

# ***Interested Party Written Comments***

**RE: Certificate of Need Applications for a Cardiac Surgery Program**

**Anne Arundel Medical Center - Docket No. 15-02-2360  
Baltimore Washington Medical Center - Docket No. 15-02-2361**

Submitted by:

The Union Memorial Hospital d/b/a MedStar Union Memorial Hospital and  
Washington Hospital Center d/b/a MedStar Washington Hospital Center

Filed: July 27, 2015



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July 27, 2015

**VIA COURIER AND EMAIL**

Paul E. Parker, Director  
Center for Health Care Facilities Planning & Development  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215

RE: Certificate of Need Applications for a Cardiac Surgery Program  
Anne Arundel Medical Center - Docket No. 15-02-2360  
Baltimore Washington Medical Center - Docket No. 15-02-2361

Dear Mr. Parker:

On behalf of our clients The Union Memorial Hospital d/b/a MedStar Union Memorial Hospital ("MUMH") and Washington Hospital Center d/b/a MedStar Washington Hospital Center ("MWHC"), please find attached our written comments regarding the Certificate of Need ("CON") applications for a new cardiac surgery program in Anne Arundel County, (Docket Nos. 15-02-2360 and 15-02-2361). MUMH's physical address is at 201 East University Parkway, Baltimore MD 21218, located in the Baltimore-Upper Shore health planning region. MWHC's physical address is at 110 Irving Street NW, Washington, DC 20010, located in the Metropolitan-Washington health planning region.

Both MUMH and MWHC are members of MedStar Health ("MedStar"), a non-profit, regional health care system in the Maryland-Washington D.C. Region. MUMH is a non-profit hospital corporation that provides cardiac surgery services similar to those prepared by the CON applicants. MWHC also provides cardiac surgery services similar to those proposed by the CON applicants and is a non-profit hospital operating the Metropolitan Washington region. Both hospitals are part of the nationally-recognized MedStar Heart & Vascular Institute ("MHVI") – a large program that includes an alliance with the Cleveland Clinic, and provides cardiovascular services to the residents of Maryland and Washington, D.C. While MHVI does not formally seek interested party status, it is important that the Reviewer, Commission, and its staff recognize that the MedStar entities seeking such status do not stand as isolated providers, but themselves are parts of a comprehensive continuum of cardiovascular services.

Paul E. Parker  
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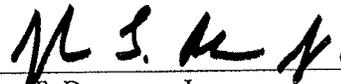
Both of the legal entities identified herein qualify as “persons” under COMAR 10.24.01.01B(31) who would be “adversely affected” under COMAR 10.24.01.01.B(2)(a) in this matter because:

- MUMH “[is] authorized to provide the same service as the applicant[s], in the same planning region used for purposes of determining need under the State Health Plan;” and
- MWHC, which is also authorized to provide the same service as the applicant, is “in a contiguous planning region [and] could reasonably provide services to residents in the contiguous area.” Id.

Both CON applicants indicate that their respective proposals will adversely affect MUMH and MWHC’s cardiac surgery patient volumes and, as a result, reduce both facilities’ revenues from cardiac surgery services. Thus, because both parties “can demonstrate to the Reviewer that [they] would be adversely affected . . . by the approval of either of the proposed projects,” MUMH and MWHC respectfully request that the Reviewer grant “interested party” status to both MUMH and MWHC with respect to the review of the aforementioned CON applications. See COMAR 10.24.01.01B(20)(e).

If you have any questions, please contact me at (202) 624-2760 or at [JTBrennan@crowell.com](mailto:JTBrennan@crowell.com).

Sincerely,



John T. Brennan, Jr.

Enclosures

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**MedStar - Interested Party Written Comments**  
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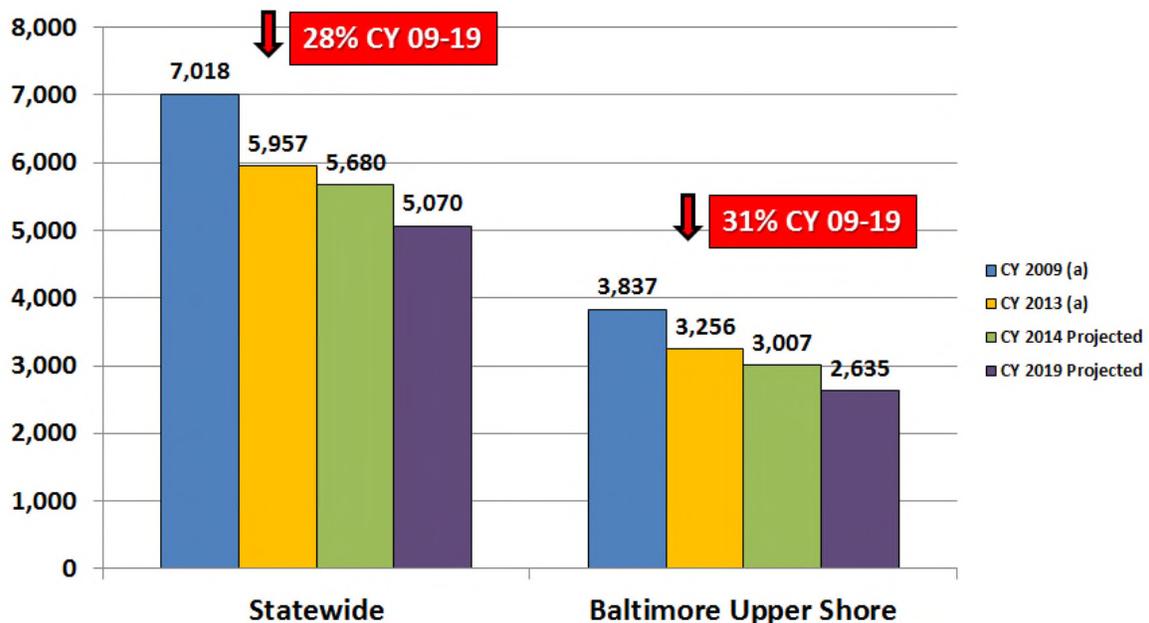
**I. INTRODUCTION**

The Anne Arundel Medical Center (AAMC) and Baltimore Washington Medical Center (BWMC) Certificate of Need (CON) applications before the Maryland Health Care Commission (Commission) to establish cardiac surgery programs in Anne Arundel County are meritless, do not meet the regulatory criteria and standards, and should be denied for the following reasons:

**No Demonstrated Need**

As the chart below depicts, Commission data shows a significant decline in the number of cardiac surgeries for both the state and Baltimore Upper Shore (BUS) planning region from 2009 to 2014. More importantly, the Commission projects a steady decline in utilization continuing through 2019.

