Each applicant has questioned the assumptions and methods made by the other applicant with respect to utilization, calculation of revenues and expenses, and calculation of net benefit to the health care system, the latter primarily in terms of the dollar savings associated with the other applicant's proposed project. Each has arrived at a similar endpoint in the somewhat iterative process of this review. Each applicant identifies system savings that are relatively modest, in the context of the overall level of spending in Maryland for cardiac surgery. AAMC and BWMC each offers a demonstration that, in terms of hospital expenditures necessary to perform cardiac surgery in Maryland and District of Columbia, if case volume is redistributed in the manner it projects, the benefit of reduced overall hospital expenditures will exceed the cost to the health care system created by each proposed program. The estimated capital cost of each project is modest, about $2.5 million for the AAMC project and $1.26 million for the BWMC project. Each hospital employs the HSCRC payment model to project revenue redistribution within hospital global budget revenues as a basis for the demonstration of this aspect of reduced costs. Each notes that, in addition to cost savings, patients will benefit from shorter travel times and greater continuity of care.

The MedStar Hospitals are the only interested parties that directly address cost effectiveness or, in the specific terms of the standard, the relationship between cost to the health care system and benefits of the proposed cardiac surgery programs. Their comments describe a relationship between charges, costs, and a delivery system with additional programs and a redistribution of case volume that does not address the specific payment model for Maryland hospitals. Thus, the paradigm MedStar Hospitals put forward is highly focused on added costs and does not address how average charges will fall if the applicants' redistribution scenarios unfold as envisioned. In the MedStar Hospitals' view, an additional cardiac surgery program will add costs to the health care system for a service that MedStar Hospitals project to be declining, with respect to case volume, as does the Cardiac Surgery Chapter. They state that more case volume can be serviced by the existing programs at lower costs, given the effect of economies of scale. From the MedStar Hospitals' perspective, no savings in system costs can be achieved by either proposed program, each of which will perform less complex cases, increasing the unit costs of existing programs, which will have fewer, but more complex, cases.

The MedStar Hospitals' comments are highly conventional economic observations that fail to give needed attention to the Maryland payment model and how it comes into play. AAMC and BWMC have each projected that its cost base will increase if it adds cardiac surgery services but that its GBR cap will not correspondingly expand as a result of adding this service to cover these additional expenses. This is expected under HSCRC's current policy that was formally announced in its August 24, 2016 memo to me. Revenue provided by cardiac surgery will decline at existing hospitals but, for Maryland hospitals, the payment model will soften this blow.

The MedStar Hospitals suggest that higher average case acuity, which will occur as part of the redistribution of cases, will bar meaningful reductions by the existing Maryland cardiac surgery hospitals in their expenditure base for cardiac surgery, a position that I find to be unpersuasive. These hospitals may be unable to reduce their cardiac surgery expenses as volume declines to a

level that fully offsets their revenue losses resulting from lower volume, but again, higher unit costs will not automatically mean proportionally higher charges at Maryland hospitals. These charges matter to a degree that the MedStar Hospitals do not recognize in their comments.

The applicants have put forth a case that allows for the possibility that higher overall spending can occur if the number of cardiac surgery programs expands, even as charges to patients and payers will be lower due to the Maryland payment model. Higher spending for the delivery of cardiac surgery services will obviously occur at any new program approved. Hospitals losing case volume as a result of a new program will reduce their spending for the delivery of cardiac surgery services, but these reductions may not offset the increase in spending at the new program, and, under the payment model, existing hospitals with cardiac surgery programs that lose cases will continue to obtain part of the revenue associated with this lost case volume. Thus, overall systems spending for the delivery of cardiac surgery may increase. However, a new cardiac surgery program will charge less for the cases that would have otherwise been performed at the higher charge existing programs and, thus, overall system charges will decrease. Isolating attention only on cardiac surgery production costs and charges, as the MedStar Hospitals do, one can view this situation as one in which both existing and new programs are experiencing lower overall profit margins. It is important to remember that patients and payers will benefit from lower charges. If quality of care can be maintained under this scenario and the hospitals involved are strong enough to support the cardiac surgery operations with the overall revenues they take in, generating excess revenue over expenses in their overall operations, this charge reduction is a system benefit that should not be dismissed, as the MedStar Hospitals do.

The MedStar Hospital asserts that there is no need for additional cardiac surgery programs that can be demonstrated and recognize no benefit associated with reductions in travel time and expense. I find that reductions in travel time will be beneficial for patients and their families but, this benefit would not offset a scenario in which there were no system savings from reduced charges or if it were likely that case volumes would fall to unacceptably low levels at certain programs. The main problem with the MedStar Hospitals' comments is that they do not recognize the need for reduced hospital charges or recognize the system benefits that result from the ability of AAMC or BWMC to charge less for cardiac surgery than most of the affected hospitals.

AAMC has provided an analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care system will change as a result of its proposed cardiac surgery program, based on its analysis of service area demand and its assumptions about the market share it will achieve. As previously noted, AAMC calculates that its proposed project will achieve system savings of $7.7 million.[32] I believe that AAMC's projection is optimistic, given that it projects a higher case volume than I have found to be likely. However, I found that AAMC can establish a cardiac surgery program that will meet the volume requirements of the Cardiac Surgery Chapter. AAMC's program will produce system savings commensurate with that case volume.

AAMC has also provided an analysis of how the establishment of its proposed cardiac surgery program will alter the effectiveness of cardiac surgery services for cardiac surgery patients

[32]See my discussion of the financial feasibility standard, COMAR 10.24.17.05A(7), *infra*, pp. 95-100 for a more in-depth discussion of systems savings.

in its proposed service area and quantified that change to the extent possible. It has explained the steps it will take to maintain the quality of cardiac surgery care, which will involve the use of experienced surgeons and perfusionists currently providing cardiac surgery services at Johns Hopkins Hospital. It has provided information on improved access and reduced travel time for cardiac surgery for patients and families in AAMC's service area for cardiac surgery, including areas of the Eastern Shore. AAMC has demonstrated that the benefits of its proposed cardiac surgery program to the health care system as a whole will exceed the cost to the health care system. I find that AAMC's proposed cardiac surgery program complies with the cost effectiveness standard. [33]

Like AAMC, BWMC provided an analysis showing how its proposed cardiac surgery program will reduce the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and to the health care system, based on its analysis of service area demand and its assumptions about its market share. As previously noted, BWMC calculates that that its proposed project will achieve system savings of $1.9 million.[34]

Like AAMC, BWMC provided 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 and quantified that change in effectiveness to the extent possible. It explained the steps it will take to maintain the quality of cardiac surgery care, including the use of experienced surgeons and perfusionists who currently provide cardiac surgery services at UMMC. BWMC has provided information on the manner in which its program could improve access for cardiac surgery patients in its service area if its project is implemented, but has not taken the position that these improvements justify its project.

As previously discussed in this Revised Recommended Decision,[35] I found that BWMC has not demonstrated that it can establish a cardiac surgery program large enough to meet the minimum volume standard in the Cardiac Surgery Chapter, especially if AAMC's proposed program, which is likely to meet the minimum volume Standard, is approved. Coupled with BWMC's more modest projection of system savings, predicated on reaching higher volumes than I have found likely, I am compelled to find that BWMC has not proposed a project that complies with the cost effectiveness standard. It has not demonstrated that the benefits of its proposed cardiac surgery program to the health care system, as a whole, are likely to exceed the cost to the health care system.

I recommend that the following four conditions be placed on any approval granted to AAMC to establish cardiac surgery services. The first two conditions reflect commitments that I asked for and received from the applicant and JHH. The third and fourth conditions involve necessary regulatory oversight of ongoing performance by cardiac surgery programs, as mandated by Maryland law. These conditions will help assure that an AAMC cardiac surgery program will be cost effective.

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[33] I note that section (a) of this standard is not applicable because neither applicant proposed new construction.

[34] See n. 32, *supra*.

[35] See my discussion of the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.

3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.

4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

(5) Access

(a) An applicant that seeks to justify establishment of cardiac surgery services, in whole or in part, based on inadequate access to cardiac surgery services in a health planning region shall:

(i) Demonstrate that access barriers exist; and

(ii) Present a detailed plan for addressing such barriers.

(b) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement cardiac surgery program.

Applicants' Responses

Anne Arundel Medical Center

AAMC states that its proposed cardiac surgery program will improve access for nearly 900,000 adults residing in Anne Arundel County and the surrounding area. (DI #3AA, pp. 110-128). It states that this will improve the continuity of care, minimize the need for patient transfers during acute episodes, bring JHH surgeons' clinical capabilities closer to this population, and provide lower cost cardiac surgery. AAMC frames its discussion of the access problem under the following headings.

Anne Arundel County and the Eastern Shore

AAMC states that Anne Arundel County has an approximate population of 550,000 and accounts for more than 500 adult cardiac surgery cases annually, and can support a cardiac surgery program. For Anne Arundel County's population, the average drive time to a hospital providing

cardiac surgery is up to 40 minutes in normal traffic. Because the county does not have a program, travel time for many residents of the four Eastern Shore Counties in AAMC's cardiac surgery service area may be greater than one hour. (DI #3AA, p. 110).

AAMC's growth in cardiac care and care management

AAMC points out that it has one of the largest cardiac care and PCI programs in Maryland. In CY 2013, it performed more than 150 emergency PCI procedures and more than 240 elective PCI procedures. In 2014, it performed more than 1,000 cardiac catheterization procedures. It notes that it has performed well, with strong performance in shortening door-to-balloon time for primary PCI and has achieved good outcomes and quality of care scores.

AAMC describes its cardiac service programming as constituting a broad continuum of services, including non-invasive and invasive diagnostic services, PCI, electrophysiology, surgical and non-surgical vascular procedures, and cardiac disease management, with advanced clinical services and high volume originating across eight jurisdictions. In this context, it describes cardiac surgery as the missing component of the continuum, which results in disjointed care management and delays in care. (DI #3AA, p. 111).

AAMC's service area accountability

AAMC states that its GBR agreement with HSCRC makes it accountable for approximately 1.1 million residents living in eight different counties in Maryland.[36] (DI #3AA, p. 111; DI #12AA, p. 4). AAMC believes that being accountable to this population requires that it provide cardiac surgery services that are lower in cost and closer to its service area population. It states that having a cardiac surgery program will support better outcomes, more efficient delivery of care, and better care management for this large population.

Delays in hospital to hospital transfers

AAMC states that it identified 162 patients transferred from AAMC in FY 2014 for cardiac surgery, valve surgery, or immediate evaluation for surgery and notes that some transfers involved significant delays. Most delays involved transfer to District of Columbia hospitals and were related to insurance coverage of the patient or lack of available beds at the receiving hospital. Self-pay patient transfers were delayed by reviews of the patient's ability to pay or non-acceptance of the patient's insurance plan. (DI #3AA, p. 112).

Travel time for the Mid-Shore

AAMC states that more than 80% of cardiac surgery patients from the four Mid-Shore counties it includes in its service area traveled an hour or more to obtain this service, with most (45%) traveling to Baltimore and most of the balance (37%) traveling to District of Columbia hospitals. (DI #3AA, p. 112).

[36] In response to Commission staff's completeness questions, BWMC clarified that this eight-county area refers to the service area defined for AAMC by HSCRC as a basis for updating its GBR for demographic changes. (DI #12AA, p. 2 and Exh. 23).

AAMC cited a 2014 journal article linking longer travel time for cardiac surgery in Pennsylvania to poorer clinical outcomes. (DI #3AA, p. 113, *citing* Chou, S, *et al.* "Travel Distance and Health Outcomes for Scheduled Surgery," *Medical Care* 52:3 (2014) ("Chou Study")). The research, as explained by AAMC, found a mortality rate of 1.9% for patients living within ten miles of a cardiac surgery hospital and a mortality rate of 2.2% for patients living beyond ten miles of the cardiac surgery hospital.[37] (DI #8AA, p. 27)

Mortality rates and episodes of care

AAMC states that the Cardiac Surgery Chapter's assessment that "geographic access to cardiac surgery is not a problem"[38] is narrowly based on the single trip made to obtain surgery. It notes that a typical episode of care for a cardiac surgery patient may require post-surgical travel to the surgery hospital for consultation and follow-up clinical care that may best be provided by the team at that hospital. Thus, it concludes that longer travel times and the disadvantages associated with them can be amplified for some patients. AAMC again referenced the Chou Study.

Post-Discharge care

AAMC notes that access involves episodes of care, pointing out that emergent post-surgical complications may require a lengthy emergency transport to a distant cardiac surgery hospital. It suggests that the episode encompasses pre-operative education, follow-up care, and care management. Having all of the services provided at one location reduces travel time and improves care coordination and the potential for effective care management.

Underserved communities

AAMC characterizes its service area population as one that has an increasing population at risk for heart disease and in which demand for cardiac surgery is growing, unlike the pattern seen in other parts of Maryland. It also reviews selected health status and use statistics, concluding that its service area population has serious disparities in health status and access for African Americans. AAMC believes these factors provide further justification for approval of its proposed cardiac surgery program.

With respect to subparagraph (a)(ii) of the access standard, establishing a cardiac surgery program is AAMC's plan for addressing access barriers. It recites the benefits that will come with implementation of its cardiac surgery program, including more immediate access to care, an integrated continuum of care, and strengthened care management. It notes that, because of the All-Payer system in Maryland, patients will not experience the delays in care seen in District of Columbia hospitals, which it views as having "disincentives" to serve self-pay patients without an ability to pay for care. (DI #3AA, p. 116). It also states that access will be broadened to new treatment modes and new clinical care protocols as a result of the proposed project implemented

[37] The median distance for the closer patients included in the study was 8.8 miles and, for the more distant patients, 23.3 miles. Only hospitals with 30 or more cardiac surgery cases were included in the study. (DI #8AA, p. 27).

[38] See COMAR 10.24.17.03: Issues and Policies.

in collaboration with JH Medicine. The hospital also states that its program will improve access to specialty services and to lower cost cardiac surgery. (*Id.).* It points out that its average payment per case is estimated to be 40% than the average payment at MedStar WHC (approximately $23,000 less) and 45% less than the average payment at the two Baltimore academic medical centers (about $30,000 less). (DI #3AA, p. 117). Finally, AAMC puts forward a quantification of travel time reductions, stating that it will reduce travel time to cardiac surgery by more than 20 minutes for 180,000 adults. It provides an analysis and maps in support of its conclusion. (DI #3AA, p. 118 and Maps at pp. 119-128).

Baltimore Washington Medical Center

BWMC states that this standard is not applicable to its proposed cardiac surgery program.[39]

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC states that AAMC's proposed project cannot be justified on the basis of inadequate access to cardiac surgery services because MHCC has not recognized geographic access as a problem in the Cardiac Surgery Chapter. It notes that cardiac surgery is usually elective and not urgent, and that AAMC relies on improving geographic access but has not identified other significant access barriers. (DI #29GF, pp. 22-26).

BWMC states that its program will have the important benefit of making cardiac surgery services more conveniently accessible but the current level of inconvenience experienced in Anne Arundel County does not rise to the level of an access barrier. It states that BWMC with its affiliation with UMMS, which has multiple sites of service and Eastern Shore hospitals and affiliated clinicians, is better positioned to improve the continuum of care in the region than is AAMC, with its single campus location in Annapolis.

BWMC argues that the gains in access projected by AAMC could reduce access for Prince George's County residents by threatening the revival of the cardiac surgery program at PGHC. It characterizes this trade-off as one that would provide improved access primarily to "more affluent residents of Anne Arundel County" at the risk of "negative impact on the access of minority and lower income residents in neighboring Prince George's County." (DI #29GF, p. 25).

Comments on BWMC Application

AAMC Comments

AAMC did not address BWMC's compliance with the access standard.

[39] This standard, COMAR 10.24.17.05A(5), only requires a response from "[a]n applicant that seeks to justify establishment of cardiac surgery services, in whole or in part, based on inadequate access to cardiac surgery services in a health planning region …."

Comments on Both Applications

LifeBridge Comments

LifeBridge states that neither applicant provided evidence that existing cardiac surgery programs are not adequately meeting current need for the service. It notes that "convenient access" is a legitimate consideration that must be balanced "against the benefits of regionalization." It identifies the State Health Plan's position on cardiac surgery as one that strongly supports the idea limiting the number of cardiac surgery programs in order to support higher quality and economies of scale in operation. (DI #33GF, pp. 1-2).

MedStar Hospitals Comments

The MedStar Hospitals state that AAMC claims that access barriers to cardiac surgery exist because it cannot justify its proposed program on the basis of unmet need. (DI #34GF, pp. 10-14 and 29-30). They claim that the Cardiac Surgery Chapter's conclusions regarding geographic access mean that there is no need for additional cardiac surgery programs to address geographic barriers to access. The MedStar Hospitals characterize the applicants' arguments as ones that show their projects would enhance access but fail to demonstrate a barrier to access. They note that BWMC does not claim that barriers exist. (DI #34GF, p. 10).

With respect to AAMC's response to this standard, the MedStar Hospitals argue that travel times such as those identified for the Eastern Shore would be unacceptable for outpatient and primary care but not for a service like cardiac surgery, a position supported by the Cardiac Surgery Chapter. (DI #34GF, p. 11). They say that the Pennsylvania study cited by AAMC does not show a significant relationship between travel time and mortality at the travel time reductions achievable through implementation of the proposed projects and also note that the author did not claim that the research necessarily supports a "policy goal" of creating new programs to reduce access, recognizing the benefits associated with higher program case volume.

MedStar Hospitals also challenge AAMC's claims of transfer delays for cardiac surgery as a meaningful indicator of access barriers to the service. They note that the transfer agreement between AAMC and MedStar WHC has been in place since 2005, is renewed annually and that both hospitals, under the terms of the agreement, can raise issues with respect to its operation but no complaints by AAMC have been received by MedStar WHC. They state that their review of the cases described in AAMC's application revealed that MedStar's records on these cases do not match the narrative provided by AAMC. The MedStar Hospitals also state that MedStar WHC's policy is to accept transfers for cardiac surgery regardless of the patient's insurance status and that more difficult cases would still be transferred, even if an AAMC program were developed. (DI #34GF, p. 13).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC defends its claim that travel time is an access barrier under this standard that justifies its establishment of a cardiac surgery program in Annapolis. It details three cases involving patients who experienced refusal or delay in receiving what AAMC considers timely cardiac surgery services. (DI #45GF, pp. 12-18). In the first case, a patient experienced a delay related to insurance status review at MedStar WHC. AAMC refutes MedStar's claim that the CON application was the first time AAMC had any complaint with respect to this patient, and provides affidavits from AAMC staff involved in the case. In the second case, AAMC said that transfer was refused by MedStar WHC, contrary to the terms of their transfer agreement. AAMC notes that this refusal is why MedStar has no record of problems arising from this case. In the third case, according to AAMC, a delay of two days occurred because MedStar WHC stated it had no bed available.

AAMC refutes the claims by BWMC, MedStar, and LifeBridge that the Cardiac Surgery Chapter establishes that travel time cannot be a barrier to access that can serve as a legitimate justification of a new cardiac surgery program. It claims that the statement concerning geographic access in the Chapter speaks to Maryland, in general, and does not prohibit consideration of this access factor in a particular hospital's case. It notes that the interested parties do not contest its analysis of the longer travel times required for its service area population but that they dispute only the importance of these travel times.

AAMC states that the travel times it has documented are not a matter of convenience, as described by LifeBridge, but have serious negative consequences, referencing the Chou study and arguing that the MedStar Hospitals have incorrectly interpreted the study's findings. AAMC claims that the study shows that a 15-mile difference in travel distance can be associated with a 15% difference in the cardiac surgery mortality rate. It also claims that the policy inferences drawn by the MedStar Hospitals are not valid given the context of the study. It notes that Pennsylvania abandoned CON regulation and saw a proliferation of many low volume cardiac surgery programs, which is not the situation in Maryland. AAMC does not argue that improving access should be pursued at any cost, only that it is an issue that supports the single new program it has proposed. DI #45GF, p. 19).

Baltimore Washington Medical Center

BWMC states that, while the access standard is not applicable to its proposed project, BWMC is a location that will provide better geographic access than the AAMC program because of the network of facilities and services provided within UMMS. (DI # 42GF, p. 27).

Reviewer's Analysis and Findings

AAMC seeks to justify establishment of cardiac surgery services based on inadequate access to cardiac surgery services in a health planning region. It has defined a service area for its proposed cardiac surgery program that is primarily located in the Baltimore/Upper Shore health planning region but includes portion of two jurisdictions in the Metropolitan Washington region,

Prince George's County and Calvert County. The standard requires that AAMC demonstrate the access barriers exist and present a detailed plan for addressing such barriers.

The primary access barrier identified by AAMC is travel distance and consequent travel time to cardiac surgery, which is outlined in AAMC's filings as a barrier for some residents of Anne Arundel County and all residents of the four Eastern Shore jurisdictions it has included in its defined service area for cardiac surgery. AAMC states that a travel time of 40 minutes or more is burdensome and should be viewed as an access barrier. This is a travel time that some residents of Anne Arundel County would experience under normal driving conditions and that more would be likely to experience during times of high traffic and traffic congestion, a regular occurrence in the core of the Washington and Baltimore metropolitan areas, the primary destinations for AAMC's defined service area population seeking cardiac surgery services. AAMC draws special attention to the Eastern Shore counties, where many residents would experience travel times of one hour or more to existing Baltimore or District of Columbia area cardiac surgery programs. AAMC's Annapolis location would serve to reduce the travel time for many of these Eastern Shore residents by 40 minutes to an hour or slightly more, depending on traffic conditions.

AAMC has also described delays in patient transfers for cardiac surgery under this standard. Because it is a large hospital that does not have a cardiac surgery program but does provide a substantial volume of cardiac diagnostic services, it is regularly involved in arranging for the transfer of patients who have an urgent need for cardiac surgery services. In these cases, it appears that AAMC is experiencing a problem encountered by any hospital without cardiac surgery services. About 79% of Maryland's general hospitals do not provide cardiac surgery but most would not encounter as many transferring patients as AAMC because of their smaller size. While all hospitals undoubtedly seek to make such transfers as seamless as possible, it is probably impossible to avoid some delay in patient transfers. In this case, AAMC has identified specific issues with transfer of patients to District of Columbia's primary provider of adult cardiac surgery, MedStar WHC, as the primary source of delayed transfers.

Some interested parties have objected to geographic access as a justification for a new cardiac surgery program because of the clear indications in the Cardiac Surgery Chapter that achieving a uniform level of relatively short travel times for cardiac surgery in Maryland is not an objective that should be pursued, given that it would, of necessity, require establishment of more programs that would make it more difficult to maintain the desired case volumes per program. As the interested parties point out, limiting the supply of cardiac surgery programs is believed to have benefits, in terms of better outcomes, that should be weighed against the benefits accruing from shorter travel times. In the case of cardiac surgery, which is not typically provided on an emergency basis, these interested parties advocate for a greater weight to be assigned to limiting the supply of programs. The decline in cardiac surgery case volume seen in recent years reinforces this view.

One interested party, the Anne Arundel County Department of Health, and participating entity Anne Arundel County highlight travel time and distance in their comments that support approval of one or both of the proposed new programs. The City of Annapolis' comment also make this case in support of the AAMC project. CareFirst also supports approval of the AAMC project and notes that it will improve access to care in the health planning region.

I find that AAMC has not demonstrated that travel distance and travel time or delays in patient transfers are an access barrier that can serve as a primary justification for its proposed program. While many residents of Anne Arundel and the Eastern Shore counties in the Baltimore/ Upper Shore region are required to travel longer to a hospital with cardiac surgery services than most residents of the health planning region, the consequences and costs for most of these cases are not sufficiently burdensome that they require preeminent consideration in a decision to approve this project.

I do find, however, that travel distance and travel time can serve as a secondary justification for AAMC's proposed cardiac surgery program. When one realistically considers the general hospitals in Maryland that do not provide cardiac surgery services but have the size and capabilities that make them credible candidates for consideration as providers of this service, AAMC would rank first among these hospitals as a new site for cardiac surgery that would have the greatest potential for reducing travel time and distance for the service. I am persuaded by AAMC's arguments that this reduction in travel time can produce tangible benefits in terms of more timely service and better coordinated care and care management. Given the clarity of the Cardiac Surgery Chapter regarding this matter, improvements in access of the type obtainable through either of these proposed projects cannot be a primary justification but need to be considered in the complete picture.

I find that AAMC has met the requirements of the access standard and has justified, in part, the establishment of cardiac surgery services based, in part, on inadequate access to these services in its planning region. I find that the access standard does not apply to BWMC's application because it did not seek to justify its establishment of cardiac surgery services, in whole or in part, based on inadequate access in its health planning region.

(6) Need

(a) An applicant shall demonstrate that a new or relocated program can generate at least 200 cardiac surgery cases per year based on projected demand for cardiac surgery by the population in its proposed service area and an analysis of the market share that the applicant expects to capture for each zip code area in the proposed service area. An applicant shall demonstrate the reasonableness of the assumptions relied upon in defining its proposed service area.

(b) An applicant's need analysis for a new or relocated program shall account for the utilization trends in the most recent published utilization projections of cardiac surgery cases in Regulation .08 for:

(i) The health planning region in which the applicant hospital is located; and

(ii) Any other health planning regions from which it projects drawing, or from which available evidence indicates that it will draw, 20 percent of more of its patients.

(c) An applicant's need analysis for a new program shall include current information about the number of patients referred for cardiac surgery following a diagnostic cardiac catheterization at the applicant hospital and address how this information supports the applicant's demonstration that the proposed new program can generate at least 200 cardiac surgery cases per year.

(d) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement program.

Applicants' Responses

Anne Arundel Medical Center

AAMC states that forecasted population growth and change, as well as forecasted use of cardiac surgery by its service area population were the basis for its projections that it would serve at least 200 cardiac surgery patients per year, consistent with paragraph (a) of the need standard. It also states that the market share assumptions it applied to its service area are evidence-based. (DI #3AA, p. 129).

AAMC describes its relevant service area as the geographic area from which 90% of its PCI patients are currently drawn. Its service area for cardiac surgery services includes: Anne Arundel County (its primary service area); four Eastern Shore counties - Caroline, Kent, Queen Anne's, and Talbot (its secondary service area); and portions of Calvert and Prince George's Counties (the "GBR segment," so-called because these zip code areas are "assigned to AAMC through its GBR agreement with HSCRC). AAMC states that this area was defined on the basis of geographic access concerns, high rates of outmigration, utilization of high cost hospitals, and "proximity to AAMC and demonstrated utilization of AAMC, particularly PCI services." (DI #3AA, p. 130).

AAMC notes that the core sub-region of its total service area, Anne Arundel and the four Eastern Shore jurisdictions, accounts for approximately 80% of the medical cardiology and PCI volume at AAMC. It states that this five county sub-region "represents a distinct market within the much larger Baltimore Upper Shore region" and a "higher need market." (DI #3AA, p. 132). AAMC presents information and analyses showing that this sub-region: (1) is older; (2) has seen cardiac surgery use rates decline less steeply in the Eastern Shore counties (a decline of about one percent between 2008 and 2013, as compared to 3.25% for the region); (3) is likely to produce a steady demand for cardiac surgery in coming years; (4) is likely to see a shift in demand from its Eastern Shore counties to the Baltimore Upper Shore region hospitals and away from District of Columbia hospitals; and (5) has a base of AAMC- affiliated physicians in this five-county sub-region. AAMC states that it has 29 cardiologists on staff practicing in Anne Arundel County and one cardiologist on staff practicing in Kent and Queen Anne's Counties. (DI #3AA, pp. 132-33).

AAMC's analysis and projection model assumes that the five-county region generated 691 of the total region's 2,631 adult cardiac surgery cases in 2013 (26.2% of total) and will generate 669 of the region's projected 2,313 cases in 2018 (28.9%). AAMC reports that, in 2013, about 30% of the cardiac surgery cases originating in the five-county area obtained this service at MedStar WHC compared with 8.3% of the cardiac surgery cases originating in the Baltimore Upper Shore Region overall. (DI #3AA, p. 133).

AAMC also states that it has two cardiologists on its medical staff practicing in the Metropolitan Washington, D.C. region, an area that accounts for 15% of its medical cardiology discharges. The 23 Prince George's County and Calvert County zip code areas included in its

defined service area receive outreach programming that will grow in intensity under its GBR agreement. (DI #3AA, p. 134).

AAMC profiles its defined service area as follows: about 65% of AAMC's representative patient population of PCI patients, medical cardiology patients, and inpatients transferred for cardiac surgery originate in Anne Arundel; 13.2% originated from its secondary service area of the Eastern Shore; and 5.8% originated from the GBR segments of Prince George's and Calvert, leaving about 10% migrating to AAMC from outside its defined service area. AAMC estimates that its service area saw a decline in its cardiac surgery use rate from 128.1 per 100,000 adults in 2008 to 109.3 in 2013. AAMC projects this use rate will decline to 96.7 per 100,000 adults by 2019, generating 883 cardiac surgery cases in that year.

AAMC notes that its and JHH's clinicians do not believe the continuing decline in use of cardiac surgery assumed in the model is likely. It cites two factors: (1) use rates appear to be plateauing, suggesting that the rate of decline seen in the last decade will not continue; and (2), changes in technology associated with less invasive procedures are likely to expand the surgical candidate pool among older adults, pushing the use rate up. AAMC estimates that MedStar WHC has the largest cardiac surgery market share in its defined service area (36%), followed by UMMC (28%), and JHH (17%). Among other interested party hospitals, MedStar Union Memorial was ranked fourth, at 7.5%, Sinai had a market share of 1.3%, and PGHC has a market share of 0.3%. (DI #3AA, pp. 135-138).

AAMC estimates that, in 2013, it had a 24% market share of all adult discharges, excluding cardiac surgery, in its defined service area, a 19% share of adult medical cardiology cases, and about 22% of adult inpatient PCI cases. It identifies its base of cardiologists as being largely represented by six cardiology practices with a total of 26 cardiologists. It states that each has expressed support for its proposed cardiac surgery program. It also attributes its current favorable position in the market and identifies as a harbinger of future success, AAMC's "outreach/case identification initiatives." These include its programs for: hypertension awareness; diabetes self-management; screenings; and heart health programs for high-risk individuals. It projects that it will be able to achieve a 25% market share of cardiac surgery in the first year of operation and expand its share to 40% by Year 3. (DI #3AA, pp. 139-140).

AAMC reviews steps, data, and assumptions that it has used under what it labels as two separate but supporting analyses; a "practice-based referral estimate" and a "transfers/referrals of AAMC hospital patients + market share growth" analysis. (DI #3AA, p. 142). In brief, AAMC, in the first analysis, notes that it had discussions with the previously noted affiliated cardiology practices and, based on this survey, projects an ability to attract 50% to 90% of the referrals from these practices, generating 272 to 312 cardiac surgery cases in the first three years of operation. (DI #3AA, p. 143).

In the second AAMC-centered analysis, the hospital addresses patients currently transferred from AAMC for cardiac surgery and JHH patients originating in the service area, net of "the currently transferred." (DI #3AA, p. 144). It projects these two cohorts will produce 219 patients by Year 3. It projects another 155 patients from: further market share growth originating in the referral base of cardiologists (i.e., net of the first two cohorts of transfers from AMMC and

purposefully shifted JHH patients); the synergistic effects of having cardiac surgery on AAMC's chronic heart disease and PCI patient base, which will stimulate further growth in cardiac surgery referrals; and continued growth in market share on the Eastern Shore. Thirteen patients are projected to come from beyond the defined service area in Year 3. Thus, AAMC states that both approaches support its case projections. With respect to paragraph (c) of this standard, AAMC notes that, in the context of its second analysis, in FY 2014, cardiologists at AAMC referred 75 outpatients for cardiac surgery or valve surgery, following an outpatient diagnostic cardiac catheterization at AAMC.[40] It states that its clinicians estimated that approximately 80% of these patients would have received surgery at AAMC if a program were available. (DI #3AA, p. 144).

AAMC offers support for the quality of its market share assumptions by stating that transfers and referrals from AAMC for cardiac surgery establish a base 19% market share (DI #3AA, p. 149). It cites the projected shift of JJH cases in its service area that will add an additional four to five percent. It notes that the additional referrals expected on the basis of its survey of cardiologists add another projected three percent. Additional market share is less explicitly sourced. AAMC states that PCI "patients and clinicians are more likely to select AAMC as the provider of choice when cardiac surgery back-up is provided on site" and being a "full-service" hospital will add to its cardiac surgery market share (DI #3AA, p. 150). AAMC also cites its estimated 2013 market share of joint replacement and bariatric surgery in the overall adult market, 41% and 32% respectively, as supporting its cardiac surgery market share assumptions.

Baltimore Washington Medical Center

BWMC responds to the need standard by referring to its response to the minimum volume standard.[41] (DI #2BW, p. 59). In responding to the minimum volume standard, it projected reaching a case volume exceeding 200 in the second year of operation. It notes that it defined a service area fully located within the Baltimore Upper Shore region as a basis for its projections and assumed declining utilization, consistent with the most recently published MHCC projections, and paragraph (b) of the standard.

BWMC reports that, in fiscal year 2013, it performed 1,003 diagnostic cardiac catheterizations, with 133 of these patients referred for coronary artery bypass surgery, and that, in 2014, it performed 979 diagnostic cardiac catheterizations, with 145 of these patients referred for coronary artery bypass surgery.[42] It states that this information corroborates its assessment of the "significant number of patients in the UM BWMC service area who need cardiac care and would choose to be treated locally at BWMC." It states that "these data corroborate UM BWMC's assessment that there are significant numbers of patients in the UM BWMC service area who need cardiac care and would choose to be treated locally at UM BWMC." (DI #2BW, p. 60). It also refers to letters of support submitted with the application.

[40] AAMC also notes that, in CY 2014, it performed 1,052 diagnostic cardiac catheterization procedures and that, in the last 7 months of 2014, 11.4% of those catheterizations resulted in cardiac surgery. It translates this into 120 cardiac surgery cases per year. (DI #3AA, p. 151).

[41] See my summary of BWMC's response to the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 21-22.

[42] See paragraph (c) of the need standard.

Interested Party and Participating Entity Comments

Comments on Both Applications

MedStar Hospitals Comments

The MedStar Hospitals provide a single thread of comments on both this specific cardiac surgery need standard and the need criterion, COMAR 10.24.01.08G(3)(b). (DI #34GF, p. 5). They state that each applicant failed to demonstrate an unmet need of the population for its proposed cardiac surgery service. The MedStar Hospitals also claim that "the SHP does not establish a methodology for determining the need for a new program in the state of Maryland" and that this standard describes no unmet need.[43]

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC states that the MedStar Hospitals' assertion that the Cardiac Surgery Chapter does not establish a methodology for determining need is false. (DI #45GF, p. 4). Rather, AAMC concludes that the Chapter establishes a standard of need for new programs that an applicant demonstrate an ability to generate a least 200 cardiac surgery cases per year. AAMC states that the Chapter provides specific guidance on how this test is to be met, including accounting for utilization trends and patient referrals. AAMC states that the notion of excess capacity cited by the MedStar Hospitals does not appear in the Chapter, which "reflects the balance sought by the Commission between adequate access and adequate volumes at each program." (DI #45GF, p. 4).

Baltimore Washington Medical Center

BWMC refutes the MedStar Hospitals' claim that the Cardiac Surgery Chapter does not provide an applicable need analysis and states that it has appropriately established need under this standard, which BWMC states is the applicable need standard of the SHP. It notes that the Chapter does not require an applicant to address existing capacity and rejects the MedStar Hospitals' approach to claiming that there is sufficient cardiac surgery capacity as one that has no basis in regulation. (DI #42GF, pp. 2-4).

BWMC reviews the analysis and assumptions it used to project an ability to perform 200 cardiac surgery cases per year in its direct response to the minimum volume standard, which is relevant to this standard as well. It notes its compliance with this standard's requirements that it account for the utilization trends in the most recent published utilization projections of cardiac

[43] Because the MedStar Hospitals commented on need in their discussion of each applicant's compliance with the need criterion, COMAR 10.24.01.08G(3), *infra*, pp. 103-104, rather than on this standard, I will cover the bulk of the MedStar Hospitals' comments regarding need under that criterion. Also, the MedStar Hospitals discuss the reasons why need cannot and has not been demonstrated by either application, but they do not specifically address the specifics of this standard in their comments on project need. Instead, they touch more directly on this standard in their critique of the applicants' case volume projections in the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, p. 25.

surgery cases in its volume projections. BWMC states that it accounted for the cardiac surgery candidates being identified through diagnostic cardiac catheterizations at BWMC in its volume analysis.

Reviewer's Analysis and Findings

The need standard is related to the minimum volume standard, and to the much more general need criterion, found in COMAR 10.24.01.08G(3)(b), that must be addressed by all CON applicants. Paragraph (a) of the need standard builds on the simple quantitative statement of the minimal required adult program case volume found in the minimum volume standard, which directs an applicant to: undertake a service area analysis at the zip code area level; analyze market share that will be needed in the service area to hit the case volume minimum; and explain why its service area assumptions are reasonable. Both standards direct an applicant to account for the Cardiac Surgery Chapter's forecast of cardiac surgery volume. The need standard adds an additional requirement – to include information regarding the number of cardiac surgery candidates identified by the applicant hospital in its diagnostic cardiac catheterization work and address how this supports the applicant's case volume projection.

The applicants and the interested parties that addressed the need standard tended to address both the need and minimum volume standards, as well as the general need criterion, together, and there are not clear and distinct divisions in the comments and responses to comments among these two standards and the criterion. I have tried to organize and present these interwoven filings of the applicants and interested parties in this Revised Recommended Decision to address the two standards and the single criterion separately using the conventional format that is typically used in recommended decisions, but there is a great deal of overlap in the filed material. I have tried to avoid large amounts of repetition in this Revised Recommended Decision, so it is necessary for the reader to review the minimum volume standard, COMAR 10.24.17.05A(1),[44] the need standard, COMAR 10.24.17.05A(6),[45] and the need criterion, COMAR 10.24.01.08G(3)(b),[46] in order to get a fuller and more integrated review of the issues regarding need.

I previously found that AAMC demonstrated that its proposed program can generate at least 200 cardiac surgery cases per year from its proposed service area. I found AAMC's analysis of market share to be questionable. AAMC defined a large service area that has a basis in the observed medical/surgical service area that it has commanded in recent years but goes beyond the relevance levels typically used in defining a hospital service area. Reaching a 40% market share of this extensive service area would be an exceptionally high level of success that should be tempered in considering this standard. However, AAMC's overly aggressive assumption is used to generate a projection approaching 400 cases within three years. My analysis of a smaller service area observed at AAMC, its MSGA service area at 85% relevance, indicates that AAMC can reach a 200-case-per-annum level by performing in line with the market share experience of existing non-urban community hospitals.[47] Its partnership with JH Medicine provides an additional level of confidence that it will be able to reach this use level. For these reasons, I find that AAMC's

[44]See my discussion of the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.
[45]See my discussion of the need standard, COMAR 10.24.17.05A(6), *supra*, pp.71-73.
[46]See my discussion of the need criterion, COMAR 10.24.01.08G(3)(b), *infra*, p. 105.
[47]See my discussion of the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

proposed cardiac surgery program complies with subparagraph (a) of this standard. AAMC also satisfies subparagraph (b) because its projection model incorporates an assumption of declining demand in cardiac surgery.

AAMC, in response to subparagraph (c) of the need standard, provided current information about the number of patients referred for cardiac surgery following a diagnostic cardiac catheterization at AAMC. It noted "clinician estimates" that 80% of surgical referrals generated by diagnostic catheterizations of this patient population were a component of its case volume projection. The most recent information it provided, for a partial year 2014, showed that 11.4% of its diagnostic cardiac catheterization procedures led to a cardiac surgery referral, or approximately 120 cases per year. I find that AAMC's proposed cardiac surgery program complies with subparagraph (c) of the need standard.[48]

BWMC did not demonstrate that its proposed program can generate at least 200 cardiac surgery cases per year from its proposed service area. For BWMC to be able to do so would require an exceptional level of penetration of its market and an even higher level of market share in the alternative service area definition that I used to test both applicants' demand assessments, i.e., the observed MSGA service area providing 85% of MSGA discharges by order of frequency.[49] BWMC's system affiliation with UMMC is clearly a factor that could potentially provide the means for overcoming this organic service area weakness if, in collaboration with clinicians, it could shift large amounts of clinicians' caseload from UMMC to the new BWMC program, producing a very high market share for BWMC. However, my analysis shows that this collaborative support would need to be much stronger in the case of BWMC than the support required of JHH for the proposed AAMC program. This results primarily from AAMC's larger service area. Furthermore, AAMC has locational advantages over BWMC with respect to service area and market share. AAMC's location in Annapolis gives it more upside potential for shifting cases from two metropolitan areas, Baltimore and the District of Columbia, while BWMC is much more anchored in the Baltimore market.

Paragraph (b) of the need standard is satisfied by BWMC's demand assessment. BWMC assigned corroborative value to the information it provided on cardiac surgery cases identified through its diagnostic cardiac catheterization program (subparagraph (c) of the standard). It indicated that 107 of the 144 patients receiving a diagnostic cardiac catheterization procedure at BWMC in FY 2014 who were subsequently referred for coronary artery bypass surgery were admitted to UMMC, 89 of these patients underwent surgery, and 72 of those surgeries could have been performed at BWMC, if it had a cardiac surgery program. BWMC adjusts this number upward by 25 patients by assuming that 67% of the 37 patients referred for CABG surgery after a diagnostic cardiac catheterization, for which it does not have detailed data, could also have received their surgery at BWMC. (DI #6BW, p.18)

With respect to the most direct comments from the applicants and the MedStar Hospitals regarding either the need standard or the minimum volume standard, I noted in my consideration of the minimum volume standard that legitimate questions were raised concerning the forecast

[48] Paragraph (d) of the need standard is not applicable in this review because no cardiac surgery program has closed in Maryland.

[49] See my discussion of the Minimum Volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

models used by each applicant. I questioned each applicant's service area definition and market share assumptions and reexamined case volumes that could be expected based on more conservative assumptions concerning service areas and market penetration.

AAMC's forecast holds up even when the most critical components of its forecast model, its service area definition and market share assumptions, are tested. The same cannot be said of the BWMC forecast.

I find that AAMC's proposed cardiac surgery program has met the need standard. I recommend that any CON issued to AAMC be issued with the following condition:

> If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

I find that BWMC's proposed cardiac surgery program does not meet the need standard.

(7) Financial Feasibility

A proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital.

(a) Financial projections filed as part of a Certificate of Need application shall be accompanied by a statement containing each assumption used to develop the projections.

(b) An applicant shall document that:

(i) Its utilization projections for cardiac surgery are consistent with observed historic trends in the use of cardiac surgery by the population in the applicant's proposed service area;

(ii) Its revenue estimates for cardiac surgery are consistent with utilization projections and account for current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, for cardiac surgery, as experienced by similar hospitals;

(iii) Its staffing and overall expense projections for cardiac surgery are based on current expenditure levels and are consistent with utilization projections and with reasonably anticipated future staffing levels as experienced by the applicant hospital, or, if applicable, the recent experience of similar hospitals; and

(iv) Within three years or less of initiating a new or relocated cardiac surgery program, it will generate excess revenues over total expenses for cardiac surgery, if utilization forecasts are achieved for cardiac surgery services.

Applicants' Responses

Anne Arundel Medical Center

AAMC states that the proposed project is financially feasible and is projected to generate a positive margin by the second year of operation. (DI #3AA, p. 160). Regarding its volume

projections, AAMC states that, in its response to the minimum volume standard[50], it projected its cardiac surgery discharges based on projected use rates for its defined service area and that these projections were based on its target market share for cardiac surgery in the defined service area. (DI #3AA, p. 161). AAMC states that its projections are consistent with utilization trends.

Regarding volume growth in its service area, AAMC notes that, between CY2012-2013, adult cardiac surgery volume in each of the sub-regions of its services area grew, reflecting population growth, the aging of the population, and the plateauing of cardiac surgery use rates. AAMC concludes that adult cardiac surgery cases grew 15% in Anne Arundel County, 37% in the four Mid-Shore counties, and 17% in the Prince George's County and Calvert County zip code areas included in its defined service area, for an overall service area growth rate of 20%.

AAMC states that its volume projections are based on the assumption that there will be less migration of patients to MedStar WHC because patients and their physicians, as well as payers, will prefer cardiac surgery services that are closer to home, with access to cardiac surgeons from Johns Hopkins, as well as the greater affordability of AAMC's program.

AAMC discusses its fundamental premise that the mix of cases at AAMC will be comparable to the FY 2014 profile at other Maryland community hospitals (non-academic medical centers) that provide cardiac surgery. (DI #3AA, pp. 161-162). This profile results in AAMC's average length of stay assumption of 8.5 days and a case mix intensity assumption of 3.42.

Table 14: AAMC: Projected Cardiac Surgery Procedures

Procedure Type	FY 2017	FY 2018	FY 2019
Cardiac Valve	83	116	134
Coronary Bypass	155	217	249
Other	3	4	4
Total	241	337	387

Source: DI #3AA, p. 162, Chart 2 (repeated from p. 62).

AAMC projects an average daily census for its cardiac surgery program of 5.7 surgical patients in the first year of operation, increasing to 9.0 patients by Year 3. (DI #3AA, App. 1, Table I). Based on its review of recent cardiac surgery transfers from AAMC to other hospitals, AAMC projects that 74% of its projected cardiac surgery cases would be transferred from AAMC to other hospitals if AAMC does not establish a cardiac surgery program. (DI #3AA, p. 162).

AAMC states that its projected charge-per-case for cardiac surgery is derived from its average charge-per-case at a case mix intensity of 1.0 ($10,962) and the average case mix intensity at community hospital cardiac surgery providers (3.4209), yielding a projected charge per case of $37,501. (DI #3AA. p. 162). AAMC reduced its projected incremental revenue to account for the impact of cases currently transferred from AAMC to other hospitals, cases that it expects to remain at AAMC and convert to cardiac surgery cases at the hospital.

[50] See my summary of AAMC's response to the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 18-20.

AAMC's initial 2015 revenue projections[51] assumed that its GBR would be adjusted for incremental volume related to the project (incremental cardiac surgery revenue less transfer cases) at an 85% variable cost factor for the first three years of the project. AAMC estimated deductions from revenue to be 15.3% based on the hospital's actual experience for regulated services year-to-date in FY 2015. These deductions include uncompensated care, contractual allowances, and assessment payments. Projected net operational results were projected as shown in Table 15, below.

Table 15: AAMC: Projected Operating Revenue, Total Operating Expenses, and Net Income from Cardiac Surgery Operations and Total Operations

Uninflated 2015 Dollars	**FY 2017**	**FY 2018**	**FY 2019**
Cardiac Surgery Program Operation			
Gross patient services revenue	$6,618,453	$9,669,525	$11,225,855
Net patient services revenue	$5,440,821	$8,025,976	$9,345,110
Net operating revenue	$5,440,821	$8,025,976	$9,345,110
Total operating expenses	$6,945,043,	$8,010,222	$8,473,780
Income from operations	($1,504,222)	$15,755	$871,330
All AAMC Operations ($000s)			
Gross patient services revenue	$558,860	$561,911	$563,468
Net patient services revenue	$473,160	$475,745	$477,064
Net operating revenue	$503,317	$505,902	$507,221
Total operating expenses	$472,194	$469,003	$465,561
Income from operations	$31,123	$36,899	$41,660

Source: DI #3AA, App. 1, Tables G and J.