**CHART 1 - Cardiac Surgery Utilization Trends CY 2009 – Projected 2019**



Notes: (a) CY 2009 and 2013 projections may be overstated as it appears that all ages were included in the Commission's analysis (vs. adult only)  
Source: Maryland Health Care Commission (MHCC) staff analysis of discharges abstract data for Maryland and the District of Columbia, CY 2009-2014 and MHCC Projected Adult Cardiac Surgery Cases by Health Planning Region CY 2014-2019, Maryland Register, Volume 42, Issue 3, 2-6-15

### **No Geographic Barriers to Access**

Contrary to the applicants' assertions, the Cardiac Surgery Services State Health Plan (SHP) chapter explicitly states that "geographic access to cardiac surgery services and elective PCI is not a problem in Maryland." This SHP finding must be accepted as fact in this review.

### **Excess Cardiac Surgery Capacity**

Existing providers of cardiac surgery services are already operating well under capacity, and well below their 2009 volumes. Were there to be any increase in cardiac surgery utilization, these existing providers are available, and clearly present far more cost-effective alternatives to the creation of any new, expensive, duplicative, low volume cardiac surgery program. Moreover, several existing programs are operating at less than the minimum volumes of required cases and/or less than the optimal number of cases. An additional low volume program would only compound the issue of excess capacity and create additional obstacles for these existing programs to meet the volume standards necessary to ensure quality outcomes.

### **Cardiac Surgery is a Specialized/Regional Service**

Cardiac surgery is appropriately designated as a specialized regional service; and, by definition, it is not appropriate or necessary for every community hospital in every jurisdiction to have a program based on perceived "convenience." As stated in the policies governing the Cardiac Surgery Services chapter of the SHP, "[f]or specialized services [like cardiac surgery], the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base. This pattern promotes both high quality care and an efficient scale of operation." Numerous empirical studies have validated, and continue to

validate, this approach. (Attachment 1 - “Rationalizing Cardiology Care in an Era of Hospital Consolidation,” CardioSource WorldNews (May 2015)).

### **The Proposed Programs Are Not Cost-Effective**

System-wide costs would significantly increase from unnecessary duplication of a high-cost regional service. The primary cost variable for a high-quality cardiac surgery program is the cost associated with the highly specialized personnel necessary to operate a comprehensive cardiac surgery program and team on a 24 hours a day, seven days a week (24/7) basis. Both applicants grossly underestimate (or fail to estimate) the personnel costs for establishing and running a quality program. Of particular concern is the applicants’ failure to address how they would provide adequate staffing by an entire team of specialists, which demonstrates a lack of understanding of, or commitment to, an essential element of a quality program.

### **Inconsistent with Goals of New All-Payer Model**

Creating an additional cardiac surgery program is completely contrary to the goals of the new all-payer model for hospital payment in Maryland and the focus on greater preventive care and keeping patients out of the hospital. (COMAR 10.24.17.03 – Cost of Care.) Under the new system, resources are to be directed towards the prevention of cardiovascular disease and not to the development of high-cost inpatient hospital programs. A new high-cost program would need to be funded with existing resources, which means that existing resources would be diverted away from the goals of prevention and wellness.

The agreement signed between the state and the Centers for Medicare and Medicaid Services (CMS) on January 14, 2014, commits Maryland to shifting virtually all hospital revenue over a five-year period into global payment models. With the new Global Budget Revenue

(GBR) system, each hospital's total annual revenue is known at the beginning of the fiscal year and the hospital must manage all costs to remain under the cap. As a result, hospitals must develop strategies to effectively improve the health of the communities they serve and prevent the need for costly inpatient admissions.

And, while this population-based approach is today measured on a per capita hospital spending basis, the agreement requires Maryland to develop a proposal in year four for a new model based on a Medicare total per capita cost test. The goals associated with next phase will further negate the need for additional high-cost inpatient hospital services. Towards this goal, discussions are already underway regarding payment policies for potentially preventable admissions.

### **Taxpayer Investments in Prince George's Hospital Center Must Be Considered**

Granting a CON for a new cardiac program in the county immediately adjacent to Prince George's County would undermine the longstanding public efforts to stabilize and redevelop Prince George's Hospital Center (PGHC). With more than \$750 million in public funds dedicated to this effort by the County and state, it is incumbent on policy makers not to jeopardize these investments.

For these above stated reasons (as more fully explained below), both of these proposals should be summarily denied.

### **II. NEITHER APPLICANT MEETS THE REQUIREMENTS SET FORTH IN THE GENERAL CON REVIEW CRITERIA AT COMAR 10.24.01.08G(3).**

The general review criteria governing every CON application are set forth at COMAR 10.24.01.08G(3). Neither application meets the requirements of the general review criteria. For

each criterion that the applicant insufficiently addresses, the Commission must deny the application.

**A. The Applicants' Proposals Do Not Meet Applicable State Health Plan Standards Under COMAR 10.24.17.05A or COMAR 10.24.10.**

The CON applicants fail to meet “all relevant State Health Plan standards, policies, and criteria,” as required by COMAR 10.24.01.08G(3)(a). We discuss the State Health Plan and the applicants' failure to conform to the applicable chapters of the SHP in Sections III and IV.