AAMC states that its clinicians and administrators developed staffing models for its project by looking to community hospital cardiac surgery programs in Maryland and considering benchmark information provided by its consultants.

Table 16: AAMC: Staffing of Proposed Program

	FY 2017	**FY 2018**	**FY 2019**
Management	0.5	0.5	0.5
Direct Care			
Physician Assistant	1.1	1.1	1.1
Registered Nurses	18..0	20.6	21.7
Support Staff			
Technical	10.2	11.5	12.3
Professional	0.5	0.5	0.5
TOTAL	**30.4**	**34.2**	**36.2**

Source: DI #3AA, p. 163.

[51]AAMC's 2015 original revenue projections were revised in its modified application filed on November 7, 2016. (DI #22AA; DI #90GF). For purposes of clarity, I note, at this point in my description of AAMC's response to this standard, that AAMC's original 2015 assumption allowed for a larger revenue expectation for AAMC than the policy articulated by HSCRC in August 2016 with respect to treatment of variable costs and how shifts in service volume among Maryland hospitals would be recognized by HSCRC in hospital global budget revenue. AAMC believed that the payment model, which was still in early stages of development and elaboration when the application was prepared, provided HSCRC with the flexibility to recognize alternatives to the 50% variable cost treatment when hospitals were seeking to introduce new services.

AAMC states that it relied on its current salary and benefit structure to project staffing expenses and notes that its partner, Johns Hopkins Hospital, will provide cardiac surgeon and perfusionist coverage for the new service. (DI #3AA, p. 163).

AAMC plans to pay for the project with cash reserves. The approximate capital expenditure will add annual depreciation expenses related to renovation ($451,000 over 20 years) and equipment (about $2.05 million over seven years) totaling $315,319. (DI #3AA, p. 164). AAMC notes that in 2015, it had a positive operating margin and is projected to maintain a positive operating margin in the first year of operation, when it projects an operating loss from cardiac surgery operations, and throughout the projection period. (DI #3AA, p. 164).

HSCRC Comments, Project Status Conference, and AAMC Modification to Application

On July 15, 2016, I requested that HSCRC staff review each applicant's financial projections and comment on the financial feasibility of each hospital's proposal and the reasonableness of each hospital's assumptions. (DI #64GF). On August 24, 2016, HCSRC staff provided comments on AAMC's 2015 application, stating that

> [u]nder the current HSCRC policy for market shift changes of Maryland residents, hospitals with increased volumes that are taken from other Maryland hospitals are allowed to retain 50% of the revenue associated with the additional volume" [and specifically noted that "AAMC's assumption that it would be able to retain 85% of the cardiac surgery revenue [associated with Maryland residents] is contrary to HSCRC policy on market shifts …."
> (DI #68, pp. 1-2).

HSCRC staff concluded that "AAMC has other sources of revenue to apply to the project and, therefore, we do not believe a change in this assumption would impact the feasibility of the new program." HSCRC staff stated that

> AAMC and BWMC could deliver cardiac surgery volumes with the increases in revenue under the new payment model using the resources that are provided in the system, including the population adjustment, capacity from reduced avoidable utilization, and reallocation of overhead already funded in the system as evidenced in each hospital's profits to cover the difference between marginal cost and fully allocated costs that includes existing overhead. However, this would require a commitment from the hospitals to avoid seeking a rate increase in a separate action.
> (DI #68, pp. 2-3).

I asked AAMC to revise its revenue projections to conform with what HSCRC clearly stated in August 2016 is the correct approach to modeling revenue gains from market shifts of Maryland residents between hospitals and I also asked both applicants for the commitment that HSCRC viewed as a requirement if the financial performance scenarios and overall systems savings outlined by the applicants were to be realized. I also requested that each applicant's partner/collaborating hospital make similar commitments not to seek adjustments in its global budget revenue aimed at offsetting any revenue loss associated with the shift of cardiac surgery

cases to its partner applicant hospital. (DI #69GF). In response, AAMC and JHH provided the requested commitment not to seek adjustments in global budgeted revenue related to cardiac surgery services. (DI #75GF). AAMC also provided revised pro forma schedules of revenues and expenses, which I subsequently struck from the record of this review prior to holding a project status conference. (DI #77GF).

At the October 27, 2016 project status conference, I requested that AAMC modify its application by revising its 2015 revenue projections in accordance with HSCRC's 2016 guidance. (DI #90GF). The final set of pro forma projected revenue and expense projections submitted by AAMC are summarized in Table 17 below. (DI #22AA). AAMC presents two alternative sets of revenue and expense projections from cardiac surgery operations. The first it labels as "direct revenues and expenses to be generated by AAMC's proposed cardiac surgery service, as a service line, from billable charges," a version that "lists the projected income derived from charges to patients and payers for cardiac surgery at AAMC, comparing it to the direct costs of the program." (DI #22AA, p. 2).

The second schedule, labeled in Table 17 below as "retained revenues, expenses, and income" is described by AAMC as a schedule that "ascribes to AAMC's proposed cardiac surgery service only the revenue AAMC expects to retain, as a facility, as a result of the service line revenue generated by AAMC's proposed cardiac surgery service [and] discounts the service line revenue generated by AAMC's proposed cardiac surgery service by 50%." (DI #22AA, pp. 2-3). As AAMC notes, this schedule is provided "pursuant to the HSCRC market shift adjustment policy's 50% variable cost factor, rather than 85%." (DI #22AA, p. 7).

Table 17: AAMC: November 2016 Revised Revenue and Expense Projections, Cardiac Surgery Operations and Overall Operations

Uninflated 2015 Dollars	**FY 2017**	**FY 2018**	**FY 2019**
Direct revenues, expenses, and income from cardiac surgery operations			
Revenue from inpatient cardiac surgery services	$7,557,221	$11,147,964	$12,980,221
Gross patient services revenue	7,557,221	11,147,964	12,980,221
Net patient service revenue	6,400,966	9.442,326	10,994,247
Total operating expenses	6,945,043	8,010,222	8,473,780
Net income from operations	($544,076)	$1,432,104	$2,520,467
Retained revenues, expenses, and income from cardiac surgery operations			
Revenue from inpatient cardiac surgery services	$3,778,611	$5,573,982	$6,490,110
Gross patient services revenue	3,778,611	5,573,982	6,490,110
Net patient service revenue	3,200,483	4,721,163	5,497,124
Total operating expenses	6,945,043	8,010,222	8,473,780
Net income from operations	($3,744,559)	($3,389,059)	($2,976,657)
All AAMC operations			
Net patient service revenue	$470,919,584	$472,440,020	$473,215,880
Other operating revenue	30,157,196	30,157,196	30,157,196
Net operating revenue	501,076,780	502,597,216	503,373,076
Total operating expenses	472,194,438	469,003,487	465,560,733
Net income from operations	$28,882,341	$33,593,728	$37,812,343

Source: DI #22AA, Tables G, J1, and J2.

Along with the revised set of schedules in its November 2016 modifications, AAMC addresses the financial feasibility standard, in the context of these changes, as I requested at the

project status conference. AAMC reiterates that "HSCRC will permit allocation of certain future adjustments to AAMC's global revenue [including] the 'population adjustment [and] capacity from reduced avoidable utilization." (DI #22AA, p. 8). AAMC equates the operating margin it generates from its overall operations with HSCRC's August 24, 2016 memo referencing "reallocation of overhead already funded in the system." (DI #22AA, p. 8). AAMC notes that its Year 2 projection of a negative $3,289,059 budget impact resulting from its cardiac surgery program is the equivalent of approximately 0.65% of AAMC's FY 2018 revenue ($502,597,216). (DI #22AA, p. 8).

AAMC recommends that, in analyzing financial feasibility, the Commission accept AAMC's "direct" revenue scenario for the following reasons: (1) the financial feasibility standard "distinguishes between the viability of the project itself, and the impact of the project on the hospital as a whole;" (2) the philosophy of the State Health Plan is to consider each project on its own merits; and (3) AAMC's view is sensible, given that HSCRC has found its project to be financially feasible under the GBR model. (DI #22AA, p. 9).

AAMC notes that its operating margin of $54.3 million is larger than the projected difference between the expenses of its proposed service and its projected budget increase associated with cardiac surgery (-$3.3 million). On this basis, it argues that the Commission should adopt the view that the project is financially feasible under either the GBR Budget methodology or as a proposed project standing alone. (DI #22GF, p. 11).

Baltimore Washington Medical Center

BWMC states that its proposed cardiac surgery program would not, as a stand-alone program, achieve excess revenue over total expenses within three years. (DI #2BW, p. 61). The applicant explains that

> under the Global Budget Revenue agreements between the HSCRC and most Maryland hospitals, it is not possible to achieve financial feasibility of a new stand-alone cardiac surgery program because revenue can only be achieved through market share adjustments and certain other adjustments to revenue.
> (DI #2BW, p. 61).

BWMC notes that the proposed program is financially feasible when viewed "as a new location in the larger cardiac surgery program managed by the UM Division of Cardiac Surgery." Analyzing the "combination of the proposed program with the existing cardiac surgery program at UMMC," BWMC states that "the combined program would be financially feasible immediately." (DI #2BW, p. 61).

Table 18: BWMC: Projected Operating Revenue, Total Operating Expenses, and Net Income from Cardiac Surgery Operations and Total Operations

Uninflated 2015 Dollars	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Cardiac Surgery Program Operation						
Gross patient services revenue	$1,703,238	$4,132,446	$4,615,868	$5,035,243	$5,334,357	$5,459,251
Net patient services revenue	$1,544,837	$3,748,129	$4,186,592	$4,566,965	$4,838,262	$4,951,540
Net operating revenue	$1,544,837	$3,748,129	$4,186,592	$4,566,965	$4,838,262	$4,951,540
Total operating expenses	$2,943,376	$5,568,759	$6,072,257	$6,533,798	$6,827,505	$6,845,491
Income from operations	($1,398,539)	($1,820,630)	($1,885,665)	($1,966,833)	($1,989,243)	($1,893,950)
All BWMC Operations ($000s)						
Gross patient services revenue	$438,290	$442,201	$445,922	$449,626	$453,255	NA
Net patient services revenue	$358,179	$361,593	$364,677	$367,740	$370,730	NA
Net operating revenue	$361,068	$364,510	$367,624	$370,716	$373,736	NA
Total operating expenses	$348,692	$355,424	$358,985	$361,249	$363,685	NA
Income from operations	$12,375	$9,086	$8,638	$9,467	$10,052	NA

Source: DI #6BW.

BWMC's analysis reflects its operational view of a single cardiac surgery program operating at the two UMMS hospitals. It assumes an FY 2016 through FY 2021 projection of cases shifting from UMMC to BWMC that ranges from 64 in the first year to 150 cases by Year 6 of operation (with peak shift projected at 157 cases in FY 2019, or Year 4). See Table 19 below, which shows BWMC's analysis that the program will result in a "net system improvement" ranging from approximately $700,000 to $770,000 in the second through sixth year of program operation at BWMC.

Table 19: BWMC: Summary Financial Feasibility Analysis of Combined UMMC Cardiac Surgery Program and Proposed Cardiac Surgery Program (millions of $)

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
UMMC cases	1,289	1,255	1,222	1,191	1,164	1,141
UMMC operating margin	$39.86	$38.80	$37.78	$36.82	$35.99	$35.27
UMMC case shift (cases shifted from UMMC to BWMC	64	145	151	157	154	150
Net revenue shift	$1.18	$2.69	$2.83	$2.93	$2.86	$2.80
UMMC direct expense savings	$2.77	$5.27	$5.46	$5.65	$5.55	$5.43
UMMC operating margin after shift	$41.45	$41.39	$40.42	$39.53	$38.68	$37.90
BWMC net operating margin	($1.40)	($1.82)	($1.89)	($1.97)	($1.99)	($1.89)
System operating margin (UMMC post shift margin minus BWMC net operating margin)	$40.05	$39.57	$38.53	$37.57	$36.69	$36.00
Net system improvement (system operating margin minus pre-case shift UMMC operating margin)	$0.19	$0.77	$0.75	$0.75	$0.70	$0.73

Source: DI #2BW, p. 62, Table 7.

BWMC projects higher operating margins at UMMC after cases shift to BWMC, identifying the key components of this net system improvement as deriving from "operating room labor savings" (62% of projected improvement in Year 6), "labor savings from productivity" (32%), and "drug and supply savings" (4%). (DI #2BW, Table 7, p. 62).

BWMC's 2015 application notes that "no specific policies or procedures have been published by the HSCRC that allow for a definitive analysis of revenue shifts as the result of volume movement between hospitals under the new GBR system." (DI #2BW, p. 62). BWMC assumed in its analysis that: (1) revenue associated with volume shifting to BWMC from UMMC will be treated differently than volume coming from other hospitals in Maryland; (2) revenue associated with volume moving from UMMC to BWMC will remain within UMMS; (3) revenue associated with non-UMMS hospitals in Maryland will be treated as a market shift, with revenue recognized at BWMC at 50% of its then-current charges; (4) revenue associated with volume coming from District of Columbia hospitals will be recognized at BWMC at 50% of FY 2014 statewide average case rate; and (5) movement of volume from UMMC to BWMC will result in a decrease in direct costs at UMMC and a corresponding increase in direct costs at BWMC to support those cases, with BWMC having a lower length of stay and more efficient staffing. (DI #2BW, pp. 62-63).

In completeness review, MHCC staff asked BWMC to provide more information regarding its assumption of cost reductions at UMMC as cases shift to BWMC. (DI #5BW). The applicant stated that UMMC would operate with two fewer cardiac surgery teams when 150 cardiac surgery cases move to BWMC. It anticipates that this reduction in cardiac surgery cases will allow an internal shift of non-cardiac surgery cases being performed in the four cardiac surgery ORs to other rooms, presumably allowing a concentration of cardiac surgery in fewer ORs with more efficient staffing. (DI #6, pp. 18-19). As previously noted, BWMC projects that it will perform an average of 243 cardiac surgery cases between FY 2017 (its second year of operation) and FY 2021, and that an average of 151 of those cases would otherwise have been performed at UMMC.[52] BWMC projects an average daily census of 4.9 surgical patients in the second year of operation, increasing to 6.5 patients by 2021 as a result of the new program, with an average length of stay assumption of 7.8 days. (DI #2BW, Exh. 1, Table I).

BWMC's Modified Application

In July 2015, BWMC modified its application to include a commitment that BWMC and UMMC would accept 50% revenue variability for cardiac surgery cases shifted from UMMC to BWMC. (DI #17BW, p. 1). It noted that the global budget agreement between the UMMS and HSCRC "permits revenue to be redistributed among UMMS affiliated hospitals without applying a revenue variability factor." BWMC states that this modification makes its proposal to introduce cardiac surgery more cost effective and financially feasible. It presented a revised financial feasibility analysis, summarized in Table 20 below.

[52] See my summary of BWMC's response to the minimum volume standard, COMAR 10.24.17.06A(1), *supra*, pp. 21-22.

Table 20: BWMC: Revisions to Summary Financial Feasibility Analysis of Combined UMMC Cardiac Surgery Program and Proposed BWMC Cardiac Surgery Program (millions of $)

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
UMMC cases	1,289	1,255	1,222	1,191	1,164	1,141
UMMC operating margin	$39.86	$38.80	$37.78	$36.82	$35.99	$35.27
UMMC cases shift to BWMC	64	145	151	157	154	150
Net UMMS revenue shift	($0.93)	($2.10)	($2.19)	($2.27)	($2.23)	($2.17)
UMMC direct expense savings	$2.53	$4.74	$4.90	$5.07	$4.98	$4.88
UMMC operating margin after shift	$40.18	$38.51	$37.44	$36.44	$35.63	$34.94
BWMC operating margin	($1.40)	($1.82)	($1.89)	($1.97)	($1.99)	($1.89)
UMMS operating margin (UMMC post shift margin minus BWMC net operating margin)	$38.78	$36.69	$35.56	$34.47	$33.64	$33.05

Source: DI #17BW, p. 8, Table 30.

BWMC states that "the UM Division of Cardiac Surgery, inclusive of UM BWMC, is financially feasible, yielding excess revenue over expenses in the range of $33 million - $38 million for the projected FY 2016 - FY 2021." (DI #17BW, p. 9). In October 2016, BWMC and UMMC, like AAMC and JHH, in response to my October 5, 2016 request, each committed not to approach HSCRC in the future to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue related to changes in its provision of cardiac surgery services. (DI #76GF).

Interested Party and Participating Entity Comments

Comments on AAMC Original Application

BWMC Comments

In response to AAMC's 2015 application, BWMC states that AAMC's proposal does not comply with the financial feasibility standard because its revenue projections are invalid, noting that "HSCRC finalized a policy for market shift adjustments to revenue on July 17, 2015 that uses a 50% revenue variability factor for incremental volumes." (DI #29GF, pp. 27). According to BWMC, the correct market shift adjustment to AAMC's revenue projections would result in losses from AAMC's cardiac surgery program that range from $2.97 to $3.79 million in the first three years. (DI #29GF, p. 28).

BWMC also provided a "break-even" analysis of AAMC's proposed cardiac surgery program that it claims shows that, using the correct variable cost factor to project revenues, the AAMC program can never be financially feasible on a stand-alone basis. BWMC states that the total number of cases needed for AAMC's program to break even is 1,600 cases, nearly twice the number of cases that BWMC states are generated by the AAMC service area. (DI #29GF, p. 28).

Comments on BWMC Original Application

AAMC Comments

Citing the losses projected by BWMC, AAMC states that BWMC's application shows that BWMC will not have a sustainable cardiac surgery program. AAMC notes that BWMC's revenue model incorrectly assumed that HSCRC would "permit a cardiac surgery program in Anne Arundel County to increase revenue at a level equivalent to 85% of charges …." It points out that BWMC should have applied HSCRC's "new 50% variable cost factor for market shift adjustments," as AAMC's model did. (DI #28GF, p. 15). AAMC states that BWMC also failed to account for a projected decline in revenue proportional to BWMC's projected reduction in charity care expenses, consistent with HSCRC rules. (DI #28GF, p. 18).

AAMC also notes that BWMC likely overstated savings at UMMC, pointing out that the savings resulting from the expected reduction of two cardiac OR teams at UMMC are not properly attributable to the proposed BWMC project. (DI #28GF, p. 15). It also contends that BWMC's project cost should have included the $5.2 million that AMMC viewed as needed for the replacement of the three ORs necessary to accommodate BWMC's cardiac surgery program. In this regard, AAMC suggests that BWMC may have under-projected surgical case times, making the case that additional OR capacity of appropriate size will be needed. (DI #28GF, pp. 16-17).

AAMC states that BWMC's proposed staffing overestimates its ability to achieve reductions in personnel expenses, suggesting that BWMC places too much reliance on current UMMC personnel performing "equivalent roles" at BWMC. It points to BWMC's plans for a part-time perfusionist director, perfusionists shared among BWMC and two other UMMS programs, support and training from UMMC's cardiac nurses, and contracted coverage with UMMS' surgeons. (DI #28GF, p. 16).

Comments on Both Original Applications

MedStar Hospitals

The MedStar Hospitals state that neither application complies with the financial feasibility standard. (DI #34GF, p. 30). They state that neither has demonstrated revenue generation that exceeds expenses on a stand-alone basis and note that BWMC explicitly acknowledged this. They claim that this failure is the result of unrealistic utilization projections, producing revenue projections that are too high and expense estimates that are too low, based on each applicant's incomplete analysis of staffing needs. The MedStar Hospitals state that, because neither application disclosed "the true costs of a fully functioning cardiac surgery program," staffing costs of each proposed cardiac surgery program are unknown, and staffing is inadequate to meet accreditation standards. (DI #34GF, pp. 19-20).

Comments on AAMC Modified Application

As previously noted, after receipt of HSCRC staff's August 2016 comments[53] and filings by the applicants, I convened a project status conference and asked AAMC to modify its application by filing revised revenue and expense projections conforming with HSCRC's current policy on changes in hospital volume resulting from shifts in market share and how those shifts would affect global budget revenue. (DI #90GF). Comments on AAMC's modifications were filed by BWMC, the MedStar Hospitals, and Dimensions.[54]

BWMC Comments

BWMC reiterates its original position that AAMC's application does not comply with the financial feasibility standard and states that the revised projections have not changed this fact. (DI #94GF, pp. 1-2). It notes that the proposed AAMC program will not generate excess revenue over expenses, as required by the Cardiac Surgery Chapter. It states that AAMC made false claims in its October 17, 2016 filing[55] of revised financial projections when it claimed that the revised projections and the original projections were "substantively" the same and that AAMC contradicted itself by claiming that it had "only added an additional revenue line to show that a portion of revenue was attributable to 'reallocated revenue' from other resources provided in the system" while also admitting that its earlier projections assumed a variable cost factor of 85% as a basis for adjusting its GBR for incremental volume. (DI #94GF, p. 5). BWMC states that AAMC's November 7, 2016 filing contained a revenue and expense projection that was not consistent with my request at the project status conference because it "portrays revenue as equal to billable charges."[56] (DI #94GF, p. 6). BWMC contends that AAMC's second set of projections[57] did comply with my instructions and demonstrates the failure of AAMC to meet the financial feasibility standard.

BWMC rejects what it characterizes as AAMC's call for reinterpretation of the standard as "referring to billable charges rather than revenue," noting that the standard became effective in 2014, after the initiation of the new hospital payment model and thus, MHCC "recognized the change to hospital revenue calculations" when the standard was adopted. (DI #94GF, p. 6). BWMC goes on to observe that this does not mean the standard cannot be met, finding that HSCRC's comments indicate that "HSCRC has the ability to grant rate increases in GBR revenue if GBR methodology does not provide sufficient revenue." (DI #94GF, p. 10). It defines AAMC's problem in this regard to be twofold: (1) HSCRC's lack of agreement to make such an accommodation; and (2) my request that AAMC and BWMC not seek such adjustments. BWMC states that the problem is not with the standard. (DI #94GF, p. 10).

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[53] DI #68GF.

[54] While PGHC filed comments in response to the November 7, 2016 filing by AAMC, those comments did not directly address the financial feasibility standard. (DI #93GF). Its comments are more appropriately considered under the criteria and standards addressing costs and impact of the proposed project.

[55] In my October 21, 2016 ruling, I struck the financial tables filed by AAMC on October 17, 2016. (DI #77GF).

[56] See "Direct revenues, expenses, and income from cardiac surgery operations" in Table 17, p.84, *supra*.

[57] See "Retained revenues, expenses and income" in Table 17, p. 84, *supra.*

BWMC argues against AAMC's suggestion that the standard can be met by demonstrating that "the viability of the hospital as a whole is not jeopardized" and notes that the express language of the standard, requiring generation of excess revenue from cardiac surgery, is the only valid interpretation of the standard's requirements. It claims that AAMC held this same view of the express language of the standard in August 2015, when AAMC commented on BWMC's 2015 modified application. (DI #94GF, p. 11). BWMC states, that, at that time, AAMC argued that BWMC was trying to "revolutionize" the CON process by implying that "merged asset systems could leverage a profitable service in one part of the system to subsidize the creation of uneconomic facilities or services in another part of the system." (DI #94GF, p. 11). BWMC contends that its application projects excess revenue generation through the provision of cardiac surgery by the UM Division of Cardiac Surgery, a two-hospital division expanding to a three-hospital division if BWMC establishes cardiac surgery services. It contrasts that with what it views as AAMC's proposal that any program in its hospital can subsidize a cardiac surgery program that generates losses. (DI #94GF, p. 11).

BWMC claims that AAMC's proposed interpretation of this standard "is inapposite to the logic" that AAMC has used in another CON application currently under review. (DI #94GF, p. 12). It also faults AAMC for a lack of detail on the shift of revenue from other services to its cardiac surgery program. BWMC claims, based on certain assumptions, that the two ordinary adjustments[58] to AAMC's GBR and reallocation of overhead, all cited as revenue sources for cardiac surgery, will not cover the projected losses from AAMC's provision of cardiac surgery. BWMC also claims that AAMC may be "double counting" in its reallocation of overhead because its calculated charge per cardiac surgery case ($37,501 in 2015 dollars) already includes an allocation for overhead. (DI #94GF, pp. 18-19).

Finally, BWMC states that AAMC's commitment not to seek additional revenue based on the provision of cardiac surgery services is overly vague because AAMC expressly stated that reallocating "revenue under the new payment model using the resources that are provided in the system [and] allocating revenue to the cardiac surgery program in connection with future revisions to the HSCRC's GBR policy or rate methodologies" is allowable in conformance with its commitment. (DI #94GF, p. 21). BWMC asks that I require AAMC to provide the requested commitment.

MedStar Hospitals Comments

The MedStar Hospitals contend that the revised financial projections filed by AAMC fail to cure the flaws of its application with respect to criteria and standards that I identified as relevant in my request for revised financial projections from AAMC. (DI #95GF, p. 2). The MedStar Hospitals identify the "fatal flaw" of the application as the lack of need for the proposed new cardiac surgery services. With respect to the financial feasibility standard, MedStar Hospitals state that the anticipated losses that AAMC now projects (in its projection of "retained" revenues) are not "the mark of a 'financially feasible' proposal, and [are] inconsistent with the SHP, which specifically requires that the program achieve more revenues than expenses on a standalone basis by the third year of operation." MedStar Hospitals characterize the basis for a finding of financial viability by AAMC as "accounting manipulation." (DI #95GF, p. 9).

[58] The population adjustment and the adjustment on capacity from reduced avoidable utilization.

The MedStar Hospitals reiterate some of their earlier comments to make the point that AAMC's losses will be greater than the applicant has projected, because, in the MedStar Hospitals' view, AAMC has underestimated the expenses it will incur in providing a high quality cardiac surgery program and overestimated revenue that will be generated, because of its "infeasible volume projections." (DI #95GF, p. 6). They state that AAMC's underestimation of expenses results from its failure to include all necessary salary and contractual labor costs in its projections, which the MedStar Hospitals state "demonstrates a lack of understanding of, or commitment [by AAMC] to an essential element of a quality program [that must have] adequate staffing by an entire team of specialists." (DI #95GF, p. 7). They also assert that AAMC has not included realistic projections of drug price inflation.

The MedStar Hospitals state that "AAMC's volume projections also remain illogical and miscalculated," pointing to MHCC's projections of declining cardiac surgery case volume. (DI #95GF, p. 7). They contend that HSCRC, in its comments on the applications,[59] supports the MedStar Hospitals' view that AAMC is unlikely to reach the volume levels it projects, specifically pointing to the statement by HSCRC that "'it is not likely that the ability of District of Columbia hospitals to negotiate charge levels for cardiac surgery will make it more difficult to shift volume away from these hospitals to new Maryland providers.'" (DI #95GF, pp. 8-9).

The MedStar Hospitals also question the value of AAMC's commitment with respect to additional revenues that might be sought to support operation of a cardiac surgery program, stating that "further, the HSCRC has never in fact taken action to enforce such a requirement on past CON applicants. The HSCRC in fact acknowledges that hospitals awarded a CON have the right to request rate increases to cover lost volumes, 'unless specifically agreed to by hospitals during the CON process,' which further limits the impact that these commitments have on AAMC and Johns Hopkins." (DI #95GF, p. 5).

Comments on BWMC Modified Application

AAMC Comments

AAMC states that the BWMC's modification is an attempt to "fix" BWMC's problem with the financial feasibility standard, which it admitted to failing in its CON application, by "conflating the feasibility of cardiac surgery at BWMC with the profitability of cardiac surgery within UMMS as a whole." (DI #45GF, p. 2). AAMC describes this as an illegitimate rewrite of the Cardiac Surgery Chapter that would "work a revolution in the CON process; merged asset systems could leverage a profitable service in one part of the system to subsidize the creation of uneconomic facilities or services in another part of the system." (DI #46GF, p. 3). It also criticizes the apparent failure of BWMC to include UMSJ Medical Center in its "system" perspective and references Prince George's Hospital Center as a missing component.[60] (DI #46GF, p. 4). AAMC also finds fault with the profitability that BWMC has projected for UMMS, claiming it is inconsistent with

[59] See DI #68GF.

[60] UMMS had articulated a plan for acquiring Dimensions Health System at the time AAMC made this comment and has since committed to this acquisition. AAMC notes that, based on what was known at that time, PGHC was on track to become a fourth UMMS cardiac surgery program.

HSCRC's mandates and methodologies and claims that UMMS has departed from standard accounting principles and the revenue and expense formats used in CON applications to produce an "unorthodox and opaque" financial feasibility analysis. (DI #46GF, p. 4). Finally, AAMC states that BWMC did not attribute any incremental operating costs to its cardiac surgery program, using a dubious assumption that operating expenses will shift from UMMC to BWMC on a one-to-one basis. It suggests that if the UMMC cardiac surgery program is as profitable as claimed by BWMC (a 33% profit margin, according to AAMC), it would be preferable for HSCRC to take direct action to reduce UMMC's revenue rather than shift revenue to a new uneconomical program as a way to reduce overcharging. (DI #46GF, pp. 4-5).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC responds to the high variable cost factor assumption (85%) in its original application that was questioned by the interested parties by stating that it could "reasonably expect to retain 85% of the revenue generated by" its proposed cardiac surgery program, noting that "HSCRC has indicated that, for new services, it has the flexibility to provide targeted funding through the annual update process for individual hospital budgets." (DI #45GF, p. 19). It states that "HSCRC recognized the opportunity to appropriately fund new programs which have the potential to achieve significant healthcare savings" and references a letter from HSCRC "expressing its intention to work with AAMC specifically to fund a new cardiac surgery program at AAMC." (DI #45, p. 20). It claims that its assumption of a revenue adjustment is not inconsistent with Maryland's agreement with CMS.

AAMC supports its staffing costs as reasonable and its staffing plan as complete. It argues that its plan has no omissions as suggested by MedStar Hospitals in their comments. It notes that it has contracted for JHH perfusionists and cardiac surgeons and that this contracting "saves AAMC from the cost and uncertainty of recruitment, and guarantees the availability of proven, skilled practitioners." (DI #45GF, pp. 20-21). AAMC states that the costs of these contract professionals were included in its expense projections.

Similarly, AAMC notes that it will obtain the services of anesthesiologists and intensivists through existing contracts. Based on existing agreements, it expects to be supplied with anesthesiologists for cardiac surgery "without a subsidy" of the professional fees on which the contracting physician group relies and describes a similar arrangement for intensivists. (DI #45GF, p. 21).

Baltimore Washington Medical Center

In response to AAMC's comments, BWMC states that the "UM Division of Cardiac Surgery would be financially feasible standing alone." (DI #42, p. 20). It contrasts this with what it characterizes as AAMC's incorrect assumptions regarding how HSCRC, under the new hospital payment model, would treat revenue that results from new service volume introduced at AAMC. Thus, BWMC concludes that AAMC incorrectly presented its proposed program as feasible on a stand-alone basis.

BWMC reiterates its analysis from its August 2015 modification that, viewed at a two-hospital surgery division level, its new cardiac surgery program should be found to be financially feasible, consistent with the treatment revenue under the hospital payment model when volume shifts from UMMC to BWMC. (DI #42GF, p. 21). It responds to criticism of its staffing plan for cardiac surgery by presenting affidavits from the clinical leaders of the UM Division of Cardiac Surgery, who state that BWMC's staffing plan is complete and supported by UMMC with respect to how the sharing of resources between the UMMC cardiac surgery program and BWMC's new program. Specifically, BWMC states that the MedStar Hospitals misunderstood and overlooked staffing information in BWMC's application. (DI #42GF, p. 22). BWMC points out that the FTE levels for perfusionists and physicians, alleged by the MedStar Hospitals to be inadequate, are only for oversight, labeled as "administrative." It notes that the cost of additional staffing in these categories is included in "direct care" expenses for contract employees, including perfusionist services ($166,000), anesthesia contract services ($141,650), and "CT assist" (described as "24/7 cardiac coverage for the OR (scheduled and emergency cases)" by a "3rd party company" in the amount of $293,250. (DI #42GF, Exh. 33).

BWMC responds to the MedStar Hospitals' call for both applicants "to document the full staffing plans and related costs of their proposed cardiac surgery programs" by providing a new exhibit it describes as summarizing its staffing projections and adding comments to correct the MedStar Hospitals' misunderstanding and incomplete examination of BWMC's previous filings. (DI #42GF, Exh. 54). This document specifically identifies one additional FTE perfusionist, as well as call coverage for anesthesiology and "CT assist," both as described and quantified in the previous paragraph.

BWMC provides data regarding the UM Division of Cardiac Surgery staffing and recent production, as follows: 12 surgeons, with two assigned to UMSJ on a full-time basis/two operating one-two days per week; one surgeon assigned to PGHC full time/two others part time; and nine surgeons at UMMC, assisting with coverage at St. Joseph and PGHC. (DI #42GF, p. 23). It identifies "individual surgeon volumes" of 125 to 400 cases per physician[61] and notes that St. Joseph physicians "carry a caseload of approximately 200 cases per physician, per year." (DI #42GF, p. 23). BWMC identifies ten departments that will be affected by cardiac surgery but that have available capacity to provide the needed support for cardiac surgery without the need for expansion of personnel. It notes that a full-time nurse practitioner employed through the University of Maryland Community Medical Group will serve cardiac surgery patients on an outpatient basis but, given that the expenses and associated revenue or these clinical services are not incurred by BWMC, they are not included in BWMC's projections. (DI #42GF, p. 24).

BWMC states that the MedStar Hospitals falsely raise the issue of non-compliance with the Joint Commission's Proposed Requirements for Comprehensive Cardiac Center Certification Program ("CCCM"). BWMC states that the CCCM is a proposed certification program, "not yet adopted." BWMC reviews the CCCM resources requirements and asserts that BWMC's staffing plan for cardiac surgery either includes these resources or that the resources are currently available at the hospital. (DI #42GF, p. 24).

[61] Presumed to be annual case volumes.

BWMC refutes AAMC's claim concerning the replacement operating room project approved in 2015 as a component of this BWMC application for cardiac surgery. It states that cardiac surgery will be performed in two ORs currently in place and approved almost six years ago. It outlines recent trends in surgical case volume to make the point that it has sufficient OR capacity to implement the proposed program and provides projections of OR capacity and use intended to make the same point. (DI #42GF, pp. 24-26).

BWMC states that AAMC's comment concerning the impact of reduced charity care on global budget revenue is unsupported and that the provision cited by AAMC as a basis for the comment does not exist in UMMS' GBR agreement with HSCRC. BWMC states that the decrease in charity care has had "no material adverse effect on revenue." (DI #42GF, pp. 26-27).

Reviewer's Analysis and Findings

AAMC has shown that it could establish a cardiac surgery program with little or no risk that implementation of the program would cause AAMC to generate losses from its hospital operations. AAMC has projected, however, that based on HSCRC policy with respect to recognizing additional revenue deriving from shifts in service volume from one hospital to another, the revenue AAMC would add as a direct effect of providing cardiac surgery will be less than the expenses of providing this new service. This creates a problem with respect to finding this application in compliance with this standard, based on the documentation requirement in subparagraph (b)(iv) and is thus, not surprisingly, the central issue with respect to financial feasibility addressed by both applicants and other interested parties in this review.

I find that AAMC has documented the assumptions it used in modeling revenues and expenses at the utilization levels projected. I found, earlier in this Revised Recommended Decision, that AAMC could reach the minimum case volume required for a cardiac surgery program, primarily based on a hospital service area-level analysis.[62] AAMC documented that its utilization projections are consistent with historic trends in the use of cardiac surgery by its service area population, as required by this standard. If AAMC achieves a case volume of 200 cases per year but is unable to significantly surpass this service volume in the first few years of operation, the information and analysis provided in this review indicates that, fundamentally, the pattern outlined in the previous paragraph will hold. That is, AAMC will not be able to account for higher cardiac surgery revenue than expenses under the current HSCRC policy for adjustment of GBR to account for inter-hospital case volume shifts but the marginal change in revenues and expenses will be unlikely to make the hospital's overall operation unfeasible. Less revenue will be realized at lower case volumes and it is quite possible that operating losses could be nominally and/or proportionally larger, depending on whether AAMC is successful in managing expenses in line with volume. AAMC projects an average of 322 cases in the first three years of operation.

My findings with respect to the proposed BWMC program are similar. It is also likely to be able to establish a cardiac surgery program with minimal risk of causing the hospital to operate at a loss. Under HSCRC's current payment policies and its market shift model used to project revenues, it is unlikely, on a stand-alone basis, to generate excess revenue over expenses in

[62] See my discussion of the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

delivering cardiac surgery services. BWMC also documented the assumptions it used in modeling revenues and expenses.

I previously found that each applicant overestimated its ability to achieve the cardiac surgery market shares it projects for its service area.[63] While I concluded that AAMC can meet the required threshold volume of 200 cases per year, it may not be able to achieve the volume levels it projects. I also found that BWMC would be unlikely to reach the minimum case volume required for a cardiac surgery program, based on a hospital service area-level analysis.

The interested parties have raised some reasonable questions with respect to expense projections and assumptions underlying some of the secondary analyses presented by the applicants regarding the benefits of the proposed projects. However, each applicant has convincingly answered the questions raised with respect to its staffing plan. Each applicant is working with a system affiliate or partner hospital that is an academic medical center. Together, the two collaborating hospitals are the largest providers of cardiac surgery in Maryland and each applicant hospital is a relatively large community hospital with substantial experience in providing major surgery procedures and helping patients recover from major surgery.

I find that there is substantial documentation in the record that each of the four organizations supporting at least one of the projects has a commitment to providing high quality health care, as evidenced by each hospital's history of accreditation, certifications, awards, and other recognitions. Obviously, each applicant is expected to put forth a staffing plan that is lean and that assumes a high degree of collaboration and, especially in the case of BWMC, integration of staffing services at a multi-hospital division level. After carefully reviewing the arguments and counter-arguments presented, I find that each applicant has documented that its staffing and overall expense projections for cardiac surgery have a basis in current expenditure levels. Each applicant has considered future staffing levels in its staffing plan for cardiac surgery using both its own cost experience and the experience of similar hospitals.

AAMC provided a credible and realistic response to the MedStar Hospitals' criticism of its staffing plan and, thus, its expense projections. I also found that BWMC provided a credible response to the criticism by AAMC and the MedStar Hospitals of BWMC's staffing plan and expense projections. It appears that these interested parties understated some of the capabilities and resources provided in that plan and I conclude that BWMC documented collaborative support in personnel planning at a system level. BWMC made a convincing case in response to AAMC's argument that its capital budget is erroneous and that BWMC is replacing OR capacity to implement the proposed project. BWMC also identified the effect of reduced charity care expense on revenue to be small under the new hospital payment model to date, effectively responding to AAMC's comment on this issue. However, I cannot agree with BWMC's description of program operational savings by UMMC because, as noted by interested parties, BWMC has not clearly and specifically linked all of the changes underlying those expense reductions to the start-up of a new program at BWMC.

[63] See my analysis of each applicant's compliance with the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

With both AAMC and BWMC, I conclude that, based on comments and responses, the level of adjustment, if any, in staffing that either applicant hospital may find necessary as it implements a cardiac surgery program will be marginal and highly unlikely to change financial performance of the hospital. It is interesting that, while the MedStar Hospitals offered general criticism of the proposed staffing levels at AAMC and BWMC, it did not give specific details of the staffing of its cardiac surgery program at Union Memorial Hospital, and neither did LifeBridge provide such information about its cardiac surgery program at Sinai Hospital.

This leaves the key issue of assessing financial feasibility of these proposed programs. BWMC proposes that this assessment should be at the system divisional level, whereas AAMC proposed that financial feasibility should be assessed at the overall hospital level. Assessment at the program level, as in subparagraph (b)(iv)'s reference to generation of excess revenues over expenses for cardiac surgery, is a reasonable and conventional interpretation of the standard's requirements.

Effective January 1, 2014, the State of Maryland and the Center for Medicare and Medicaid Innovation entered into a new initiative to modernize Maryland's all-payer rate-setting system for hospital services, the All Payor Model Agreement. This initiative, replacing Maryland's 36-year-old "Medicare waiver," allowed Maryland to adopt new and innovative policies aimed at reducing per capita hospital expenditures and improving patient health outcomes.[64] As a fundamental structural reform, the new payment model uses hospital Global Budget Revenue agreements that are updated over time to recognize inflation and service area population growth and aging, among other factors and, most importantly with respect to this review, can also be adjusted to recognize shifts in market share for specific services that would be expected to occur when hospitals introduce new services.

It is important to note that HSCRC's current policy on adjusting GBRs for market shifts was formally first stated in its August 24, 2016 memorandum to me. This policy is based on the idea that increases in service volume at a hospital provide an opportunity for more efficient production of services by the hospital. Higher production of services should allow for economies of scale in operation so there does not need to be a one-to-one correspondence between the additional dollars coming into the hospital and the expenses by the hospital to produce the additional services responsible for the revenue increases. The HSCRC's current policy of not increasing the hospital's budget to recognize all additional revenue associated with the shift in volume, incentivizes the hospital to increase expenses only to the degree absolutely necessary to handle the additional service volume.

HSCRC's current policy shows that it also is cognizant that hospitals losing service volume are likely to experience increases in the unit cost of production. The "losing" hospital's fixed costs, which are usually not adjustable in the short-to-medium term, will be spread over a smaller volume of service. In the short-term, the hospital must focus on reducing variable costs but this may also take time and, to address this cost-of-production problem, the hospital may need to evaluate broader changes in its service delivery model rather than merely implementing

[64] More information on the HSCRC and Maryland hospital activities can be found on the HSCRC's website: http://www.hscrc.maryland.gov

incremental staffing and other variable cost reductions that leave the fundamental mode of operation in place. It is for this reason that HSCRC's current policy also provides these losing hospitals with the ability to retain some of the revenue that is leaving.

The Commission's standard regarding financial feasibility of a proposed cardiac surgery program was adopted as proposed permanent regulation on April 17, 2014. At that time, HSCRC was only three months into implementation of the new GBR-based hospital payment policy. It had not yet established a final policy with respect to recognizing shifts in case volume from one hospital to another but had established a Payment Models Work Group, first convened on February 21, 2014, to discuss that question, among others. Market shifts were not used as a basis for updating and adjusting hospitals' budgeted revenue for the fiscal year that ended on June 30, 2015. Market shifts as a factor in adjusting GBR were not part of the HSCRC's update process until FY 2016.[65]

The CON applications in this review were filed in early 2015. As I previously noted, AAMC projected its financial projections on the basis that it would seek and obtain from HSCRC, through adjustment of its GBR, recognition of 85% of the full revenue associated with cardiac surgery cases shifting from other hospitals. At that point in time, HSCRC had already articulated a plan for using a 50% variable cost factor in adjusting GBR when case volumes shifted (or, in other words, when one hospital increased its market share of a service at the expense of another hospital). BWMC chose to use what could be considered HSCRC's latest guidance, the 50% variable cost factor, in its projection model. By July 1, 2015, the manner in which market shifts were recognized in updating hospital budgets can be viewed as established by HSCRC, given that policy was used in the update of hospital GBRs at that time. Definitive guidance contrary to AAMC's assumption was not provided until August 24, 2016, in HSCRC's response to questions I posed on the projects. (DI #68GF).

When the Commission adopted the Cardiac Surgery Chapter as a final regulation on July 27, 2014, it could not have foreseen that later HSCRC policy would make it extremely difficult (and virtually impossible) for a new cardiac surgery program to generate excess revenues over total expenses when isolating just on the revenues and expenses directly attributable to the cardiac surgery services. This is particularly true under the circumstances acknowledged in the Cardiac Surgery Chapter, where introduction of a new cardiac surgery program would necessitate redistribution of service volume among hospitals. The Commission did not intend for later-adopted HSCRC policy to thwart its intent to permit appropriate entry of one or more additional high quality cardiac surgery programs in Maryland.

If it had been possible to know in the 2013 to 2014 period during which the Cardiac Surgery Chapter was developed, how HSCRC would elaborate its payment model to account for shifts in market share for specific services from one hospital to another in adjusting GBR, the Commission would not have adopted a financial feasibility standard that required a new service line, on a stand-alone basis, to generate revenue over expenses. Instead, it is likely that the Commission would have adopted a financial feasibility standard more like the one that is in place for general hospital services. That standard, COMAR 10.24.10.04B(13) is, in its primary form, very similar to the cardiac surgery financial feasibility standard. It provides that "[a] hospital capital project shall be

[65] A detailed explanation of the factors used in updating GBRs for FY 2014 through FY 2016 can be found on the HSCRC website at http://www.hscrc.maryland.gov/hsp-gbr-tpr-update.cfm

financially feasible and shall not jeopardize the long-term financial viability of the hospital." However, the general hospital service standard goes on to state "that a hospital may receive a Certificate of Need for a project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project when the hospital can demonstrate that overall hospital financial performance will be positive and that the services will benefit the hospital's primary service area population."

Thus, while I believe the differences in these two standards were intentional, the ultimate jelling of the HSCRC's new payment model's policy details were, unfortunately, unknown at the time this standard was developed and adopted. The ultimate impact of HSCRC's current payment policies on this standard was not foreseen. However, the standard, in its simplest form, grants the Commission some flexibility, if certain other conditions hold. The simple initial statement of the standard is that "[a] proposed new or relocated cardiac surgery program shall be financially feasible and *shall not jeopardize the financial viability of the hospital*." (COMAR 10.24.17.05A(7)) (emphasis added). This wording provides support for an alternative to an overly rigid interpretation of the requirement at subparagraph (b)(iv) to arrive at one that is in accord with regulatory intent in adopting the financial feasibility standard. If the only test of financial feasibility were adequate documentation that the program will be profitable on a stand-alone basis, there could never be any question that a proposed new program, if financially feasible, could ever be a basis for jeopardizing the financial viability of the sponsoring hospital. Thus the language in .05A(7) evidences the intent of the Commission, particularly given the policies of the HSCRC that were only firmly enunciated in August, 2016.

I find that, when the entirety of the financial feasibility standard and the context of its adoption are considered, the Commission's regulatory intent was to permit flexibility in its assessment of financial feasibility at the hospital level. The Commission intended that it could authorize introduction of a new cardiac surgery program (or relocation of an existing program) that meets all other standards and criteria and that will benefit Maryland's health care delivery system if the financial viability of the hospital is not jeopardized by the introduction of the cardiac surgery program. Such flexibility is especially important with respect to the particular circumstances in this review. As I have previously discussed,[66] I find that each project is likely to create a more cost-effective alternative for the delivery of cardiac surgery in Maryland than is possible under the status quo. It is an overarching priority policy objective for Maryland to look for more cost-effective ways to provide hospital-based care, which has been a major focus of health policy in the State since its execution of the new All-Payer agreement with CMS. As noted, neither proposed program is likely to jeopardize the successful operation of any existing cardiac surgery program.

I find that each proposed program would be able, from a conventional accounting perspective, to generate payments for cardiac surgery, at their projected charge levels, that would exceed their expenses to provide the service. Each applicant's inability to realize all the revenue that could be collected from billable charges is a function of Maryland's hospital payment model and HSCRC's current treatment of shifts in volume.

[66] See my discussion of each applicant's compliance: with the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra*, pp. 62-66; and with the impact standard, COMAR 10.24.17.05A(2), *supra*, pp. 42-45.