**B. There is “No Need” for the Proposed Projects Under COMAR 10.24.01.08G.**

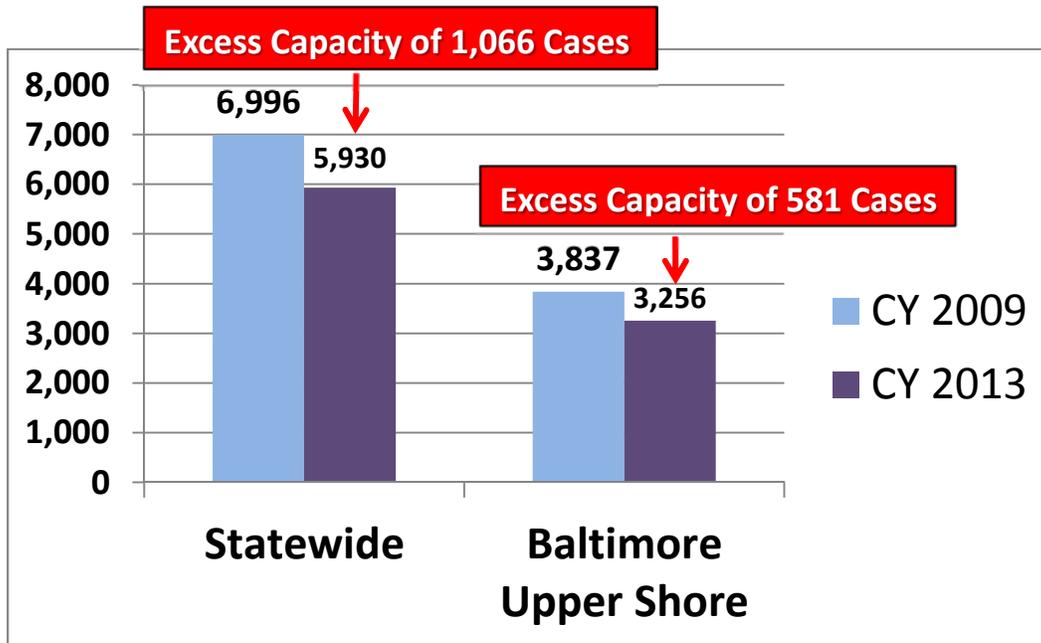
The applicants fail to “demonstrate[] unmet needs of the population to be served” and cannot “establish[] that the proposed project meets those needs” as required under COMAR 10.24.01.08G(3)(b).

i. The Commission's Utilization Projections for Cardiac Surgery Services Show No Need.

The SHP does not establish a methodology for determining the need for a new program in the state of Maryland. Furthermore, the Cardiac Surgery Services chapter of the SHP describes no “unmet need” at 10.24.17.05A(6). Absent any established need for cardiac surgery services, the burden is on the applicants to demonstrate need. This has not been done. The Commission's projections of future cardiac surgery utilization reflect a consistently declining number of cardiac surgery services from 2009-2019. (Chart 1.)

The projections also show available and growing capacity at existing cardiac surgery facilities. Based on anticipated declining utilization and given increasing available capacity, there is no unmet need for cardiac surgery services.

**CHART 2 - Excess Capacity in Health Planning Region and Statewide**



Source: MedStar Analysis of MHCC Adult Cardiac Surgery Cases by Health Planning Region and Hospital, CY 2009-CY 2013 (excluded Children's National Medical Center).

Throughout the state of Maryland:

- Cardiac surgery utilization has been decreasing since 2009 and is expected to continue to decrease through 2019; and
- Existing, high quality providers have growing excess capacity when comparing prior historical volume levels to current utilization.

If one were to assume that in 2009 providers were functioning at 100% capacity – and they were not – the gap between that level of service capacity and the 2014 level of service capacity is significant, indicating a large delta of additional capacity in the existing system.

The combination of declining utilization and increasing excess capacity, particularly in the BUS health planning region, must lead the Commission to determine that there is “no need” for additional cardiac surgery services. On this basis alone, the applications must be denied.

ii. Cardiac Surgery Services Are Regional, Tertiary Services that Need Not be Located Everywhere.

Cardiac surgery has long been considered a specialized, regional service by the Commission, not a jurisdictional or local service. (See, COMAR 10.24.17.03 – Specialized Hospital Services). As such, cardiac surgery is not expected to be available in every community hospital. Slightly longer travel times to access these tertiary services are commonly-accepted and appropriate under the concept of regionalization. In fact, for specialized services like cardiac surgery, the public is best served through a limited number of hospitals providing these specialized services to a substantial regional population base. This delivery structure promotes both high quality and an efficient scale of operation. (Attachment 1.)

iii. Sufficient Availability Exists in the State of Maryland.

Today, there are already five cardiac surgery hospitals in the BUS region alone. In contiguous regions, eight additional facilities are available to serve those residents of Anne Arundel County requiring cardiac surgery. Seven are in the Metropolitan Washington health planning region (one exclusively for children). As shown by Table 1, several cardiac surgery programs have very low caseload, including Prince George’s Hospital Center. Thus, there are no availability issues here.

**TABLE 1 - Utilization Trends, Cardiac Surgery Cases by Health Planning Region and Hospital, CY 2009 – CY 2014**

Hospitals	Year					
	2009	2010	2011	2012	2013	2014*
<b>Baltimore Upper Shore Region</b>						
Johns Hopkins Hospital	969	946	1,014	1,081	1,182	906
St. Joseph Medical Center	717	534	335	279	296	336
Sinai Hospital	465	408	294	317	343	285
MedStar Union Memorial Hospital	953	677	665	543	573	450
University of Maryland Medical Center	733	714	777	807	862	659
Region Totals	3,837	3,279	3,085	3,027	3,256	2,636
<b>Washington Metropolitan Region</b>						
Children's Medical Center (adult cases only)	22	24	22	22	27	NA
George Washington University Hospital	182	116	122	108	96	NA
Howard University Hospital	7	10	18	20	16	NA
Prince George's Hospital Center	27	44	15	17	6	13
Suburban Hospital	231	240	201	275	200	178
Washington Adventist Hospital	463	370	347	334	321	220
MedStar Washington Hospital Center	1,562	1,414	1,399	1,216	1,447	NA
Region Totals	2,494	2,218	2,124	1,992	2,113	
<b>Eastern Shore Region</b>						
Peninsula Regional Medical Center	437	442	420	366	425	307
<b>Western Maryland Region</b>						
Western Maryland Regional Medical Center	250	250	222	213	163	127
<b>State Totals</b>						
	7,018	6,189	5,851	5,598	5,957	

Source: Maryland Health Care Commission

iv. Cardiac Surgery Utilization is Decreasing.