These realities compel each applicant to model its financial performance on the Maryland payment model's rules for adjusting GBR in response to shifts in market share. Thus, to some extent, the perspective on assessment of financial feasibility imposed by a "blinders on" interpretation of subparagraph (b)(iv) of this standard is an artifact of the payment model. At some point, if a new program is established, the dynamic of case volume shifting from one hospital to another will have no actual force or particular relevancy in looking at the performance of the involved hospitals. Eventually, a new program will begin to experience a relatively stable share of the cardiac surgery market in its service area and market share would also stabilize at the programs that exist today, i.e., the market would "settle" following a period of adjustment to the new market entrant. At that point, I believe it is highly likely that AAMC and BWMC, if each operated a cardiac surgery program, would be operating "in the black," even if its cardiac surgery program has not reached projected volume levels and even if its program expenses are marginally higher than currently anticipated. I conclude that it would not be reasonable, at that point in time, to find that the hospital had not implemented the provision of cardiac surgery services on a financially feasible basis. My interpretation of this standard is in accordance with regulatory history and the Commission's mission and its legislative directive to assure Marylanders' access to quality health care services at a reasonable cost to patients and to the health care delivery system.

For this reason, I find that AAMC's proposed project is financially feasible and that it will not jeopardize the financial viability of AAMC.

I also find that, from the narrow perspective of this standard and my assessment of the most logical way to interpret the standard, that BWMC's proposed project would be financially feasible and that it would not jeopardize the financial viability of BWMC. However, I earlier found[67] that the BWMC proposal is not feasible from a market standpoint, given the minimum case volume standard of the Cardiac Surgery Chapter and my assessment that BWMC would have difficulty reaching and maintaining an annual volume of 200 cardiac surgery cases per year.

(8) Preference in Comparative Reviews

In the case of a comparative review of applications in which all policies and standards have been met by all applicants, the Commission will give preference based on the following criteria.

(a) The applicant whose proposal is the most cost effective for the health care system.

(b) An applicant with an established record of cardiovascular disease prevention and early diagnosis programming that includes provisions for educating patients about treatment options.

(c) An applicant with an established record of cardiovascular disease prevention and early diagnosis programming, with particular outreach to minority and indigent patients in the hospital's regional service area.

(d) An applicant whose cardiac surgery program includes a research, training, and education component that is designed to meet a local or national need and for which the applicant's circumstances offer special advantages.

Because I did not find that both applicants have met all policies and standards, this standard is not applicable in this comparative review.

[67] See my discussion of the minimum volume standard, COMAR 10.24.01.05A(1), *supra*, pp. 29-35.

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(b) Need. The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

Applicants' Responses

Anne Arundel Medical Center

AAMC refers to its response to COMAR 10.24.17.05(6), the cardiac surgery project review standard for need, for its "applicable quantitative need analysis." (DI #3AA, p. 204). It states that its project would address an unmet need for "more affordable, local, and integrated cardiac care" for Anne Arundel County and its broader service area. It notes that cardiac surgery is critical when a patient requires it and often life-saving in cases of advanced cardiac pathology. It states that access is "ultimately a matter of timely availability of the service to the patient when it is needed" and notes that the delays experienced by patients when transfer and transport are arranged and implemented can impact heath status and that all delays add risks. AAMC contends that, ultimately, delays in obtaining care are detrimental to quality of care. It states that timely access and availability are inherent in the definition of quality of care and that inter-hospital patient transfers add additional risk through communication problems and increased risk of medical errors associated with "hand-off" of patients. It notes that post-surgical complications can generate another round of quality issues when quick, local access to the service is not available. AAMC references its discussion of the impact of reduced access under COMAR 10.24.17.05A(5), the access project review standard. (DI #3AA, pp. 204-206).

Baltimore Washington Medical Center

BWMC's sole response to this criterion was to reference its responses to the minimum volume standard, COMAR 10.24.17.05A(1), and to the need standard, COMAR 10.24.17.05A(6), that have been previously considered in this Revised Recommended Decision.[68] (DI #2BW, p. 112).

[68] See my summary of BWMC's responses to: the minimum volume standard, COMAR 10.24.01.05A(1), *supra*, pp. 21-22; and to the need standard, COMAR 10.24.01.05A(6), *supra*, p. 76.

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

BWMC did not specifically address the need criterion in its comments but did address a related standard, minimum volume, and at one point equates that standard with need for the project. (DI #29GF).[69]

Comments on BWMC Application

AAMC Comments

Like BWMC, AAMC did not specifically comment on the need criterion but did address, at some length, the ability of BWMC to reach the minimum volume standard's requirement of 200 cardiac surgery cases per year. (DI #28GF). AAMC argues that BWMC is unlikely to reach 200 cases per year because BWMC's analysis is based on faulty assumptions.[70]

Comments on Both Applications

LifeBridge Comments

While not specifically referencing this criterion, LifeBridge comments that neither applicant established a need for additional cardiac surgery programs in Maryland and that neither is consistent with the Cardiac Surgery Chapter. (DI #33GF). It cites the MHCC forecast of declining demand for cardiac surgery and faults the applicants for providing no evidence of inadequate servicing of need by existing programs. It claims that the applicants' justification is grounded in providing greater convenience for patients and the applicant hospitals' institutional goals. (DI #33GF, p. 2).

LifeBridge states that access to cardiac surgery, while a "legitimate consideration," is "balanced against the benefits of regionalization" in the Cardiac Surgery Chapter and, in this case, the risk of reducing case volume at existing hospitals with a consequent negative impact on quality of care. It cites a 2014 journal article that found that higher risk-adjusted mortality for CABG was correlated with lower case volume programs. (DI #33GF, p. 2, *citing* Gonzalez, Dimick, Birkmeyer, Ghaferi, "Understanding the Volume-Outcome Effect in Cardiovascular Surgery: The Role of Failure to Rescue": JAMA Surgery, 2014: 149(2): 119-123). It indirectly challenges the case volume projections of the applicants by noting that Suburban Hospital, the newest cardiac surgery program in Maryland, has not managed to build the case volume it projected. (DI #33GF, pp. 2-3).

[69] See my discussion of the minimum volume standard, COMAR 10.24.01.05A(1), *supra*, pp. 29-35.
[70] See n. 78, *supra*.

MedStar Hospitals Comments

The MedStar Hospitals provide a single thread of comments on both this need criterion and the specific need standard in the Cardiac Surgery Chapter, COMAR 10.24.17.05A (6). (DI #34GF, p. 5). They state that both applicants failed to demonstrate an unmet need of the population for their respective proposed programs. They also claim that "the SHP does not establish a methodology for determining the need for a new program in the state of Maryland" and that the need standard describes no unmet need. (DI #34GF, p. 5).

The MedStar Hospitals discuss population need and the reasons why they claim that need has not been demonstrated by either of the applications. They note that the Commission has identified cardiac surgery case volume as declining in the Baltimore/Upper Shore region between 2009 and 2014. They note that the Cardiac Surgery Chapter states that "'[g]eographic access to cardiac surgery services and elective PCI is not a problem in Maryland'" and state that the Commission must accept this as a finding in this review. (DI #34GF, p. 2, *quoting* COMAR 10.24.17.03: Issues and Policies, p. 11).

The MedStar Hospitals claim that existing programs are operating below their service capacity, based on the higher case volumes experienced in the previous decade, and are capable of absorbing growth in demand, indicating a lack of need for additional programs. They also cite the Cardiac Surgery Chapter's support for regionalization of cardiac surgery services as a policy that supports limiting the number of cardiac surgery programs to improve the chances for higher volume programs, higher quality service, and more efficient operation. (DI #34GF, p. 3, *citing* "Rationalizing Cardiology Care in an Era of Hospital Consolidation," CardioSource WorldNews (May 2015)).

The MedStar Hospitals predict that cardiac surgery case volume will continue to decline due to the growth in preventive care and early intervention. (DI #34GF, p. 9). They state that new techniques, such as trans-aortic valve replacement, will replace the need for cardiac surgery and new drugs, such as those used to treat high cholesterol, will also dampen demand. (DI #34GF, p. 9). They point to changing payment policies as a factor that predict less surgery in the future. The MedStar Hospitals claim that effective population health management will reduce costly inpatient service treatment whenever possible in order to profit under the new payment models. (DI #34GF, pp. 9-10).

The MedStar Hospitals state that there are no access barriers to cardiac surgery services in Maryland that can "serve as a surrogate for proving 'unmet need'" by the applicants. (DI #34GF, p. 10-12). They reiterate their view that no barriers to access have been demonstrated or could be, given that the Cardiac Surgery Chapter does not find access to be an issue. They specifically state that BWMC only claims to be improving access for persons without automobiles, a claim that the MedStar Hospitals find "farfetched" in the context of barriers to access. (DI #34GF, pp. 10-11). They see need as a disqualifying issue for each applicant, which they try to overcome by resorting to claims of inadequate access. They state that the Chou study,[71] cited by AAMC as associating the access improvements that would be created through the proposed AAMC project with better

[71] Chou *et al*., "Travel Distance and Health Outcomes for Scheduled Surgery," Medical Care, Vol. 52 No. 3 (March 2014).

outcomes, does not make that case. Rather, the MedStar Hospitals estimate levels of improvement at "an order of magnitude (in terms of travel distance) that is simply not relevant to these applications and their travel time arguments." (DI #34GF, p. 1).

Finally, the MedStar Hospitals dispute the information that AAMC provided concerning problems with transfer of patients and refusal of patients at MedStar WHC, based on its review of the record concerning transfers from AAMC and states that the Transfer Agreement between AAMC and MedStar's District of Columbia hospital "has worked well and has been renewed annually." (DI #34GF, pp. 12-14).

Anne Arundel County Comments

Neither the Anne Arundel County Department of Health nor Anne Arundel County t commented on the need criterion, but each supports authorizing the general hospitals in Anne Arundel County to provide cardiac surgery services. These comments can be viewed as stating that the County needs better access to this service. (DI #27GF; DI #26GF).

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC states that the MedStar Hospitals' assertion that the Cardiac Surgery Chapter does not establish a methodology for determining need is false. (DI #45GF, p. 4). Rather, AAMC states that the SHP Chapter establishes a standard of need for new programs, which is that a proposed new program must demonstrate an ability to generate at least 200 cardiac surgery cases per year. It notes that the Cardiac Surgery Chapter provides specific guidance on how this test is to be met, including accounting for utilization trends and patient referrals. AAMC states that the notion of excess capacity cited by the MedStar Hospitals does not appear in the Cardiac Surgery Chapter, which it notes "reflects the balance sought by the Commission between adequate access and adequate volumes at each program." (DI #45GF, p. 4).

AAMC rejects the LifeBridge's and MedStar Hospitals' references to Suburban Hospital's experience as a basis for doubting the credibility of AAMC's projections, noting closer proximity of this Bethesda hospital to existing programs when compared to AAMC's longer distance from the nearest existing cardiac surgery hospitals. (DI #45GF, pp. 5-6). It concludes with a defense of its market share assumptions, citing its relationship with JH Medicine, its success in other surgical fields, and the access improvement that its proposed project will bring to Eastern Shore residents. (DI #45GF, pp. 11-12).

Baltimore Washington Medical Center

BWMC refutes the claim made by the MedStar Hospitals that the Cardiac Surgery Chapter does not provide an applicable need analysis and states that BWMC has appropriately established need under the applicable need standard. It notes that the Cardiac Surgery Chapter does not require that an applicant address existing capacity and rejects the MedStar Hospitals' claim that there is sufficient cardiac surgery capacity as one that has no basis in regulation. (DI #42GF, pp. 2-4).

Reviewer's Analysis and Findings

I find that there is a need analysis that is applicable in this review. It is the need standard found in the Cardiac Surgery Chapter at COMAR 10.24.17.05A(6), which requires that a hospital seeking to introduce cardiac surgery as a new service demonstrate the need for that service by: analyzing the population it serves; and demonstrating that it is capable of generating at least 200 cardiac surgery cases per year from this population under reasonable assumptions concerning the market share that it will be able to achieve in the service area. The applicant hospital must also: incorporate the Commission's most recent cardiac surgery demand forecast in its need analysis; identify how many patients diagnosed with coronary artery disease at its own cardiac catheterization facilities are referred for cardiac surgery; and address how that information supports its case volume projections. Finally, the Cardiac Surgery Chapter explicitly provides that the hospital cannot "demonstrate the need" for its new cardiac surgery program on the basis that an existing cardiac surgery program has closed.

The need criterion, COMAR 10.24.01.08G(3)(b), is a general criterion established many years ago in MHCC procedural rules for the review of CON applications. The need project review standard in the Cardiac Surgery Chapter, COMAR 10.24.17.05A(6), was first established in 2014 and its title and wording show that it was intended to serve the purpose, under the need criterion, of defining an applicable need analysis for projects involving the establishment of a new cardiac surgery program or the relocation of an existing cardiac surgery program.

In my review of this applicable need analysis, I find that the AAMC proposed project meets the need standard and that the BWMC proposed project does not meet this standard, specifically subparagraph (a) of the standard.[72] On that basis, I find that AAMC has demonstrated a need for its proposed project through its compliance with the applicable need analysis of the SHP and that BWMC has failed to demonstrate a need for its proposed project through its failure to demonstrate compliance with the applicable need analysis of the State Health Plan.

I recommend that any CON issued to AAMC be issued with the following condition:

> If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(c) Availability of More Cost-Effective Alternatives. The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through

[72] See my consideration of the need standard, COMAR 10.24.17.05A(6), *supra*, pp. 78-80, and my consideration of the related minimum volume standard, COMAR 10.24.17.05A(1), s*upra*, pp. 29-35.

alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Applicants' Responses

Anne Arundel Medical Center

AAMC states that establishment of a cardiac surgery program at AAMC will create a more cost-effective alternative for cardiac surgery services than can be found at the existing programs used by its service area population. (DI #3AA, p. 207). It presents FY 2014 information on payments per cardiac surgery case and payment per-case-mix-adjusted cardiac surgery discharge for the Baltimore/Upper Shore region cardiac surgery hospitals, for Washington Adventist, and for D.C. hospitals (in the aggregate). It notes that all of the existing hospitals have higher payments per case and discharge than the corresponding payment rates AAMC calculates for its proposed program. (DI #3AA, p. 208).

AAMC also states that, "throughout this application the significant improvement in closer access, coordinated episode of care, and an historical record of enhanced patient care experience" at AAMC are effectiveness factors that should be considered along with its cost reduction. (DI #3AA, p. 208).

Baltimore Washington Medical Center

BWMC references the collaborative planning undertaken with UMMC and cardiologists in the community and affiliated with the UM School of Medicine for both PCI services and, now, cardiac surgery. (DI #2BW, p. 113). It concludes that the absence of a cardiac surgery program in Anne Arundel County is notable, given that Baltimore City and County have five programs and the D.C. suburban counties of Montgomery and Prince George's have three programs. It notes that the Cardiac Surgery Chapter identifies the mid-Shore and Southern Maryland as regions with the poorest geographic access to emergent PCI services and states that its parent system, UMMC, has a significant footprint in these areas, given UM Shore Health System and UM Charles Regional Medical Center. (DI #2BW, p. 114).

It states that the alternative to its project, maintaining the status quo, will not meet the "need for high-quality, locally available cardiac surgery services in Anne Arundel County." BWMC notes that its proposed program will provide the benefits of lower costs for cardiac surgery, integration of the BWMC and UMMC program, "enhanced geographic access for local residents," especially indigent patients in the BWMC service area without transportation options, more and better outreach programs for cardiovascular disease prevention and treatments, and "integration and shared management of quality of care initiatives and programs for cardiac surgery care between UMMC, UM SOM, and UM BWMC." (DI #2BW, pp. 114-15).

BWMC points out that it August 2015 modification made its proposed project more cost effective by allowing HSCRC recognition of market shifts between UMMC and BWMC related to cardiac surgery in the same way that market shifts among non-affiliated hospitals would be recognized. It reiterated the point in its application that its proposed program will also reduce "personal and societal costs," beyond actual charge reductions. (DI #17BW, pp. 2-6).

Interested Party and Participating Entity Comments

Comments made by AAMC, BWMC, and MedStar Hospitals on the cost effectiveness of the CON applications were focused on the cost effectiveness standard, COMAR 10.24.17.05A(4), aiming the same set of comments at this general review criterion. (DI #28GF; DI #29GF; DI # 34GF). For the sake of brevity, I will not repeat those comments here.[73] In summary, with reference to the specific construction of this criterion, AAMC touts its position as a lower cost hospital than BWMC that will have lower charges for cardiac surgery. BWMC questions the actual cost effectiveness of AAMC's proposal, on the basis that its low-cost position is not a positive characteristic of the hospital but, rather, is based on AAMC's failure to shift a large enough volume of outpatient service out of the hospital to lower cost settings. BWMC casts doubt upon AAMC's assumptions about volume and, in particular, the proportion of cases that AAMC assumes will be shifted out of District of Columbia hospitals and states that the associated savings are doubtful. The MedStar Hospitals, in opposition to both projects, emphasize that denying both applications is the most cost effective alternative to these projects, given that this means no change in the supply of cardiac surgery programs and no additional cost related to increasing supply. They state that no need exists for the proposed programs and neither would provide any benefit and would only negatively impact the existing health care system.

The comments of Dimensions and LifeBridge do not address this criterion. Dimensions' comments concern the impact of the AAMC project on PGHC's cardiac surgery program. (DI #30GF). LifeBridge states that no new cardiac surgery programs are needed in Maryland and that adding additional programs may have a negative impact, particularly on PGHC and Suburban Hospital. (DI #33GF). Neither the Anne Arundel County Department of Health, nor Anne Arundel County addressed the need criterion.

Applicants' Response to Comments

As with the comments, the responses to comments by AAMC and BWMC specifically identify with the applicable cost effectiveness standard rather than this criterion.[74] In summary, AAMC reiterates its analysis of its lower charge position among the two applicants and BWMC calculates that the difference in charges is not very large when correctly calculated.

Reviewer's Analysis and Findings

I found in my earlier review of the cost effectiveness standard of the Cardiac Surgery Chapter, COMAR 10.24.17.05A(4), that the MedStar Hospitals do not recognize the benefit to the health care delivery system from reductions in hospital charges for cardiac surgery. They also do not acknowledge the ability of AAMC or BWMC to charge less for cardiac surgery than most of the affected hospitals. The MedStar Hospitals equate lack of substantive barriers to obtaining cardiac surgery through existing facilities with a lack of need for either proposed program.

[73] See my summary of each party's comments regarding the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra,* pp. 56-62,

[74] See my summary of each applicant's responses to comments regarding its compliance with the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra,* pp.61-62.

However, the availability of cardiac surgery programs in Maryland does not mean that Maryland residents and the health care system will not benefit from a reconfiguration of the delivery system for cardiac surgery that results in additional programs that provide cardiac surgery a lower cost, if those additional programs are located at the right hospitals. I also concluded that hospitals likely to lose a substantive number of cardiac surgery cases if a new program is developed have the ability to reduce their variable costs and limit increases in unit cost associated with the proportionally small case loss.

I find that a cardiac surgery program located at AAMC is likely to have a lower cost-to-effectiveness ratio than a program located at BWMC. This finding rests on the fact that AAMC is a larger hospital that has a larger service area population than BWMC. Also, because of AAMC's location and historic referral patterns, it is in a stronger position, geographically, than BWMC. to shift cardiac surgery market share from two metropolitan areas. Thus, AAMC has the ability, on its own, to build a larger volume of cases than BWMC. Additionally, AAMC is a lower charge hospital that will be able to provide cardiac surgery at a lower charge than BWMC. Finally, AAMC's service area population, on average, resides at a greater distance from existing cardiac surgery programs than BWMC's service area population. The greater distance from existing programs increases the improved access benefit for the AAMC proposed program when compared to the BWMC proposed program.

I previously found that AAMC complies with the cost effectiveness standard, demonstrating that the benefits of its proposed cardiac surgery program to the health care system as a whole will exceed the cost to the health care system.[75] I noted that AAMC defines the benefits of its proposed project as lower charges for cardiac surgery and improved availability and access to this service for its service area population. I found that AAMC provided a quantified analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care system would be reduced as a result of its proposed cardiac surgery program. I also found that AAMC provided 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. Finally, I found that AAMC provided information on improved access and reduced travel time for cardiac surgery that would be associated with creation of a cardiac surgery program at AAMC.

I also found that BWMC provided 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 and quantified the change in effectiveness to the extent possible. It explained the steps it will take to maintain the quality of cardiac surgery care, which will involve the use of experienced surgeons and perfusionists currently providing cardiac surgery services at UMMC. It provided information on the manner in which access could improve for cardiac surgery patients in the BWMC service area. It made the case that it can be an effective provider of cardiac surgery services.

However, while BWMC provided a positive quantified analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care

[75] See my analysis of each applicant's compliance with the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra,* pp. 62-65.

system will change as a result of the proposed cardiac surgery program, I previously found that it did not demonstrate that it could establish program that will meet the minimum volume standard, especially if AAMC's proposed project is approved. Coupled with BWMC's more modest projection of system savings, which is predicated on reaching higher volumes than I found to be likely, I find that BWMC has not proposed a project that demonstrates that it is the most cost effective alternative for improving access to cardiac surgery or reducing charges for this service.

For the reasons discussed, I find that AAMC has demonstrated the cost effectiveness of its proposed cardiac surgery program. I recommend that the following three conditions be attached to any approval granted to AAMC to establish a cardiac surgery program, that relate to cost effectiveness. The applicant and JHH have agreed to the commitment embodied in these conditions:

1. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.

2. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.

3. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

I find that BWMC has failed to demonstrate the cost effectiveness of its proposed cardiac surgery program.

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(***d) Viability of the Proposal. The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.***

Applicants' Responses

Anne Arundel Medical Center

AAMC references its financial projections for its proposed cardiac surgery program and the positive operating margin it projects based on the assumptions it has made with respect to adjustment of its GBR agreement as a demonstration that the project will contribute to the

projected positive operating margin of AAMC and be sustainable. It also cites the reasonableness of its volume and expense assumptions. (DI #3AA, pp. 209-210).

In reviewing key elements of its manpower plan, AAMC notes that the three surgeons (2.5 FTEs) anticipated to perform cardiac surgery at AAMC will be full time faculty members of the Johns Hopkins University School of Medicine who are Board certified by the American Board of Thoracic Surgery. Two will be based at AAMC, and at least one cardiac surgeon will be on-call at all times. The third surgeon will be at AAMC one to two days per week and will participate in on-call activities at night during the week and on weekends. AAMC states that the cardiac surgery team will include physician assistants with experience and/or training in cardiac surgery involved in-patient evaluation, intra-operative assistance, post-operative care in the intensive care unit, the step-down unit and the outpatient clinic. Perfusionists will be full time JHU employees assigned to AAMC. (DI #3AA, pp. 209-212).

Table 21: AAMC: Staffing Plan for Proposed Cardiac Surgery Program (Third Year of Operation); Current Staffing and Staffing Expenses in Applicable Staffing Categories

Job Category	Current FTEs	Current Expense	FTE Changes Resulting from Proposed Project	Projected Expense
REGULAR EMPLOYEEES				
Administration	191.1	$26.681,926	0.5	$76,330
Direct Care				
Physician Assistant	0.0	$0	1.1	$141,585
Registered Nurse	877.9	$74,567,461	22.7	$2,070,007
Total Direct Care	*877.9*	*$74,567,461*	*23.8*	*$2,211,592*
Support				
Technical	806.5	$44,490,116	11.3	$646,957
Professional	244.2	$23,510,937	0.5	$65,896
Total Support	*1,050.7*	*$68,001,053*	*11.8*	*$712,853*
TOTAL	***2,119.7***	***$169,250,440***	***36.2***	***$3,000,775***

Source: DI #3AA, App. 1, Table L.

AAMC notes that it has strong community support for its proposed program and relates this to its history of cardiac service development which, in its view, has now reached the point that cardiac surgery is perceived as a "pressing" need. (DI # 3AA, p. 212). It references the large number of letters of support from patients, physicians, other health professionals, elected officials, and members of AAMC's Board of Directors. (DI #3AA, App. 3). Documentation of support from the existing JH program with which it will partner in developing the program was also provided. Some of the correspondence provided information about specific cases in which delays were experienced in transferring patients in Annapolis to other hospitals for cardiac surgery. AAMC states that a minimum of $5 million in program support has been pledged. (DI # 3AA, p. 212). It projects an ability to implement its proposed cardiac surgery program within nine months. (DI # 3AA, p. 213). It documents the availability of funds necessary to implement the project with its audited financial statements. (DI #3AA, Exh. 6).

After the project status conference in this review, AAMC file revised revenue and expense projections conforming with current HSCRC policy regarding changes in hospital volume resulting from shifts in market share of services and the impact of those shifts on global budget revenue.(DI #22AA). These projections show that AAMC would not generate excess revenues

over expenses in the provision of cardiac surgery services. AAMC asks for consideration of the financial feasibility of its proposed project at an institutional rather than a service program level, because the losses projected in offering cardiac surgery are not large enough to alter the ability of the hospital, as a whole, to be profitable.

Baltimore Washington Medical Center

BWMC identifies the two years of audited financial statements of UMMS as documenting the availability of sufficient cash for funding the approximate $1.3 million cost of its proposed project. (DI #2BW, p. 116). It projects an ability to implement the proposed new service within seven months of approval. (DI #2BW, pp. 29-30). BWMC included approximately 100 letters of community support for the project, highlighting support from the Anne Arundel County Executive, the County Health Officer, State legislators, leaders of religious and community organizations, and the leadership of the University of Maryland School of Medicine and Maryland Primary Care Physicians. (DI #2BW, pp. 116-117). BWMC also noted letters of support from cardiac surgery patients who spoke to the benefit of having a cardiac surgery program at BWMC as an alternative to the more distant programs available in Baltimore City. (DI #2BW, p. 117).

Table 22: BWMC: Staffing Plan for Proposed Cardiac Surgery Program (Sixth Year of Operation); Current Staffing and Staffing Expenses in Applicable Staffing Categories

Job Category	Current FTEs	Current Expense	FTE Changes Resulting from Proposed Project	Projected Expense
REGULAR EMPLOYEES				
Administration	138.0	$14,923,017	0.5	$67,000
Direct Care				
Laboratory	63.5	$3,556,000	0.5	$31,000
Patient Care Technician	246.8	$7,897,600	3.6	$136,842
Perioperative Technician	60.3	$2,592,900	1.2	$77,418
Pharmacy	37.8	$2,986,200	0.8	$95,250
Rehabilitation Services	27.3	$2,050,500	1.2	$68,034
Registered Nurse	640.9	$44,860,900	9.6	$1,089,799
Total Direct Care [1]	*1,076.6*	*$63,944,100*	*17.0*	*$1,498,343*
Support				
Quality/Care Management [2]	31.7	$2,345,800	1.0	$170,200
Other	296.0	$12,137,230	1.0	$75,000
Total Support [3]	*327.7*	*$14,483,030*	*2.0*	*$245,200*
CONTRACT EMPLOYEES				
Administration				
Physician/Dept. Agreement	-	-	0.2	$200,000
Perfusion Director	-	-	0.25	$49,500
Medical Director Anesthesia	-	-	NA	$50,000
Resident	-	-	NA	$75,000
Total Administration [4]	-	-	0.5	$374,500
Direct Care				
Perfusionists	-	-	NA	$166,000
Anesthesia Contract	-	-	NA	$166,155
CT Assist	-	-	NA	$293,250
Total Direct Care	-	-	NA	$625,405
TOTAL [5]	***1,542.3***	***$93,350,147***	***19.0***	***$2,810,469***

Source: DI #2BW, Exh. 1, Table L (revised May 6, 2015).

In July 2015, BWMC modified its application to include a commitment that BWMC and UMMC would accept 50% revenue variability for cardiac surgery cases shifted from UMMC to BWMC. (DI #17BW, p. 1). It noted that the global budget agreement between the University of Maryland Medical System and HSCRC "permits revenue to be redistributed among UMMS affiliated hospitals without applying a revenue variability factor." BWMC states that this modification makes its proposal to introduce cardiac surgery more cost effective and financially feasible.

Interested Party and Participating Entity Comments

Comments on AAMC Application

BWMC Comments

While BWMC did not specifically reference the viability criterion, it commented on AAMC's non-compliance with the financial feasibility standard in the Cardiac Surgery Chapter.[76] In summary, it stated that AAMC's program will not generate revenues that exceed expenses as required by the standard, if it had used the correct revenue model employing HSCRC's policy with respect to revenue adjustment resulting from inter-hospital market shifts, rather than AAMC's invalid assumption. (DI #29GF, pp. 27-28).

Comments on BWMC Application

AAMC Comments

While AAMC did not specifically reference the viability criterion, in its comments regarding BWMC's compliance with the financial feasibility standard of the Cardiac Surgery Chapter, COMAR 10.23.17.05A(7), it stated that BWMC's application does not show that it will have a sustainable cardiac surgery program. (DI #28GF, p. 15).

Comments on Both Applications

MedStar Hospitals Comments

The MedStar Hospitals state that neither proposed project can demonstrate that, on an on-going basis, it would have the available resources necessary to sustain the project. (DI #34GF, p. 17). They say that the core problem for both applications is "the fact that there is no unmet need to justify the addition of a new cardiac surgery service provider." The MedStar Hospitals also insist that each applicant has overestimated projected revenue and underestimated expenses, particularly for highly skilled personnel. They complain that, in addition to being short of the

[76]See my summary of BWMC's comments regarding AAMC's compliance with the financial feasibility standard, COMAR 10.24.17.05A(7), *supra*, pp. 88, 90-91.

necessary staff resources, each applicant gave incomplete details of its staffing plan. (DI #34GF, pp. 17-20).[77]

Comments on AAMC Modified Application

BWMC, the MedStar Hospitals, and Dimensions filed comments on AAMC's revised financial projections. Only the MedStar Hospitals' comments specifically reference the viability criterion. With regard to BWMC, the comments focus on the financial feasibility standard of the Cardiac Surgery Chapter.[78]

Comments on BWMC Modified Application

AAMC Comments

While AAMC did not specifically reference the viability criterion in commenting on BWMC's modification, AAMC addressed the financial feasibility standard and claimed that BWMC had produced an "unorthodox and opaque" financial feasibility analysis that failed to document financial feasibility.[79]

Applicants' Responses to Comments

As outlined in my summary of interested party comments regarding the applicants' responses to the viability criterion, few comments were specifically directed at how each or both applicants addressed this criterion, which is related to the financial feasibility standard. That standard drew many specific comments that bear, to some extent on this criterion.[80]

Reviewer's Analysis and Findings

Neither applicant specifically provided its financial projections for cardiac surgery in its response to the viability criterion, but their projections have been covered elsewhere in this Revised Recommended Decision.[81] In brief, BWMC has shown that, from the perspective of the integrated UMMC and BWMC programs described in its application, operation of the BWMC program can be sustained and generate excess revenues and expenses under the utilization, revenue, and expenses assumptions it made. BWMC does not project that its additional realized revenue will exceed its marginal expenses for adding cardiac surgery to its service mix, on a stand-alone basis, under the HSCRC payment model for recognizing budgeted revenue adjustments related to market shifts. In the case of BWMC, the volume shifts come primarily from UMMC.

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[77] See my summary of the MedStar Hospitals' comments regarding the closely related financial feasibility standard, COMAR 10.24.17.05A(7), *supra,* pp. 91-92.
[78] See n. 77, *supra*.
[79]See my summary of AAMC's comments regarding BWMC's compliance with the financial feasibility standard, COMAR 10.24.17.05A(7), *supra*, p. 89
[80] See my summary of each applicant's response to comments regarding their compliance with the financial feasibility standard, COMAR 10.24.17.05A(7), *supra*, pp. 93-95.
[81] See n. 91, *supra*.

AAMC has shown that, as a general hospital operation with its projected ability to generate operating income under the State's payment model, it can support the operation of a cardiac surgery program, under the same HSCRC treatment of revenue following market share shifts. With AAMC, these shifts are expected to come primarily from MedStar Washington Hospital Center and The Johns Hopkins Hospital.

Each applicant has shown that it has available financial and non-financial resources, including community support, necessary to implement its proposed cardiac surgery service and can meet the Commission's performance requirements in implementing its program. The availability of resources necessary to sustain either project has been widely and substantively questioned in this review and I have discussed this issue in depth in my review of the financial feasibility standard of the Cardiac Surgery Chapter.[82] Regarding the issue of long-term sustainability, I found that there is negligible risk that implementation of either proposed program or both programs would cause either hospital to generate losses from its hospital operations. AAMC has documented the assumptions it used in modeling revenues and expenses at the utilization levels projected and has also answered the questions raised regarding its staffing plans. BWMC has documented the assumptions it used in modeling revenues and expenses at the utilization levels projected and has also answered the questions raised about its staffing plans.

From a conventional accounting perspective, AAMC will be able to generate payments for cardiac surgery, at its projected charge levels, that will allow the hospital to be operationally profitable. The financial viability of AAMC will not be jeopardized. BWMC, from a conventional accounting perspective, will be able to generate payments for cardiac surgery, at its projected charge levels, that will allow the hospital to be operationally profitable. The financial viability of BWMC will not be jeopardized.

I found, in my review of the minimum volume standard, that only AAMC can demonstrate an ability to meet a projected volume of 200 adult cardiac surgery cases in the second full year of operation, without making extraordinary assumptions with respect to service area and/or market share assumptions[83]. The MedStar Hospitals argue that these projects are not viable because there is no need for a new cardiac surgery program and because projected service volumes will not be achieved. They urge me to accept their view as a basis for a negative finding on the specific criterion of viability. I cannot do so because it is inconsistent with applicable regulations and MHCC regulatory history. The MedStar Hospitals call for a narrowing of the criteria and standards that MHCC has established for CON review to a single dimension and then seek to narrow the perspective on this dimension. Their view is at odds with the approach to evaluating CON applications established in regulation, and also at odds with the need standard in the Cardiac Surgery Chapter as well as with the general need criterion in COMAR 10.24.01.08G(2), which points us to standard in the Cardiac Surgery Chapter. The MedStar Hospitals emphasize declining volume and the ability of existing programs to provide additional surgery if case volume grows, an elusive concept for a service that only requires hospital surgical facilities and an adequate staff to expand almost any existing cardiac surgery program. The MedStar Hospitals' position would eliminate the Commission's ability to consider the health care delivery system's need for lower hospital charges or the population's need for improved access to services.

[82] See my analysis of the financial feasibility standard, COMAR 10.24.17.05A(7), *supra*, pp. 95-100.
[83] My analysis of the minimum volume standard, COMAR 10.24.17.05A(1), *supra*, pp. 29-35.

I find that each applicant has the resources necessary to sustain the operation of its proposed cardiac surgery program. I note that, based on their 2015 revenue as shown in Tables 23 and 24, if AAMC and BWMC had been authorized to provide cardiac surgery in 2015, they would have ranked as the second and fourth largest community hospitals (data not shown) providing such a service in Maryland (without accounting for revenue gains from the service itself). Both hospitals generate levels of excess revenue from operations that compare favorably with the experience of existing community hospitals that provide this service. AAMC did not generate excess revenue over expenses in FY 2015 or FY 2016. In FY 2015, this was the result of advanced refunding of bonds in late 2014, to obtain lower interest rates, which required funding of an escrow account with the amount required to call the bonds in 2019. AAMC recognized a non-cash, non-operating loss on extinguishment of the debt of approximately $32 million in FY 2015. In FY 2016, this was primarily the result of net realized and unrealized losses on interest rate swap contracts, a loss of approximately $40 million, which are unique, one-time events. As shown in Table 23, AAMC had operating income in FY 2015 of $31.5 million and, in FY 2016, of $32.1 million. This compares very favorably with the operating income generated by non-academic medical center hospitals providing cardiac surgery. In FY 2015, only one community hospital with a cardiac surgery program, Sinai Hospital of Baltimore, reported a larger operating income figure. Tables 23 and 24 below, profile the financial performance of the six multi-hospital systems and two single hospital organizations that operate Maryland cardiac surgery programs.

Table 23: Financial Performance of AAMC and BWMC, FY 2014 and FY 2015 and Projected Performance, FY 2016 (dollars in millions)

	Revenue[1]	Operating Expenses	Operating Income	Excess Revenue
FY 2014				
Anne Arundel and Subsidiaries	508.3	489.5	18.8	39.2
UM Baltimore Washington Consolidated	380.2	368.2	12.0	14.9
FY 2015				
Anne Arundel and Subsidiaries	535.8	504.3	31.5	(16.2)
UM Baltimore Washington Consolidated	410.2	388.0	22.2	57.6
FY 2016				
Anne Arundel and Subsidiaries	551.1	519.0	32.1	(12.4)
UM Baltimore Washington Consolidated	387.7	373.4	14.3	8.6

Source: Audited Financial Statements, FY 2014-FY 2016 at http://www.hscrc.maryland.gov/hsp-AFS.cfm.

Table 24: Financial Performance of Hospitals Operating Cardiac Surgery Programs in Maryland and MedStar Washington Hospital Center, FY 2015 (dollars in millions)

	Cardiac Surgery Cases	Revenue [1]	Operating Expenses	Operating Income	Excess Revenue
Washington Adventist	285	227.6	218.0	9.6	8.4
Prince George's (Dimensions)	105	264.2	246.5	17.7	17.7
Sinai Consolidated (LifeBridge)	409	728.0	690.5	37.5	45.2
MedStar Union Memorial	626	431.2	421.1	10.1	9.6
MedStar Washington	1,694	NA	NA	NA	NA
Peninsula Regional	433	393.8	378.3	15.4	24.1
Suburban Consolidated (JH)	212	275.1	262.9	12.2	9.8
The Johns Hopkins	1,262	2,096.7	2.028.3	68.5	11.2
UM St. Joseph Consolidated	454	391.0	398.7	(7.7)	(11.1)
University of Maryland	1,000	1,416.0	1,362.5	53.5	13.1
Western Maryland Regional	174	305.3	280.3	24.9	24.5

Source: Audited Financial Statements, FY 2015 at http://www.hscrc.maryland.gov/hsp-AFS.cfm.
Note: Cardiac surgery cases figures are for CY 2015 except for MedStar Washington (FY 2015). Source is HSCRC Database for Maryland hospitals and. http://www.medstarwashington.org/our-hospital/facts-and-figures/#q={} for MedStar Washington.

Table 25: Financial Performance of Hospital Organizations Operating Cardiac Surgery Programs in Maryland, FY 2014 (dollars in millions)

	Cardiac Surgery Programs	Cardiac Surgery Cases	Revenue[1]	Operating Expenses	Operating Income	Excess Revenue
Adventist HealthCare	1	301	695.3	682.9	12.4	14.7
Dimensions Health Corp.	1	29	382.4	381.2	1.2	47.4
LifeBridge Health, Inc.	1	382	1,077.8	1,046.5	31.3	85.1
MedStar Health, Inc.	2	2,212	4,628.1	4,492.4	135.7	304.7
Peninsula Regional Health System, Inc.	1	431	380.2	373.9	6.3	31.1
Johns Hopkins Health System Corp.	2	1,426	5,125.5	4,938.7	186.8	338.3
UMMS Corp.	2	1,432	3,026.8	2,978.6	48.2	225.9
Western Maryland Health System Corp.	1	170	301.7	280.1	21.6	28.3

Source: Audited Financial Statements, FY 2014 at http://www.hscrc.maryland.gov/hsp-AFS.cfm.
Notes: Cardiac surgery cases are for CY 2014. Source is HSCRC and D.C. Discharge Databases.
[1] Reported as "Total unrestricted revenues, gains and other support" by UMMS; "Total unrestricted revenue and other support:" by Dimensions and Peninsula; "Total revenues, gains and other support" by Western Maryland; "Total operating revenues" by LifeBridge and Johns Hopkins; and "Net operating revenues" by MedStar.

Table 26: Financial Performance of Hospital Organizations Operating Cardiac Surgery Programs in Maryland, FY 2015 (dollars in millions)

	Cardiac Surgery Programs	Cardiac Surgery Cases	Revenue[1]	Operating Expenses	Operating Income	Excess Revenue
Adventist HealthCare	1	285	746.6	725.9	20.7	21.1
Dimensions Health Corp.	1	105	393.2	374.3	19.0	20.1
LifeBridge Health, Inc.	1	409	1,213.1	1,162.4	50.7	65.5
MedStar Health, Inc.[2]	2	2,320	5,027.2	4866.4	160.8	111.3
Peninsula Regional Health System, Inc.	1	433	397.9	384.0	13.9	25.8
Johns Hopkins Health System Corp.	2	1,474	5,540.1	5,321.2	218.9	94.1
UMMS Corp.	2	1,454	3,373.5	3,255.8	117.7	95.1
Western Maryland Health System Corp.	1	174	312.0	288.3	23.7	23.1

Source: Audited Financial Statements, FY 2015 at http://www.hscrc.maryland.gov/hsp-AFS.cfm.
Note: Cardiac surgery cases are for CY 2015 with exception of MedStar, which represents the sum of CY 2015 cases at Union Memorial and FY 2015 cases reported for MedStar Washington. Source is HSCRC Discharge Database and http://www.medstarwashington.org/our-hospital/facts-and-figures/#q={}
[1] Reported as "Total unrestricted revenues, gains and other support by UMMS; "Total unrestricted revenue and other support:" by Dimensions and Peninsula; "Total revenues, gains and other support" by Western Maryland; "Total operating revenues" by LifeBridge and Johns Hopkins; and "Net operating revenues" by MedStar
[2] The 2015 case volume for MedStar Washington is not available.

I find that AAMC and BWMC each demonstrated the availability of financial and nonfinancial resources, including community support, necessary to implement its proposed cardiac surgery program within the time frames set in the Commission's performance requirements. I also find that each applicant has demonstrated the availability of resources necessary to sustain its proposed program.

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(e) Compliance with Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

Applicants' Responses

Anne Arundel Medical Center

AAMC identified five CONs issued to it in the last 20 years and reports that all projects were satisfactorily completed. (DI #3AA, p. 215).

Baltimore Washington Medical Center

BWMC identified two CONs issued to it in the last 11 years. Each CON two conditions, which BWMC reports were met. (DI #2BW, pp. 118-19).

Interested Party and Participating Entity Comments

No party filed comments on either applicant's response to this criterion.

Reviewer's Analysis and Findings

Commission records confirm that the applicant hospitals have performed well in implementing approved capital projects. I find that the performance of each applicant in implementing previously awarded CONs has been excellent.

COMAR 10.24.01.08G(3) Criteria for Review of an Application for Certificate of Need.

(f) Impact on Existing Providers and the Health Care Delivery System. An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

Applicants' Responses

Anne Arundel Medical Center

AAMC states that its proposed project will have an impact on other hospitals, but it will not have an adverse impact on access or occupancy. (DI #2AA, p. 216). It repeats the case volume impact projections it had earlier provided in responding to the impact standard in the Cardiac Surgery Chapter, COMAR 10.24.17.05A(2). It projects having the largest nominal impact on MedStar WHC, shifting 221 cases in 2018, the first year of full operation of the proposed program. It projects "relocating" 69 cases from JHH, 29 cases from UMMC, and only very small volume shifts are projected for other hospitals.

AAMC notes that, in Maryland, the financial impact on hospitals losing volume to a new market entrant is mitigated by HSCRC policies that allow each such hospital to retain 50% of the revenue it would have received if it had retained the cases. It describes this policy as one that assures no adverse impact on Maryland hospitals in this situation, so long as the hospital can manage costs appropriately. (DI #2AA, pp. 217-218). For District of Columbia hospitals, no market share adjustments of this type would occur. MedStar WHC will lose all the revenue associated with cases it loses to AAMC. With respect to occupancy, AAMC notes that the impact of its proposed program on census is relatively small. It also projects very small impacts on the cost per equivalent case mix adjusted discharge at the affected hospitals, ranging from a half of a percent increase at MedStar WHC down to less than a tenth of one percent increase at UMMC. (DI #2AA, pp. 218-219).

Baltimore Washington Medical Center

BWMC states that its proposed program will have a positive impact on access and choice, and will result in lower costs for its service area population. (DI #2BW, p. 120). It references its

response to: the impact standard, COMAR 10.24.17.05A(2); its financial projections for the entire hospital as a source of information on the impact of the project on BWMC's revenues and expenses. (DI #2BW, Exh. 1); and its discussion on costs to the health care system in response to the cost effectiveness standard, COMAR 10.24.17.05A(4).[84]

Interested Party and Participating Entity Comments

Comments on the AAMC Application

BWMC Comments

As previously noted, BWMC states that AAMC failed to address the impact of its proposed cardiac surgery program on PGHC.[85] (DI #29GF, p. 18). It states that the AAMC project will have a negative impact on PGHC's cardiac surgery program and, for this reason, AAMC did not comply with this criterion or with the impact standard, COMAR 10.24.01.05A(2).

Dimensions Comments

Dimensions states that AAMC failed to account for PGHC in its analysis of project impact, insisting insists that the impact of an AAMC cardiac surgery program on PGHC's cardiac surgery program is likely to be existential. (DI #30GF). It notes that it is rebuilding a program that has operated at very low volume levels and states that its thus-far promising rebuilding effort is unlikely to succeed if AAMC is competing with PGHC to shift cases from District of Columbia hospitals, and if AAMC draws cases away from Prince George's County and PGHC's service area.

Comments on Both Applications

MedStar Hospitals Comments

With specific reference to the impact criterion, the MedStar Hospitals state that each proposed cardiac surgery program would adversely impact some existing programs, as acknowledged by the applicants. (DI #34GF, p. 21). They state that neither applicant has acknowledged that MHCC has "already determined that geographic access to cardiac surgery is 'not a problem' in the state of Maryland," implying that arguments with respect to the positive impact on access are invalid. It specifically references PGHC as a hospital with a "rebounding" cardiac surgery program that will be "undermined" by a new cardiac surgery program. (DI #34GF, p. 22).

[84] See my summary of BWMC's response to the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra*, pp. 57-58.

[85] See my summary of BWMC's comments on AAMC's response to the cost effectiveness standard, COMAR 10.24.17.05A(4), *supra*, pp. 58-59.

Applicants' Responses to Comments

Anne Arundel Medical Center

AAMC addresses the issue of impact on PGHC.[86] (DI #45GF, p. 26). It notes that its impact analysis identified no cardiac patients transferring to PGHC from AAMC in its impact analysis and that it identified only five cardiac surgery cases at PGHC in CY 2013. It maintains that its approach to impact analysis was legitimate and, of necessity, focused on impact on existing programs with meaningful levels of volume. AAMC argues that it cannot be expected to analyze impact on "theoretical" future volumes of an existing program but notes that its case projections are based on AAMC capturing only 14% of cardiac surgery cases generated by the Prince George's County population, indicating that its proposed program will not prevent PGHC from reaching the desired case volume or from operating a financially viable cardiac surgery program. (DI #45GF, pp. 28-29).

Baltimore Washington Medical Center

BWMC again states that its proposed program would have little impact on existing cardiac surgery programs, noting that "only 30.7% (70 cases) of the total projected volume would come from non-UMMS hospitals." (DI #42GF, p. 2).

Reviewer's Analysis and Findings

Each applicant has provided information and an analysis about the impact it projects for its proposed cardiac surgery program on: existing health care providers; occupancy; costs and charges of other providers; and costs to the health care delivery system. With respect to the impact of a new cardiac surgery program on PGHC, as I have already found, the markets that will be tapped for cases by PGHC and AAMC are sufficiently large that each can reach the target level of 200 cases per annum without having an unacceptable impact on other programs.