As the Commission's utilization projections indicate, the utilization of cardiac surgery services has steadily declined since 2009. (Chart 1.) The official adopted estimates for future utilization of such services were published in the Maryland Register in February 2015 and show a continuation of this trend through 2019.

**TABLE 2 - Projected Adult Cardiac Surgery Cases by Health Planning Region, CY 2014 – CY 2019**

Health Planning Region	Year					
	2014	2015	2016	2017	2018	2019
Baltimore Upper Shore	3,007	2,935	2,853	2,777	2,704	2,635
Eastern (Lower Shore)	416	408	401	394	388	383
Metropolitan Washington	2,104	2,076	2,039	2,004	1,971	1,940
Western	153	143	134	126	119	112
Total – All Regions	5,680	5,562	5,427	5,301	5,182	5,070

Source: Maryland Health Care Commission, Maryland Register, Volume 42, Issue 3, Friday, February 6, 2015.

Declining volumes and use rates will continue for some time beyond 2019. There is clearly a greater emphasis and attention now on preventive care and early intervention. In addition, the introduction of new medical therapies for cardiac disease, which has spawned approaches to care such as non-invasive heart valve replacement (TAVR) as a potential alternative to surgery for patients with high surgical risk, will continue to evolve.<sup>1</sup> Advances in pharmaceutical treatments have also reduced the need for cardiac surgery. For example, a new class of cholesterol-lowering drugs (PCSK9 inhibitors) is demonstrating great promise in reducing cardiac disease. (Attachment 4 - Steven Ross Johnson, “Promising Findings Shown for Heart-Related Issues,” Modern Healthcare (Mar. 16, 2015)). And, on July 23, 2015, the FDA approved the first of this new class of drugs.

Finally, at both the national and state level, reforms in health care payment policies are now requiring health care providers to focus on population health management. This is even more pronounced in Maryland under the state’s New All-Payer Model for hospital payment and

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<sup>1</sup> Attachment 2 - Mack et.al., “5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomized controlled trial,” The Lancet; Vol. 385 No. 9986, pp. 2477–2484, (June 20, 2015); and Attachment 3 - Sabatine et.al., “Efficacy and Safety of Evolocumab in Reducing Lipids and Cardiovascular Events,” N Engl J Med 2015; 372:1500-1509 (Apr. 16, 2015).

the focus on greater preventive care and keeping patients out of the hospital. With the new GBR system, each hospital's total annual revenue is known at the beginning of the fiscal year and the hospital must manage all costs to remain under the cap. As a result, hospitals are incentivized to develop strategies to effectively improve the health of the communities they serve and prevent the need for costly inpatient services. Resources should be directed to prevention of cardiovascular disease and not to the development of high-cost inpatient hospital program. These factors do not support the need for a new cardiac surgery program in Anne Arundel County.

Thus, the Commission should determine that neither CON application can demonstrate unmet need now or into the foreseeable future.

v. Purported Access Barriers Cannot Serve as a Surrogate for Proving "Unmet Need"

There are absolutely no signs of any access difficulties in the BUS Health Planning Region. The Commission itself, in its adoption of the SHP, concluded that geographic access is not a problem with respect to patient travel time and survival in Maryland. (See, COMAR 10.24.17.03 – Access to Care). The addition of any new service is thus unneeded even from an accessibility perspective. (Id.)

Regardless, the applicants simply argue that access as defined under COMAR 10.24.17.05A(5)(a)(i) would be "enhanced" by their approval. "Barriers to access" simply cannot be demonstrated by the applicants, as the Commission itself states that geographic access is not an issue in Maryland. COMAR 10.24.17.03. This conclusion is dispositive on the issue of whether or not access barriers exist that could be addressed.

In fact, BWMC does not claim any general access barriers to cardiac surgery care. Instead, it simply offers to "improve access for families" that do not have an automobile and

“could continue to face such hardship.” (BW App. at p. 57-58). BWMC then provides comparative taxi costs by zip code. This is a farfetched interpretation of whom “access” is intended to apply to and of what a “barrier” might be. We submit this argument is not demonstrative of an “access” barrier – and certainly does not prove “need.”

AAMC seeks to evade the “need” disqualifier by pointing to very specific primary “access barriers” to cardiac surgery services (AA App.at 112-115):

- “burdensome” travel times; and
- transfer difficulties with MWHC and Johns Hopkins Hospital.

As stated in the Cardiac Surgery Services chapter of the SHP, there are no geographic access issues with regard to cardiac surgery services in the state of Maryland. Despite the SHP’s conclusion, AAMC claims that 80% of those cardiac surgery patients that live in the Eastern Shore Counties must travel an hour or more to receive cardiac surgery services; AAMC claims this is “burdensome” and those patients may, as a result, “carry higher risks” (AA App. at 112). There is certainly general agreement from both practicing clinicians and patient communities that it is important that outpatient and primary care services be readily available and in close proximity to where people work and live. However, this is absolutely not the case with cardiac surgery. Virtually all Maryland residents are within a two-hour, one-way driving time to at least one hospital that provides adult cardiac surgery services.