Each proposed cardiac surgery program would have a negligible impact on bed occupancy at the applicant hospitals and at affected hospitals. The average daily census associated with each proposed program, even when volume reaches stable levels, will be fewer than five patients. Each proposed program would also reduce charges for cardiac surgery, with AAMC likely to affect the largest charge reduction, per case and overall, based on my assessment that its potential for building case volume exceeds that of BWMC and its lower charge base. This charge reduction will have a positive impact on costs to the health care delivery system. Hospitals losing case volume to a new program are likely to see their unit cost increase, as fixed expenses are spread over a smaller base of cases. The affected Maryland hospitals will obtain some relief under HSCRC policies, which will allow them to retain 50% of the revenue associated with the lost cases. The hospitals likely to lose the most cases have large programs that can absorb this cost impact. Each applicant hospital and its partner hospital have pledged not to seek additional budgeted revenue based on the impact of the proposed program. (DI #75GF; DI #76GF).

[86] AAMC's response is summarized in my consideration of the impact standard, COMAR 10.24.17.05A(2), *supra*, pp. 36-37.

Each proposed program would have a positive impact on access to cardiac surgery. However, AAMC is geographically positioned to have the most positive impact on geographic access.

I find that AAMC's proposed cardiac surgery program will have a positive impact on charges for and access to cardiac surgery and a positive impact on health systems costs and would not result in increased costs or charges at existing facilities that outweigh these positive impacts.

I find that BWMC's proposed cardiac surgery program will have a positive impact on charges for and access to cardiac surgery and a positive impact on health systems costs and would not have the result of increasing cost or charges at existing facilities that outweigh these positive impacts. However, I have found that BWMC's proposed project should not be approved, on the basis that it does not comply with all applicable criteria and standards.

V. REVIEWER'S RECOMMENDATION

This comparative review of proposals to establish new cardiac surgery programs in Maryland is the first conducted under a relatively new State Health Plan chapter that was influenced by statutory changes that involved a rethinking of regulatory oversight for both cardiac surgery and PCI services in Maryland. It is also significantly influenced by the relatively new and evolving hospital payment model that was recently established in Maryland that creates a global hospital budget for the State. The establishment of this model is important because it constrains growth in hospital revenue in ways that were not fully known and, thus, were not considered by the Commission in 2014 when it adopted revisions to COMAR 10.24.17, the Cardiac Surgery Chapter of the State Health Plan.

The Cardiac Surgery Chapter does not provide any clear indication that Maryland needs additional cardiac surgery programs. The decline in cardiac surgery volume that began about 15 years ago suggests a need for caution and prudence in making recommendations to expand capacity. While overall case volumes have stabilized and risen in recent years, this rebound has primarily benefited the largest programs and, in the case of the two Baltimore academic medical centers, the state's highest charge programs. Maryland still has a program, at Prince George's Hospital Center that, while improving, is still operating at lower than desirable volume levels. The program at Western Maryland Health System has also slipped below the 200 cases per annum volume target. As pointed out by several parties in this review, the Cardiac Surgery Chapter does not provide support for the idea that improving access to cardiac surgery is an important need if increasing access will create poorly utilized programs. This is not the situation in this review.

Each proposed project is appealing in that it would engage the Maryland academic medical centers in support of a community hospital, in a partnership or as a system component. The basis of the appeal is the promise this brings for development of high-quality programs, sharing clinical resources, while also reducing charges for cardiac surgery cases that shift from the higher charge academic medical centers and other higher charge urban hospitals to the lower cost settings of AAMC and BWMC. As health care delivery technologies evolve, it is important that the health system reduce the costs of technologies and this is one important option that allows taxpayers to

receive the financial benefit of innovation that reduces costs. It has been an important health policy objective in Maryland to search for strategies to improve the cost-effectiveness of care in the hospital setting. I believe this type of project is a strong positive cost-effective strategy for developing cardiac surgery in Maryland at this point in time. The impact on costs to the health care system of the movement of surgery cases from high cost to lower cost settings should be monitored to confirm that this is a cost-reducing strategy and not one where costs are allowed to balloon elsewhere. To help assure that this does not happen, I requested and received financial commitments from both applicants and their collaborating partners that neither would approach HSCRC seeking to increase rates based on shifts in cardiac surgery volumes. The financial commitments received by MHCC create an important precedent.

I have concluded that AAMC brings the highest potential for establishment of a lower charge program that can also be high performing. It is the larger of the two applicants and has a larger service area base than BWMC from which to draw patients. Geographically, it is better positioned than BWMC to draw from the two urban areas where existing programs are concentrated and also better positioned to have the most positive impact on reducing travel time for cardiac surgery services, especially for the population of the Eastern Shore.

I have also concluded that only one new program should be approved at this time. The potential for maximizing the reduction of charges for cardiac surgery led me to closely and seriously consider the ability for both of these proposed projects to go forward at this time. This possibility was also based on my belief that both hospitals, with the support of their partner hospitals, could succeed in program development. As I looked through that scenario, I also considered the competitive dynamics that would result from having two new programs enter the market at the same time and the likely impact on volumes. This has a much different impact on the market than entry of an individual project, especially in the context of the overall environment of declining cardiac surgery volume. I looked at the impact on volumes objectively through a more conservative and realistic model than the different models used by each applicant. I used this model to assess the applicants' forecasts of achievable cardiac surgery case volume. In the end, I concluded that the most prudent approach is to recommend approval of the stronger AAMC application and to recommend denial of BWMC's weaker proposal, especially given its high dependence on requiring academic medical center transfers to meet minimal volumes. This recommendation does not preclude BWMC from coming back to MHCC at a future time, once there is concrete evidence of the impact on the movement of cardiac surgery volume from a high cost center to a lower cost center on cost, quality and access.

I am aware that this recommendation will not only disappoint UMMS and BWMC but will also be likely to have a proportionately small but meaningful impact on one of the MedStar Hospitals. The MedStar Washington Hospital Center probably has the greatest potential for reduced surgical cases as a result of an AAMC program. My recommendation will not necessarily be welcomed by PGHC, which is poised to join the UMMS system. My assessment is that MedStar Washington Hospital Center will continue to function as a major provider of cardiac surgery and other cardiovascular services despite added competitive pressure. PGHC and UMMS will have to compete harder for referrals if AAMC joins them as an alternative choice for Anne Arundel County and Prince George's County residents. However, as I stated in this Revised Recommended Decision, there is sufficient demand in these jurisdictions to support both the PGHC program and

a new program at AAMC at the 200 cases per year level. Obviously, neither program is guaranteed to succeed nor is it the objective of this review to provide such guarantees. The recent performance of PGHC suggests that it may soon be operating at levels of volume it has not previously experienced, making its challenge one of holding market share rather than gaining market share, which may be an easier objective. It is also relevant that PGHC will be reborn at a new location with new hospital facilities in just a few years. This development also provides some assurance that PGHC can more effectively compete in an altered landscape. In short, I do not believe that Maryland stakeholders should forego the positive gains from lower charges, improved access, and cost-effective health system innovation offered by the AAMC project in order to shelter existing providers from healthy competition. It is not the role of MHCC to create barriers to competition. Rather, the entire health system benefits from healthy competition within the guidance of the Maryland State Health Plan.

The basis for my recommendation that the Commission approve the AAMC project, with conditions, is my finding that AAMC complied with all applicable State Health Plan standards in this review. I also found, under the other review criteria, that AAMC demonstrated that it will meet a need for lower charges for and improved access to cardiac surgery services, that it is a cost-effective alternative for meeting those needs, that it will be a viable project, and that it will have a positive impact on the health care system and generate systems saving while not having an adverse impact on existing hospitals that would warrant denial of the project. In terms of the financial feasibility standard, I find that when the entirety of that standard and the context of its adoption are considered, the Commission's regulatory intent was to permit flexibility in its assessment of financial feasibility at the hospital level and that AAMC meets the financial feasibility standard at the hospital level.

The basis for my recommendation that the Commission deny the BWMC application is my finding that BWMC did not comply with all of the applicable State Health Plan standards in this review. I found that it did not comply with the Minimum Volume standard, the Need standard, or the Cost-Effectiveness standard in the Cardiac Surgery Chapter. BWMC did not propose improved access as a justification for its proposed project under the Access standard.

I recommend that the AAMC application, (Docket No. 15-02-2360) for a Certificate of Need to establish a cardiac surgery program be approved with four conditions:

1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.

3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.

4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

I also recommend that the Commission staff monitor the impact of any approval in this review on the movement of cardiac surgery volume from a high cost center to a lower cost center. This impact assessment should examine the impact on the cost of, quality of, and access to cardiac surgery services. This assessment should be reported to the Commission on an annual basis for the next four years.

IN THE MATTER OF	*	**BEFORE THE**
	*	
BALTIMORE/UPPER SHORE	*	**MARYLAND HEALTH**
	*	
CARDIAC SURGERY REVIEW	*	**CARE COMMISSION**
	*	
Anne Arundel Medical Center	*	
Docket No. 15-02-2360	*	
	*	
University of Maryland	*	
Baltimore Washington Medical	*	
Center	*	
Docket No. 15-02-2361	*	

*** ***

Based on the analysis and findings in the Reviewer's Revised Recommended Decision, it is this 23rd day of March, 2017, **ORDERED:**

That the application of Anne Arundel Medical Center for a Certificate of Need to introduce cardiac surgery services at a total project cost of $2,500,381 is **APPROVED** subject to the following conditions:

1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).

2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.

3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.

4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.

It is further **ORDERED:**

That the application of the University of Maryland Baltimore Washington Medical Center for a Certificate of Need to introduce cardiac surgery services is **DENIED**.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1

Procedural Record

Anne Arundel Medical Center

Docket No. 15-02-2360

Docket Item #	Description	Date
1	Commission staff acknowledged receipt of Letters of Intent to file CON applications.	12/8/14
2	Montgomery to McDonald, Certificate of Service for Letters of Intent to local health departments.	12/8/14
3	The applicant filed its application for Certificate of Need.	2/20/15
4	The applicant certified that it delivered copies of its Application for Certificate of Need to the health departments of Anne Arundel County, Baltimore City, Baltimore County, Caroline County, Carroll County, Cecil County, Kent Count, Harford County, Howard County, Queen Anne's County, Talbot County and Baltimore Washington Medical Center.	2/23/15
5	Commission staff acknowledged receipt of application for completeness review.	2/24/15
6	Various letters of support for the project were filed.	Various dates
7	Following completeness review, Commission staff requested additional information before a formal review of the CON application could begin.	3/10/15
8	Commission staff received responses to completeness questions from counsel for the applicant, Jonathan Montgomery.	3/30/15
9	Montgomery to McDonald, Certificate of Service for the completeness information.	3/31/15
10	McDonald to Widerlite, request for clarification re: Chart 45	4/21/15
11	Commission staff requested additional information from the applicant.	4/22/15
12	Commission staff received responses to additional information questions from counsel for the applicant, Jonathan Montgomery.	5/6/15
13	Montgomery to McDonald, Certificate of Service for the completeness information.	5/8/15

14	Commission staff notified the applicant that the formal start of the review of its application would be June 26, 2016.	6/4/15
15	Commission staff requested comments from the Health Departments of Baltimore City, and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Queen Anne's, and Talbot Counties on the application in this matter.	6/5/15
16	Montgomery to McDonald, Exhibit 28, Letter from Howard County Health Department in support of application.	6/16/15
17	Commission staff received notice from Harford County Health Department that it declined to comment on this matter.	6/17/15
18	Commission staff received notice from Baltimore County Health Department that it declined to comment on this matter.	6/18/15
19	Commission staff received Notice from Talbot County Health Department that it declined to comment on this matter.	6/22/15
20	Letter of support for AAMC from CareFirst BCBS	7/27/15
21	Commission staff to Hall acknowledging receipt of its request to receive notification of the review on behalf of Peninsula Regional Medical Center	10/1/15
22	AAMC's modification as a result of the project status conference	11/7/16
23	Disc containing AAMC's modification	11/8/16

Baltimore Washington Medical Center

Docket No. 15-02-2361

Docket Item #	Description	Date
1	Commission staff acknowledged receipt of Letters of Intent to file CON applications.	12/8/14
2	The applicant filed its application for Certificate of Need.	2/20/15
3	Commission staff acknowledged receipt of application for completeness review.	2/24/15
4	Dame to McDonald, Certificate of Service for application.	2/25/15
5	Following completeness review, Commission staff requested additional information before a formal review of the CON application could begin.	3/30/15
6	Commission staff received responses to completeness questions from counsel for the applicants, Thomas Dame.	3/30/15
7	McDonald to McCollum, request for second set of completeness information.	4/22/15
8	Dame to Potter, BWMC's response to second set of completeness questions.	5/6/15
9	Dame to Potter, supplemental response to completeness questions.	5/20/15
10	Dame to Potter, copy of letter Adil Daudi at UMMS that addressed certain statements made by AAMC.	6/3/15
11	Commission staff notified the applicant that the formal start of the review of its application would be June 26, 2016.	6/4/15
12	Commission staff requested comments from the Health Departments of Baltimore City, and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Queen Anne's, and Talbot Counties on the application in this matter.	6/5/15
13	Dame to Potter, response to additional information question in docketing letter.	6/11/15
14	Commission staff received Notice from Harford County Health Department that it declined to comment on this matter.	6/17/15
15	Commission staff received notice from Baltimore County Health Department that it declined to comment on this matter.	6/18/15

16	Commission staff received Notice from Talbot County Health Department that it declined to comment on this matter.	6/22/15
17	The applicant filed its modified application for CON.	8/10/15
18	Commission staff posted Notice for Request for Comments on the Modified Application on the MHCC website.	8/11/15
19	Thomas Dame filed a clean copy of page 11 for BWMC's modified application.	8/11/15

Baltimore/Upper Shore Cardiac Review

General File

Docket Item #	Description	Date
1GF	List of attendees for the pre-application conference	12/17/15
2GF	Email from Thomas Dame on behalf of UM-BWMC to Commission staff requesting information on cardiac utilization and a 30-day extension to file CON applications for cardiac surgery. The applicant filed its application for Certificate of Need	1/16/15
3GF	Letter to Commission staff from Jerry Walker, Chairman of the County Council of Anne Arundel County, with a copy of a resolution urging the Commission to support the establishment of a cardiac surgery program in Anne Arundel County.	1/21/15
4GF	Email from Jonathan Montgomery on behalf of AAMC requesting that the Commission not extend the application due date.	1/22/15
5GF	Email from Suellen Wideman. A.A.G. to Dame and Montgomery regarding the revised review schedule for applications for CON to establish cardiac surgery services and updated 2019 cardiac surgery utilization projections.	1/26/15
6GF	Email from Jonathan Montgomery on behalf of AAMC requesting clarification of Table L of the CON application for cardiac surgery.	2/4/15
7GF	Letter from Kevin McDonald to Montgomery and Dame regarding completion of Table L in the CON application.	2/6/15
8GF	Email from Wideman to Dame and Montgomery regarding documents in response to Dame's request of January 16, 2015 for projections and data.	2/10/15
9GF	Commission staff requested that the *Baltimore Sun* publish notice of receipt of applications in this matter.	2/24/15
10GF	Commission staff requested that *The Capital* publish notice of receipt of applications in this matter.	2/24/15
11GF	Commission staff requested that the *Maryland Gazette* publish notice of receipt of applications in this matter.	2/24/15
12GF	Commission staff requested that the *Maryland Register* publish notice of receipt of applications in this matter.	2/24/15

13GF	Acknowledgment of receipt of MedStar's request to receive notification on the review	2/24/15
14GF	Notice of receipt of applications as published in the *Baltimore Sun.*	3/3/15
15GF	Notice of receipt of applications as published in *The Capital.*	3/11/15
16GF	Emails from McDonald to Dame and Montgomery granting extension of time to file responses to the Commission's completeness questions.	3/24/15
17GF	Commission staff requested that the *Baltimore Sun* publish notice of docketing of applications in this matter.	6/4/15
18GF	Commission staff requested that *The Capital* publish notice of docketing of applications in this matter.	6/4/15
19GF	Commission staff requested that the *Maryland Gazette* publish notice of docketing of applications in this matter.	6/4/15
20GF	Commission staff requested that the *Maryland Register* publish notice of docketing of applications in this matter.	6/4/15
21GF	Dame to McDonald and Wideman regarding whether the CON applications would be a comparative review or separate reviews.	6/9/15
22GF	Willis to Wideman request for clarification on preliminary procedure for MedStar's interested party status.	6/11/15
23GF	Certification from the *Baltimore Sun* of publication of docketing notice in this matter.	6/16/15
24GF	Certification from the *Maryland Gazette* of publication of docketing notice in this matter.	6/27/15
25GF	Request from Mayor Mike Pantelides that City of Annapolis be a participating entity in the review.	7/15/15
26GF	Request from County Executive Steven R. Schuh that Anne Arundel County be a participating entity in the review and comments on applications.	7/21/15
27GF	Interested party request and comments from Anne Arundel County Health Department.	7/23/15
28GF	Montgomery to Park, AAMC's comments on BWMC's application.	7/27/15
29GF	Dame to Potter, BWMC's comments on AAMC's application.	7/27/15

30GF	McSherry to Parker, interested party Dimensions Health Corp., d/b/a Prince George's Hospital Center, request and comments on the AAMC application.	7/27/15
31GF	McSherry to Parker, request for Evidentiary Hearing.	7/27/15
32GF	McSherry to Parker, request to be advised of further notice of proceedings.	7/27/15
33GF	Meltzer to McDonald, interested party request and comments on AAMC and BWMC applications from LifeBridge Health.	7/27/15
34GF	Brennan to Parker, interested party request and comments on AAMC and BWMC from MedStar Union Memorial and MedStar Washington Hospital Center.	7/27/15
35GF	Burrell to Parker, comments from CareFirst BCBS on the applications	7/27/15
36GF	McSherry to Parker, attestation of Lisa Goodlett and Certificate of Service for Dimensions' Comments on the AAMC application.	7/31/15
37GF	Email request from Richard McAlee (representing LifeBridge Health) request to receive notice.	8/6/15
38GF	Brennan to Parker, Request for an Evidentiary Hearing on behalf of MedStar.	8/7/15
39GF	Dame to Potter, Request for Evidentiary Hearing on behalf of BWMC.	8/10/15
40GF	Wideman email to Dame, Montgomery, Brennan, Wills, McAlee, Suldan, McSherry, Schuh regarding guidance request for submitting response to comments	8/14/15
41GF	Wideman email to Dame, Montgomery, Brennan, Wills, McAlee, Suldan, McSherry, that response to comments and comments on BWMC application would be due on 8/25/15	8/14/15
42GF	Dame to Potter, BWMC's Response to Comments Submitted by Interested Parties.	8/25/15
43GF	Dame to Potter, BWMC's Opposition to the City of Annapolis' Request to be Granted Participating Entity Status and Motion to Strike City of Annapolis' Comments.	8/25/15
44GF	Dame to Potter, Opposition to the CareFirst BCBS' Request to be Granted participating Entity Status and Motion to Strike CareFirst BCBS' Comments.	8/25/15
45GF	Montgomery to Parker, AAMC's Response to Interested Party Comments.	8/25/15
46GF	Montgomery to Parker, AAMC's Comments on Modified Application of BWMC.	8/25/15

47GF	Burrell to Parker, CareFirst BCBS' letter of 7/27/15 was intended as a letter of support for AAMC and not a request for participating entity status.	9/3/15
48GF	Email request and grant of extension for BWMC to file response to AAMC's comments on modified application.	9/4/15-9/8/15
49GF	Email for CareFirst BCBS' Chet Burrell that he does not want to be copied on correspondence.	9/8/15
50GF	Email, AAMC request to replace Exhibit 23f with corrected version.	9/11/15
51GF	Montgomery to Parker, AAMC's Response to BWMC's Request for Evidentiary Hearing.	9/14/15
52GF	Montgomery to Parker, AAMC's Response to BWMC's Opposition to the City of Annapolis' Request to be Granted Participating Entity Status and Motion to Strike City of Annapolis Comments.	9/14/15
53GF	Dame to Potter, BWMC's Response to Comments Submitted by AAMC Concerning BWMC's Modification to CON Application.	9/28/15
54GF	Aiken to Potter, Reply in Further Support of BWMC's Motion to Strike City of Annapolis' Comments.	10/9/15
55GF	Tanio to Montgomery/Dame/McSherry/Meltzer/Brennan/Chan Interested Party Status granted to MedStar Union Memorial, MedStar Washington Hospital Center, Prince George's Hospital Center, Sinai Hospital, and Anne Arundel County Health Department.	12/8/15
56GF	Steffen to Pantelides and Schuh, denying participating entity status to City of Annapolis, granting participating entity status to Anne Arundel County.	12/8/15
57GF	Montgomery to Parker, AAMC Motion to Enter Supplemental Statements of Support.	1/12/16
58GF	BWMC Response to AAMC Motion to Enter Supplemental Statements of Support.	1/26/16
59GF	MedStar Health's Opposition to AAMC Motion to Enter Supplemental Statements of Support and Motion for Declaratory Ruling to Close Substantive Record Pending Establishing of Evidentiary Hearing Procedures.	1/27/16
60GF	Email from Washington Adventist, report for record, Delivering Value in Cardiac Surgery for the State of Maryland.	1/28/16

61GF	Malick to Parker, Interested Party Dimensions Health Corporation d/b/a Prince George's Hospital Center's Opposition to AAMC's Motion to Enter Supplemental Statements of Support.	6/24/16
62GF	McSherry to Parker, Interest Party Dimension Health Corporation d/b/a Prince George's Hospital Center's Motion to Supplement its Comments to the Application for CON of AAMC.	6/24/16
63GF	Montgomery to Tanio, request a status update on the review.	7/14/16
64GF	Tanio to Kinzer/Schmith, request for HSCRC comments on applications.	7/15/16
65GF	Tanio to Montgomery/Dame/McSherry/Suldan/Brennan/Chan, Ruling on Request for Evidentiary Hearing.	7/21/16
66GF	Montgomery to Tanio, AAMC's Response to Dimensions' Motion to Supplement Comments.	7/29/16
67GF	McSherry to Parker, Dimensions' Response to AAMC's Response to Dimensions' Motion to Supplement Comments.	8/12/16
68GF	Kinzer/Schmith to Tanio, HSCRC comments on applications.	8/24/16
69GF	Tanio to Montgomery/Dame, request commitments from applicants on matters raised by HSCRC.	10/5/16
70GF	Emails Wideman/Montgomery/Dame, response to October 5, 2016 letter should be submitted by October 14, 2016.	10/7/16
71GF	Montgomery to Tanio, request that response to October 5, 2016 request be due by October 19, 2016.	10/11/16
72GF	Dame to Tanio, comments on allowing AAMC to revise its financial schedule to conform with standard HSCRC policy.	10/11/16
73GF	Tanio to Montgomery/Dame, responses will be due October 17, 2016.	10/11/16
74GF	Montgomery to Tanio, Motion to Enter a Revised Curriculum Vitae.	10/5/16
75GF	Montgomery to Potter, AAMC's response to the October 5, 2016 letter requesting commitments.	10/17/16
76GF	Olscamp to Tanio, BWMC's response to October 5, 2016 letter requesting commitments.	10/17/16