Even AAMC’s reference to “travel times” and “clinical risks” (the Chou study) does not support the conclusion that surgery services should be located within 30-45 minutes of the populous (Attachment 5 - Chou et al., “Travel Distance and Health Outcomes for Scheduled

Surgery,” *Medical Care* Vol. 52 No. 3 (March 2014)). Rather, the Chou study<sup>2</sup> finds an estimated 0.021 increase in CABG mortality for every additional 100 miles of travel, an order of magnitude that is simply not relevant to these applications and their travel time arguments. Among the other questions that arise in reviewing the Chou study, it indicates that travel distance has little effect on readmission, even when accounting for patient severity. The Chou study only considered in-hospital mortality events – a significant limitation on the use of its findings.

The narrow nature and the results of the Chou study do not conclusively state that the travel distance itself harms patients. In fact, the Chou study states that “more research on why travel distance affects health outcomes is necessary.” (*Id.* at 256.) Finally, the Chou study, used to support AAMC’s concept of an existing access barrier and “need” for a new cardiac surgery program, states in the conclusion: “given the potential gains from increased surgical volume and the cost of new programs, the appropriate policy goal may be to try to improve the quality of care at existing locations rather than increasing the number of providers.” (*Id.*)

AAMC also complains of “transfer delays” with MWHC as an “access barrier.” (AA App. pp. 9, 17, and 94; Exhibit 7a). Because of our long track record with AAMC, concerns about transfers surprise us. Attachment 6 is a copy of the existing “Patient Transfer Agreement by and Between Anne Arundel Medical Center, Inc. and Washington Hospital Center” (hereafter, “Transfer Agreement”). This Transfer Agreement has been in place since February 2005. It remains in place. There are provisions in the Transfer Agreement that permit either party to raise issues concerning the operations of the Agreement. MWHC has not received any

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<sup>2</sup> Incidentally, Table 1 of the Chou study shows the nearly 50% dramatic decline in CABG volume in Pennsylvania over the ten years of data.

such complaints. Indeed, the Transfer Agreement has worked well and has been renewed annually.

MedStar Transport's records indicate 215 cardiac transfer requests were initiated in Fiscal Year (FY) 13, FY 14, or FY 15 from AAMC to MWHC, and 213 transfers were completed. None were denied or refused. A few flight transfer requests were changed to ground transfers due to weather, and two referrals were cancelled by AAMC – one patient they decided to take to the catheterization lab after the transfer request, the other died prior to transport.

In its application, AAMC “identifies” (for the first time to us) four instances of problem transfers. Two allegedly involve MWHC, one involves only Johns Hopkins Hospital, and one involves both facilities. (AA App. Exhibit 7a.) A review of MWHC's transfer records shows that none of the three match the narrative provided by AAMC. All cardiac transfers go through MedStar Transport, after a call to a physician informing the physician team of the need for transfer. Thus MedStar Transport is the only point of entry for cardiac transfers. MWHC's policy for cardiac patients states that we accept all transfers regardless of insurance status. (See Attachment 6 - Transfer Agreement ¶ 8.4). The admissions office is contacted in order to register the patients and notify the insurance carrier of the transfer. We have investigated these instances and, respectful of patient privacy concerns, determined:

- that in two of the three cases, neither MedStar's Transport Division nor, in one case, the named MWHC physician, had any record of those transfer requests.
- that in the third case, MedStar's transport records for that patient indicates that this patient was transferred to MWHC as requested, and was treated at MWHC. The patient did not die en route as AAMC claims.

MWHC continues to be vigilant to any concern, should issues arise. In any event, if there were transfer issues, AAMC's proposed cardiac program would not address or resolve these concerns. If approved, AAMC would continue to have to transfer its more difficult patient cases to others for treatment since its unit would not be qualified to treat those types of cases.

In sum, there are no "transfer barriers" between AAMC and MWHC. There can be no finding that additional cardiac surgery capacity is "needed" on this basis.

**C. Maintaining the Status Quo is a "Substantially More Cost-Effective Alternative" than the Approval of New Services (COMAR 10.24.01.08G(3)(c)).**

Neither application has demonstrated "the cost effectiveness of the proposed project [is more than] the cost effectiveness of providing the service through alternative existing facilities" as required under COMAR 10.24.17.08G(3)(c). In particular, neither application has demonstrated that CON approval is more cost-effective or would improve quality more than "maintaining the status quo." 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" – so doing would only add expense. If there were a need for additional services, meeting that need through higher use of existing facilities would be far less costly than creating a new program. Finally, if there were a need for additional new services, the provision of these services through existing high-volume providers would clearly be more cost-efficient. The fact is that these applications would only 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.

As stated in the policies governing the Cardiac Surgery Services chapter of the SHP, "[f]or specialized services [surgery], 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.” (COMAR 10.24.17.03 – Specialized Hospital Services.) Both CON applications propose to upset this concept because they propose the creation of low, selective volume, cardiac surgery services. They admittedly do not intend to treat high-risk patients. In contrast, they would likely siphon lower risk patients away from existing providers, which may affect the existing providers’ cost-efficiency. Each application proposes a low volume program where efficiencies would be difficult to achieve. Higher volume providers are simply more efficient and are more likely to offer higher quality. (Attachment 7 - Auerbach et al., Case Volume, Quality of Care, and Care Efficiency in Coronary Artery Bypass Surgery (2010)).

The Auerbach study 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. Thus, facilities such as MWHC and MUMH – tertiary providers that are part of an existing high volume system of care are more likely to be cost-effective and, indeed, have the capacity to handle additional volumes, if that became necessary. The additional services proposed by the CON applications would ultimately make all cardiac surgery programs more expensive and less cost-effective.

Furthermore, the Commission’s clinical advisory group recommended that the “regulation of cardiac surgery services should place greater emphasis on quality rather than on volume.” (See COMAR 10.24.17.05A(3) – Quality of Care). An essential component of quality is cost-effectiveness. As discussed in the Cardiac Surgery Services chapter of the SHP, “[n]umerous research studies also show a strong inverse relationship exists between the volume of cardiac surgery performed and patient mortality and surgical complications.” COMAR

10.24.17.03. The Commission has also recognized in the policy statements at COMAR 10.24.17.04 that, for the episodic patient experience, having a high volume cardiac surgery program is more likely to provide better quality of services than one with a lower case volume, as would be the likely scenario if either CON application were approved. (Attachment 8 - Vassileva et al., “Hospital Volume, Mitral Repair Rates, and Mortality in Mitral Valve Surgery in the Elderly: An Analysis of US Hospitals Treating Medicare Fee-For-Service Patients,” The Journal of Thoracic and Cardiovascular Surgery (Mar. 2015); Attachment 9 - California CABG Mortality Reporting Program 2003; Attachment 10 - Cheryl Clark, “Welcome Back, Volume – The Original Quality Measure,” HealthLeaders Media (May 21, 2015)).

As implied above, the connection between quality and volume has implications for cost-efficiency. Dr. Peter Pronovost, a Johns Hopkins physician and prominent authority on the connection between volume and quality, acknowledged hospitals’ financial interest in conducting high-revenue procedures despite evidence of no need. But even he notes that the differences in volumes and outcomes are staggering between the hospitals in the lowest and highest quintiles, which puts cost-efficiency at risk. (Attachment 11– Peter Pronovost, M.D., “Low Volume Hospitals Create Big Risks for Surgery Patients” U.S. News & World Report: Opinion (June 3, 2015); Attachment 12 - Steve Sternberg and Geoff Dougherty, “Risks Are High at Low-Volume Hospitals U.S. News & World Report (May 18, 2015); Attachment 13 - Steve Sternberg, “Hospitals Move to Limit Low-Volume Surgeries” U.S. News & World Report (May 19, 2015)). This is precisely what both CON applicants are pursuing here and by definition, it is not a cost-efficient strategy. This alone should be a key reason why the Commission should deny both applications.

**D. Neither Application Proposes a Financially Viable or Sustainable Cardiac Surgery Program.**

Neither CON application can demonstrate that on an ongoing basis there would be “the available resources necessary to sustain the project.” COMAR 10.24.01.08G(3)(d). At the very core of the applications’ inability to demonstrate financial viability is the fact that there is no unmet need to justify the addition of a new cardiac surgery service provider. Both applicants submitted business plans that on their face meet their financial objectives but are inconsistent with Maryland state health policy. Even the business aspects of these plans are flawed, because the applications have overestimated anticipated revenues and grossly underestimated start-up and ongoing expenses – particularly those costs associated with having the necessary highly skilled personnel available for establishing and running a quality program.

i. Overestimated Volumes Would Lead to Reduced Revenue.

The applicants’ revenue estimates are based on unsupported guesses as to what their ability would be to “shift market share” from existing providers. It is unrealistic for the CON applicants to expect that either would be able to “shift” patients to simply meet their own expectations, and to achieve even the minimum volume standards recognized by the Cardiac SHP. Cardiac surgery utilization projections reflect decreasing utilization. (See, Tables 1 and 2). Well-regarded existing providers are operating well below potential capacity. Many existing providers are operating well below capacity. And, under the state’s new All-Payer Model for hospital payment, the focus of cardiac care has shifted and continues to move toward increasing access to primary preventive care and reducing the need for cardiac surgery.

ii. Underestimated or Unrecognized Staffing Costs.

While overestimating revenues, both applicants have also underestimated their expenses because they have failed to show a complete staffing plan. The staffing projections in each application fail to show all the staffing necessary to operate a cardiac surgery program 24 hours a day, seven days a week. Apparently, each applicant intends to rely on another hospital to staff its surgery service. Yet, the contractual costs for these resources, and/or the salary and benefit costs for hiring this staff, are not reflected in the applications. Table 3 shows the staffing plan taken from Table L in the applications.

**TABLE 3 – Applicants’ Proposed Staffing Plans**

Job Category Title	FTEs		Total Cost		FTEs/Case*	
	AAMC	BWMC	AAMC	BWMC	AAMC	BWMC
<b>Contract - Admin</b>						
Physician		0.2		200,000		0.88
Perfusion		0.25		49,500		1.10
Anesthesiology		0		50,000		
Resident		0		75,000		
<b>Contract - Direct Care</b>						
Physician	2.5**					
Perfusion	0	0		166,000		
Anesthesia		0		166,155		
CT Assist		0		293,250		
<b>Employee - Admin</b>						
Supervisor/Mgt	0.5	0.5	76,330	67,000	1.29	2.19
<b>Employee - Direct Care</b>						
Cardiac Nursing	22.7	9.8	2,070,007	1,089,799	58.66	42.98
Lab Personnel		0.5		31,000		2.19
Patient Care Techs		3.6		136,842		15.79
Peri-Op Techs		1.2		77,418		5.26
Pharmacy Personnel		0.8		95,250		3.51
Rehab Services		1.2		68,034		5.26
Physician Assistant	1.1		141,585		2.84	
Hospitalist						
Nurse Practitioner						
<b>Employee - Support Staff</b>						
Quality/Data Manager		1		170,220		4.39
Other Support Staff		1		75,000		4.39
Support Staff - Technical	11.3		646,957		29.20	
Support Staff - Professional	0.5		65,896		1.29	
	36.1	20.05	3,000,775	2,810,468	93.28	87.94
Source: Tables L and I in CON applications						
* Numbers multiplied by 1,000, then reduced to 2 decimal points for ease						
** Shown on page 210 of the application						

The FTE and cost details of their contracted physician, anesthesia and perfusion services are incomplete or completely missing. The true costs of a fully functioning cardiac surgery program are not disclosed in the applications, and thus the financial feasibility cannot be fully understood.