77GF	Tanio to Montgomery/Dame/ McSherry/Meltzer/Brennan/Chan – ruling and notice of project status conference and request availability of representatives to attend project status conference on 10/27/16	10/21/16
78GF	Dame to Tanio – BWMC seeks decision and direction concerning procedural posture of review	10/21/16
79GF	Aiken to Tanio – BWMC's Motion to Strike the Modification of Anne Arundel Medical Center	10/21/16
80GF	E-Mail –Montgomery to Wideman – AAMC's availability and representatives for status conference	10/24/16
81GF	Dame to Tanio – BWMC's availability for status conference	10/24/16
82GF	Willis to Tanio/Dame/ Montgomery/Meltzer/McSherry/ Chan – MedStar's availability for project status conference	10/24/16
83GF	McSherry to Tanio – Dimensions' availability for status conference	10/24/16
84GF	E-mails Wideman/Dame/ Montgomery/Meltzer/Brennan/ McSherry/Chan – confirmation that 10/27/16 will be date of status conference	10/24/16
85GF	E-mail Wideman/Dame/ Montgomery/Meltzer/Brennan/ McSherry/Chan – additional representative for AAMC for status conference	10/25/16
86GF	Tanio to Dame/ Montgomery/Meltzer/Brennan/ McSherry/Chan – project status conference date and time	10/25/16
87GF	Dame to Tanio – List of BWMC's representatives for status conference	10/25/16
88GF	McSherry to Tanio – List of Dimensions' representatives for status conference	10/25/16
89GF	Transcript of Project Status Conference	10/27/16
90GF	Tanio to Dame/Montgomery – Project Status Conference Summary	10/28/16
91GF	Montgomery to Tanio – AAMC will submit revised application	10/31/16
92GF	Tanio to Montgomery/Dame Meltzer/Brennan/ McSherry/Chan - ruling on pending motions and notice of closing of record	10/31/16
93GF	Jeffries to Tanio/Potter – Dimensions' comments on modification by AAMC	11/14/16
94GF	Dame to Tanio – BWMC's comments on modification by AAMC	11/14/16
95GF	Brennan to Tanio – MedStar's comments on modification by AAMC	11/14/16
96GF	Brennan to Tanio – MedStar's Motion for Oral Argument	11/14/16

97GF	Tanio to Montgomery/Dame/ McSherry/Meltzer/Brennan/Chan – ruling and entry in record of: zip code area population data sets obtained by MHCC from Neilsen Claritas; FY 2016 audited financial statements of AAMC and UMMS	12/30/16
98GF	Tanio to Commissioners/ Applicants and Interested Parties – Reviewer's Recommended Decision	12/30/16
99GF	Anne Arundel Medical Center Response to Recommended Decision	1/11/17
100GF	Dame to Potter – BWMC's Exceptions to Recommended Decision	1/11/17
101GF	McSherry to Parker – Dimensions Exceptions to Recommended Decision	1/11/17
102GF	MedStar Health Exceptions to Recommended Decision	1/11/17
103GF	Anne Arundel Medical Center's Response to Exceptions to Recommended Decision	1/19/17
104GF	Dame/Aiken to Tanio – BWMC's Motion to Strike Recommended Decision and Data Entered into the Record 12/30/16	1/19/17
105GF	Tanio to Montgomery/Dame/ McSherry/ Suldan/Brennan/Chan – Ruling on Motion to Strike by BWMC and date for filing comments on Virginia Health Information Data (CD) Record layout Key	1/23/17
106GF	Dame to Tanio – BWMC' Response to 1/23/17 letter and request for additional time to review all data	1/24/17
107GF	Dame to Tanio – Request Commission not act on proposed recommendation at 3/16/17 meeting due to scheduling conflicts	1/25/17
108GF	Tanio to Dame – Comments on Data will be due by 2/3/17 [HSCRC Discharge Database and DC Discharge Database entered in this review (CD Under Seal)]	1/25/17
109GF	P.G. County Government to Tanio – Request MHCC Remand Cardiac Care back to the Reviewer for additional analysis	1/23/17
110GF	Sen Paul Pinksy – Request MHCC Reconsider approving proposed Cardiac Surgery Recommendation	1/24/17
111GF	John Barrella to MHCC – Support for the proposed recommendation for cardiac surgery	1/27/17
112GF	BWMC's Comments in Response to the January 23, 17 Ruling	2/3/17
113GF	Montgomery to Potter – AAMC's Response to Evidentiary Ruling	2/3/17
114GF	Montgomery to Potter – AAMC's Response to BWMC's Comments on Ruling	2/10/17

115GF	Busch/Schuh to Tanio – Support for the AAMC Project	2/10/17
116GF	McSherry to Parker – Interested Party Dimensions Health Corporation PGHC Response to AAMC's Comments in re Evidentiary Ruling	2/13/17
117GF	Ertle to Parker – Motion for Recusal and to Strike the Recommended Decision filed by Dimensions Health Corporation	2/21/17
118GF	Dame to Tanio/Potter – Request to be notified if any Commissioners recuse themselves before the 3/23/17 Commission meeting	2/24/17
119GF	Montgomery to Potter – Opposition of AAMC to Motion for Recusal and to Strike the Recommended Decision	2/24/17
120GF	Tanio to Montgomery/Dame/McSherry/Meltzer/Brennan/Chan – ruling on motion for recusal and to strike recommended decision	3/2/17
121GF	Tanio to Commissioners/ Applicants and Interested Parties – Reviewer's Revised Recommended Decision	3/3/17

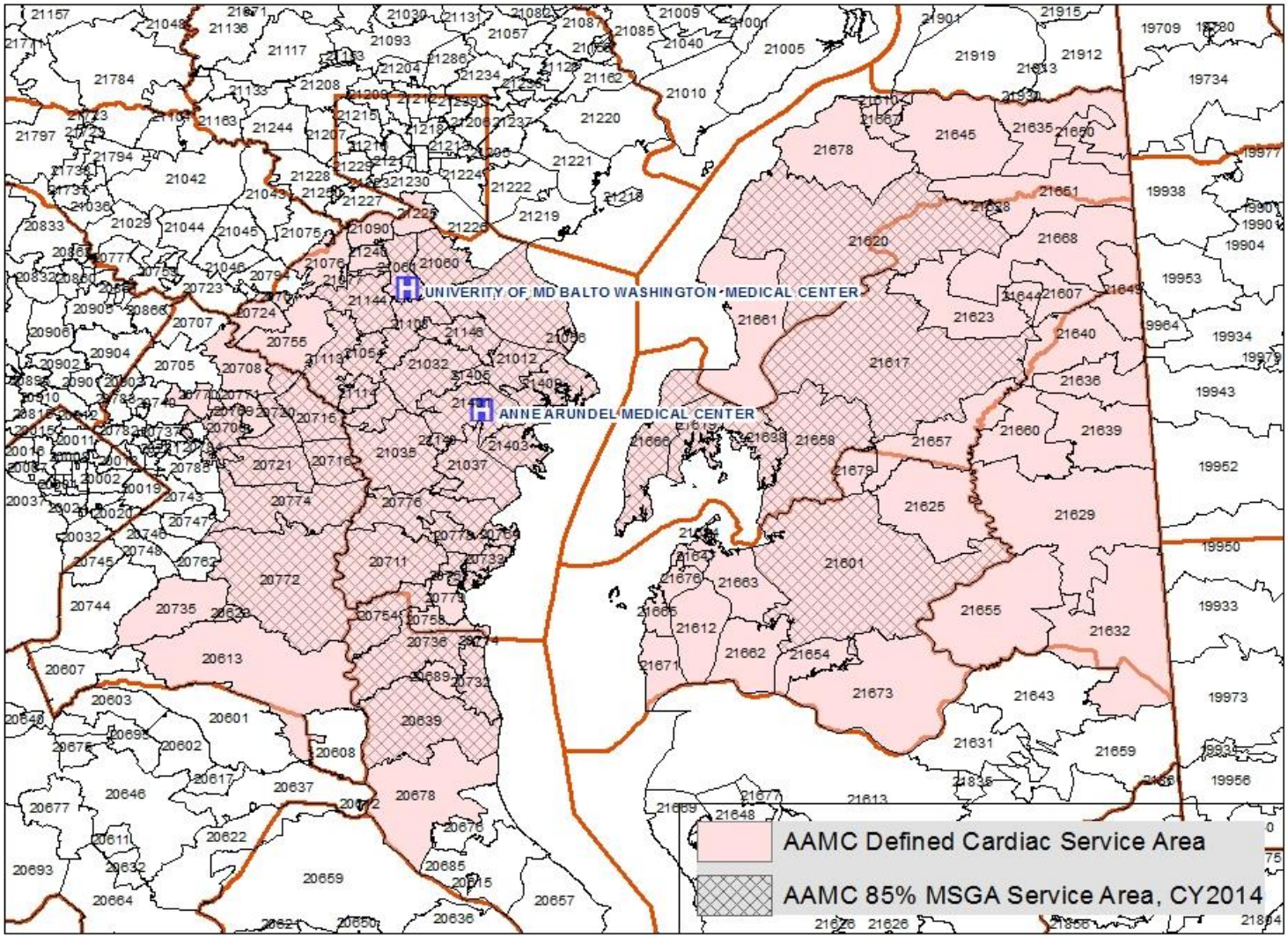
APPENDIX 2

Service Area Maps

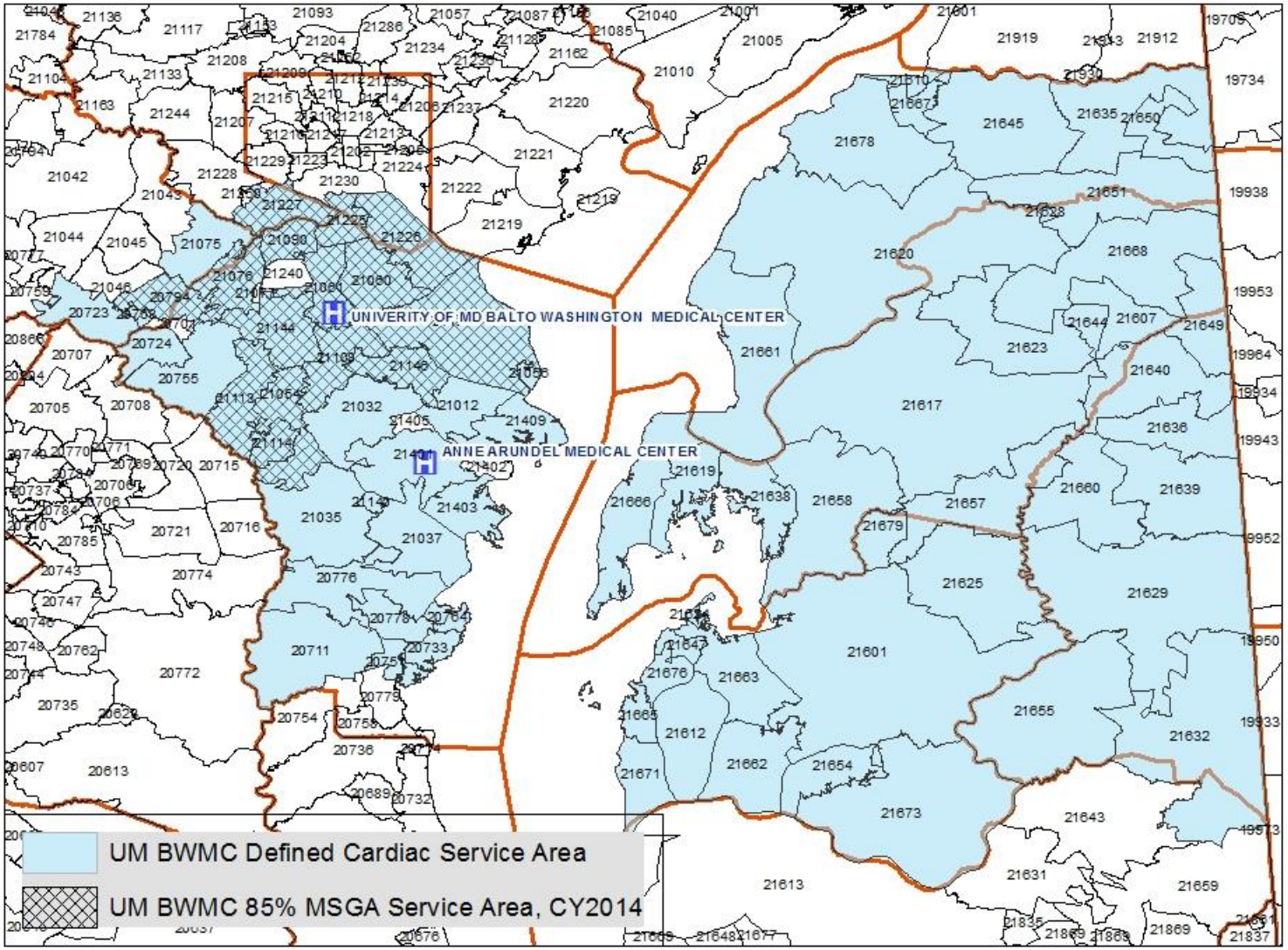
Map 1 illustrates the service area defined for cardiac surgery by AAMC in its CON Application (DI #3AA, Appendix 2) and the CY 2014 85% relevance MSGA service area of AAMC.

Map 2 illustrates the service area defined for cardiac surgery by BWMC in its CON Application (DI #2BW, Exhibit 4) and the CY 2014 85% relevance MSGA service area of BWMC.

Anne Arundel Medical Center



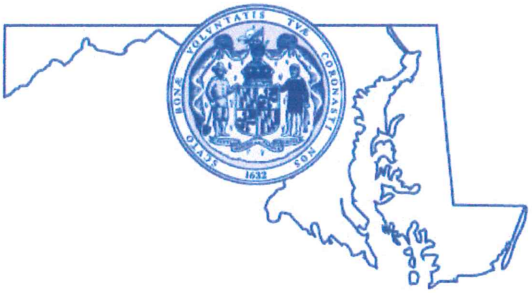
UM Baltimore Washington Medical Center



APPENDIX 3

Health Services Cost Review Commission Staff Comment

Exhibit 3



Health Services Cost Review Commission
4160 Patterson Avenue, Baltimore, Maryland 21215
Phone: 410-764-2605 · Fax: 410-358-6217
Toll Free: 1-888-287-3229
hscrc.maryland.gov

Date: August 24, 2016

To: Craig P. Tanio
Commissioner/Reviewer, MHCC

From: Donna Kinzer, Executive Director, HSCRC
Gerard J. Schmith, Deputy Director, Hospital Rate Setting, HSCRC

Subject: Applications for Certificates of Need to Establish Cardiac Surgery Services at Anne Arundel Medical Center (Docket No. 15-02-2360) and University of Maryland Baltimore Washington Medical Center (Docket No. 15-02-2361)

On July 15, 2016 you requested that we review and comment on the financial feasibility and underlying assumptions of proposed new Cardiac Surgery programs at Anne Arundel Medical Center (AAMC) and University of Maryland Baltimore Washington Medical Center (BWMC).

Per your request we will address each of the six specific questions outlined in your letter regarding the Certificate of Need (CON) applications for the two new proposed programs.

1. **Does either or both applications accurately reflect the shifts in revenue that will occur under the new payment model if the applicant hospitals succeed in building the cardiac surgery case volume they project?**

AAMC assumed that it would be able to retain 85% of the additional revenue associated with the cardiac surgery program. Under the current HSCRC policy for market shift changes of Maryland residents, hospitals with increased volumes that are taken from other Maryland hospitals are allowed to retain 50% of the revenue associated with the additional volume while hospitals that lose volume to other Maryland hospitals are allowed to retain 50% of the revenue associated with the lost volume. Additionally, under the HSCRC market shift policy, hospitals are not allowed to retain any of the increases in revenue related to volume increases that are not matched by reductions in other Maryland hospitals.

AAMC has projected that Maryland residents will comprise the 67% of its cardiac surgery cases that will come from D.C. and other out-of-state providers. Under the Hospital's GBR agreement, AAMC would be able to retain 50% of the cardiac surgery revenue associated with these Maryland residents. Verifying the AAMC projections requires analysis of Medicare data (which the HSCRC

obtains monthly), commercial data (which is reported to MHCC with a greater lag time), and estimates from Medicaid. Likewise, Systems associated with Maryland-based providers are required to provide the HSCRC with claims data for their DC-based facilities under the GBR agreement. AAMC could also retain 50% of the revenue related to the 33% of its projected volume for transfers from other Maryland hospitals. AAMC's assumption that it would be able to retain 85% of the cardiac surgery revenue is contrary to HSCRC policy on market shifts; however, as discussed below, AAMC has other sources of revenue to apply to the project and, therefore, we do not believe a change in this assumption would impact the feasibility of the program.

BWMC's assumption that it will retain 50% of the new revenue associated with the cardiac surgery program is consistent with HSCRC market shift policy.

2. **Is the revenue impact at each of the applicant hospitals correctly modeled and is the revenue impact correctly modeled for the hospitals that are projected to lose cardiac surgery case volume if the new cardiac surgery programs are put into operation?**

Please see answer to Question 1 for the revenue impact at the applicant hospitals.

The applicants correctly modeled the impacts on revenue for those hospitals projected to lose significant cardiac surgery case volume if the new cardiac surgery programs are put into operation. However, as discussed below, those assumptions do not address the possibility that the affected institutions will "backfill" the cases from other areas of Maryland or for other services.

3. **Does each application provide a plausible scenario for an overall reduction in the cost of producing cardiac surgery services in Maryland and a reduction in the charges that will be incurred by payers for cardiac surgery services in Maryland, if the hospital is authorized to establish cardiac surgery services and is successful in shifting the projected volumes of service to their lower cost hospitals? More specifically, does each application provide sufficient information for HSCRC staff to assess the following capabilities and, if so, what is HSCRC staff's assessment on:**
    a. **The capability of AAMC and the capability of BWMC to deliver cardiac surgery at the costs each hospital projects;**
    b. **The capability of AAMC and the capability of BWMC to deliver cardiac surgery with the increases in revenue that each hospital will realize under the payment model; and**
    c. **The capability of Maryland hospitals projected to lose cardiac surgery if either or both the AAMC and BWMC programs are approved to adjust their variable costs so that net income derived from this service will not be greatly affected?**

AAMC and BWMC could deliver cardiac surgery volumes with the increases in revenue under the new payment model using the resources that are provided in the system, including the population adjustment, capacity from reduced avoidable utilization, and reallocation of overhead already funded in the system as evidenced in each hospital's profits to cover the difference between marginal cost

and fully allocated costs that includes existing overhead. However, this would require a commitment from the hospitals to avoid seeking a rate increase in a separate action.

In certain cases related to replacement facilities, a hospital could secure a CON exemption by taking the "Pledge," which prevents a hospital from requesting an increase to revenue or patient charges related to the capital cost of the project in the future. However, in this case there is no such mechanism, per se, that would preclude a hospital from requesting a rate or revenue increase for an approved CON. If the hospital represents that it will not need an increase to accomplish the project during the CON process, the HSCRC staff would do all that it could to ensure that the hospital lived up to its statements. Under the current GBR methodology, hospitals have the right to approach the HSCRC to request an increase in their allowed GBR revenue if the GBR methodology does not provide sufficient revenue. Additionally, in the future, hospitals will be able to submit full rate applications requesting increases in rates if their approved GBR revenue is not sufficient. If not addressed in the CON process, this could leave the system open to unexpected hospital revenue increases from a new program.

Dimension Health Services (DHS) has provided the HSCRC with a proposed GBR arrangement that DHS believes will allow it to operate at a profit in the future based on a set of assumptions. One of DHS' assumptions is that DHS' cardiac surgery program will grow significantly over the next 5 years. AAMC draws some of its patients from Prince George's County, and this could impact the DHS program. While many of the patients that would be served in DHS' cardiac program may not be likely to travel to AAMC for services based on historic migration patterns, changes in volume levels at Washington Hospital Center resulting from a new program at AAMC may impact available capacity at Washington Hospital Center, making it more difficult for DHS to grow its volumes in the face of this increased capacity. Thus, there is the potential to directly or indirectly impact program volumes at DHS, and, therefore, its financial performance.

4. **If a hospital currently providing cardiac surgery services experiences a net reduction in revenue because of the loss of cardiac surgery volume resulting from the creation of a new cardiac surgery program at AAMC or BWMC, or at both hospitals and that hospital is unable to reduce its cost sufficiently to offset this lost revenue, will that hospital be able to approach HSCRC and seek rate relief, negating the projected savings in charges that the applicants project to result from their prospective proposals? Does the payment model or HSCRC policy prevent such an outcome? Are there mechanisms by which hospitals, within the context of this project review, can waive any "right" to seek such rate relief, thus assuring that systemic savings for Maryland payers achievable by shifting cardiac surgery case volume to lower charge hospitals will actually occur and be sustained? Are there other mechanisms that would help insure system savings that we have not considered?**

The CON process does not affect the rights of a competing or cooperating hospital to request rate increases to cover lost volumes in the event of a comprehensive rate review. The CON process does not limit this ability, unless specifically agreed to by hospitals during the CON process. Additionally, the savings may be undermined through "backfill," whereby the hospital losing market share secures market shift for patients from another service area of the State or for an alternative

service for patients from the State. Nevertheless, there could be an inherent advantage of moving lower severity patients out of high cost academic medical centers and teaching facilities into lower cost settings, thereby freeing up capacity for new procedures under development, referrals of patients for highly specialized services from outside the service area, and other high value activities without expanding capacity at the academic medical center or teaching facility. Therefore, the desirability of moving services out of these settings should be weighed in considering the ability to assure cost savings over time through reducing the need for capacity in these high cost environments.

5. **Does the shift of cardiac surgery case volume from Washington, D.C. hospitals to Maryland hospitals paid for by Medicare, which is more pronounced in the case presented by AAMC, have a concerning negative impact on the spending and savings targets HSCRC must meet under the Maryland waiver?**

The Maryland Medicare waiver targets limit the increase in total annual Medicare spending per Maryland Medicare enrollee. Under the targets, Maryland would benefit if the average Medicare payment for a cardiac surgery patient is lower compared to the current Medicare payment at Washington area hospitals. For those Medicare cardiac surgery patients treated at AAMC, the estimated Medicare payment could be lower depending on how much additional revenue AAMC were allowed to generate under its GBR Agreement.

Of more concern, if a new cardiac surgery program at either AAMC or BWMC would result in new cardiac surgery cases that were not previously performed, the waiver would be negatively impacted.

6. **Is it likely that the ability of D.C. hospitals to negotiate charge levels for cardiac surgery with individual payers will make it more difficult to shift volume away from these hospitals to new Maryland providers?**

In the current environment, it is not likely that the ability of D.C. hospitals to negotiate charge levels for cardiac surgery with individual commercial payers will make it more difficult to shift volume away from these hospitals to new Maryland providers. This is because patients and doctors make the decisions about where patients receive services and not payers. Further, out-of-pocket costs for a high cost procedure are generally not affected by the choice of facility. However, as physicians and patients become more price sensitive through the use of PCMHs, ACOs, episode payments, value-based insurance design, and other mechanisms, the point of emphasis may change. There is an increasing number of employers, for example, that are determining which facilities employees can use for tertiary procedures, using both cost and outcomes measures. CareFirst encourages its PCMH physicians to consider episode costs when referring patients. If Washington Hospital Center lowers its episode prices in response to competition from AAMC, it could potentially affect facility selection in a more price sensitive environment.

In a situation with no additional variables, Washington Hospital Center's net income could decrease by as much as half of the $12,000,000 in reduced revenue it may experience if AAMC's program were approved. This loss in net income would provide a strong incentive for Washington Hospital Center to negotiate with third parties to retain the cardiac surgery volume

that AAMC would be attempting to recapture, to backfill the same procedure from other areas of the state, or to backfill with some other service. The same analysis would apply to BWMC. The results are difficult to model in the short run. If the addition of the service at AAMC or BWMC results in increased volumes in the system due to increased supply, then system costs may be affected negatively. Conversely, if the outcome is slower growth, or contraction at high cost academic centers, then system costs may be affected positively, so long as the services produced by AAMC or BWMC are high quality efficient services with equal or better outcomes.

Finally, a look at prior CON cases can be instructive. For example, Suburban Hospital previously projected that it would perform more than 400 cardiac surgeries annually by 2008 in its cardiac surgery CON. Suburban is presently performing around 200 cardiac surgery cases annually. In spite of the fact that it is less expensive than Washington Hospital Center, it has been unable to attract a higher market share of these services historically. The recent overall statewide reduction in cardiac surgery also contributed to Suburban's much lower than projected cardiac surgery volumes.

Please advise if you have further questions.