Based on the information provided in the proposals, neither staffing plan is sufficient to run a fully functioning cardiac surgery program. Surgeons, anesthesiologists, perfusionists, physician assistants (PAs), and nurse practitioners (NPs) are important members of a cardiac surgery team, yet the FTEs and/or associated costs quoted in the applications are not sufficient to sustain full-time, 24/7 coverage for urgent and emergent cases, as well as covering peak demand that can cause overlapping or many back-to-back cases. Neither application differentiates registered nursing staff who would work in the operating room or the Intensive Care Unit.

iii. **BWMC**

BWMC proposes 0.25 full-time employees (FTEs) for a perfusionist, and .2 FTEs for a physician, clearly grossly insufficient for 24/7 coverage. A cardiac surgery program cannot operate without cardiac anesthesiology. In addition, there is no FTEs allocated for CT assistants, physician assistants or nurse practitioners. The applications' proposed cardiac surgery staffing plans are set forth at Table 3. (See also, Table L in each application).

iv. **AAMC**

AAMC's staffing plan is even more inadequate. The application does not provide for a team of professionals needed for a quality program. (AA App. p. 163). Specifically, the following staff appear to be missing from its staffing plan and staffing expenses:

- Cardiac anesthesiologists

- Perfusionists;
- Direct care surgeons;
- On-call coverage for cardiac surgeons on a 24/7 basis;
- Physician administration or Medical Director; and
- Cardiac rehab services.

The Joint Commission’s Proposed Requirements for Comprehensive Cardiac Center Certification Program (CCCM) provides recommendations for appropriate staffing (Attachment 14). The CCCM requires that a “comprehensive cardiac center” establish “an interdisciplinary team” that includes direct and non-direct patient care staff, with at least one of an array of individual professional specialists available 24 hours a day, seven days a week (Attachment 14 - CCCM p. 16). A review of the Joint Commission’s CCCM proposal also suggests that both CON applications neglect to include key personnel in their staffing plans for the proposed CON projects. In addition to the missing expenses associated with staffing, expenses for education and training, follow-up care, rehabilitation, and ancillary services are also not included in these staffing plans or the financial projections. (Attachment 14 - CCCM p. 17.)

Both applicants should be required to document the full staffing plans and related costs of their proposed cardiac surgery programs including the contract provisions for specialized staff. Without this, the applications cannot be found consistent with this criterion. By overestimating revenues and underestimating expenses, each application has failed to demonstrate the ongoing financial viability of its proposal.

**E. Both Applicants’ Proposals Would “Negatively Impact Existing Providers and the Health Care System.”**

Neither applicant’s CON proposal demonstrates it would not negatively affect existing health care providers as required under COMAR 10.24.01.08G(3)(f). In fact, both applications

explicitly acknowledge that they would adversely impact a number of existing providers, including the MUMH and MWHC, and notably, PGHC. (See, e.g., AA App. p. 93-96; BWMC App. p. 46-47 and 55).

COMAR 10.24.01.08G(3)(f) requires that both applicants analyze the impact of their proposals and “geographic [] access to services, occupancy, . . . and costs to the health care delivery system.” As we stated in Sections II.B.ii, II.B.iii, and II.B.v above, the Commission has already determined that geographic access to cardiac surgery services is “not a problem” in the state of Maryland. See also, COMAR 10.24.17.03. Neither applicant acknowledges this finding. Instead, each of them focuses on shortening travel times and the costs for “family” travel, although the Commission already states that “quick access to cardiac surgery is not essential.” (Id.)

Next, there is existing and growing capacity available for cardiac surgery, given that utilization of existing cardiac surgery services is declining. (Table 2 and Chart 2). And last, as we discuss above in Section III.C regarding cost-effectiveness, neither applicant has acknowledged the viability of a “status quo” option, which would be based on common sense and would have no detrimental impact on the costs of the health care delivery system. Both applications have failed to meet this criterion.

Aside from the impact on the system as a whole, of particular note would be the impact either approval would have on PGHC. AAMC is located only 22 miles of both the current and proposed campuses of PGHC. As shown by the slow but steadily increasing volumes at its facility recently, PGHC’s existing cardiac surgery program is rebounding. (Table 1). In FY 2014, PGHC treated only 12 cardiac surgery cases. (Id.) With its recent association with

University of Maryland Medical System's cardiac surgery program, these numbers have increased significantly. One year later, in FY 2015, PGHC treated 85 cardiac surgery cases. This shows that this program is rebounding, and becoming a viable provider.

Further, granting a CON for a new cardiac program in the county immediately adjacent to Prince George's County would undermine the longstanding public efforts to stabilize and redevelop PGHC. With more than \$750 million in public funds dedicated to this effort, it is incumbent on policy makers not to jeopardize these investments. For these reasons, the Commission should deny both applications for their inability to meet all of the above-described general CON review criteria at COMAR 10.24.01.08G.

**III. NEITHER APPLICATION MEETS THE STANDARDS SET FORTH IN THE CARDIAC SURGERY SERVICES STATE HEALTH PLAN AT COMAR 10.24.17.**

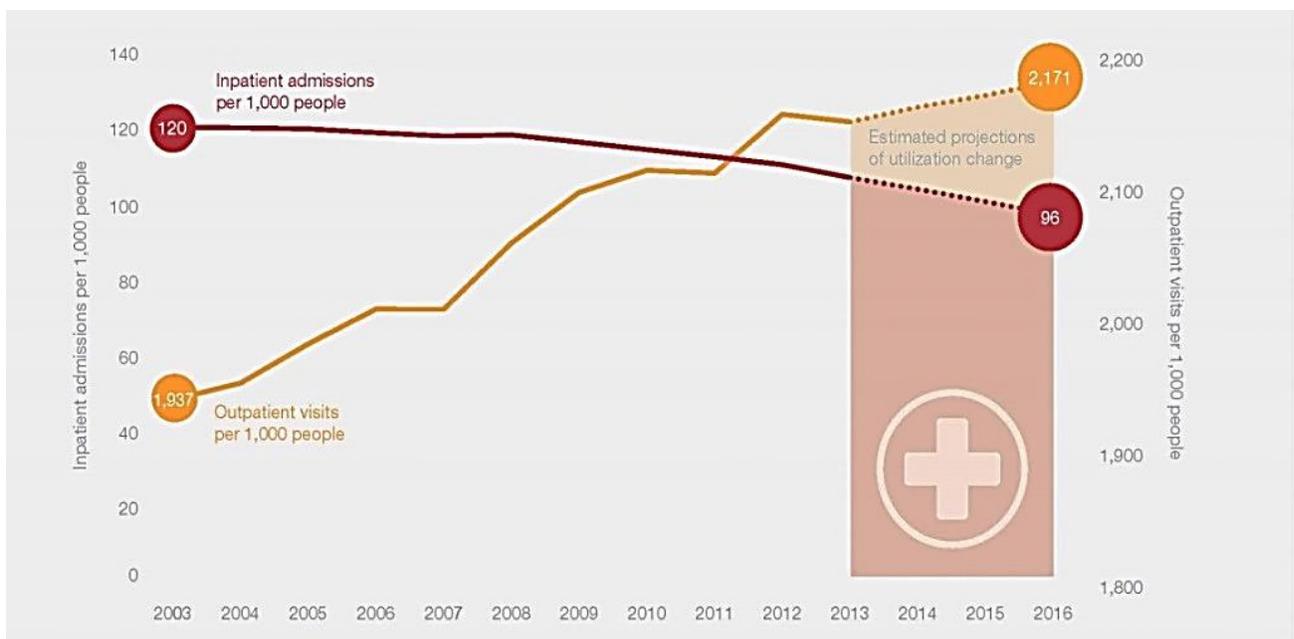
**A. Both Applicants Use Faulty Assumptions to Reach the Minimum Volume Standard Prescribed in COMAR 10.24.17.05A(1).**

The applicable standard in the Cardiac Surgery Services chapter of the SHP requires that, in order to file an application, an applicant demonstrate "the ability to meet a projected volume of 200 cardiac cases in the second full year of operation" and address the most recent published utilization projection methodology for cardiac surgery cases in COMAR 10.24.17.08 COMAR 10.24.17.05(A)(1)(a) (emphasis added). Not surprisingly – since it is a qualifier for filing an application – both applicants' estimates projected volume of cardiac surgery services slightly above this standard. Both applicants' assumptions are faulty: (1) the applications ignore the obvious decline in projected utilization expected by the Commission, and (2) the applications presume that they can entice patients and effectuate market shifts in the delivery of cardiac

surgery services. The Commission should conclude that neither application can meet this standard and deny both proposals.

Simply put, projected volume for cardiac surgery is decreasing – the pie is becoming smaller, not larger. (Chart 1; Tables 1 and 2). This number would likely decline in future years, consistent with declining use rates in Maryland. Of note, even beyond the cardiac surgery context, inpatient care volume is declining nationwide as illustrated by this chart:

**CHART 3 – Inpatient Care Volume on Rapid Decline**



Source: American Hospital Association 2013 data and HRI analysis (PwC Health Research Institute).

In this light, this 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”, but the reasoning of those projections ought to be tested. Here: a) there is no “unmet need” for cardiac surgery services that existing providers cannot meet, b) utilization is going down, and c)

there are no access barriers. In other words, the applicants' surgical case estimates are derived from a market of shrinking utilization and growing unused capacity.

BWMC projects that its cardiac surgery volume would reach 250 procedures by FY 19 (BW App. pp. 44-47). AAMC is even more exuberant and projects 387 cases by the third year (FY 19). (AA App. pp. 141). In breaking down the assumptions supporting the applicants' methodologies, the assumptions are significantly lacking rationality. But, the ability to mathematically meet the 200 minimum threshold through unrealistic market share shifts cannot be confused with proving "need."

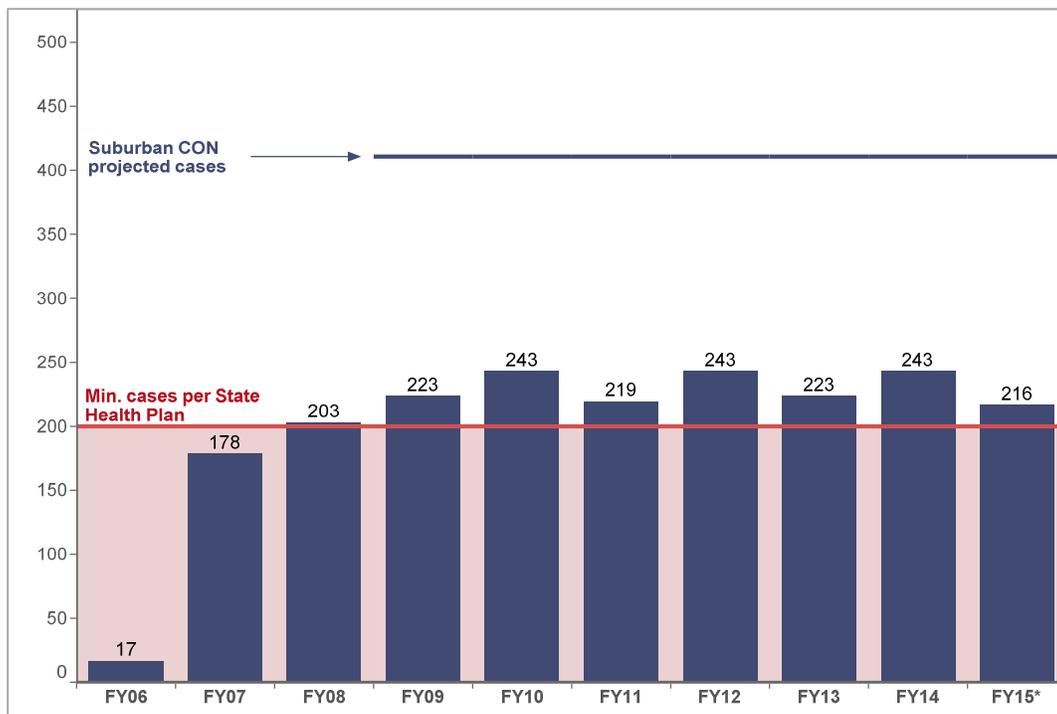
AAMC's projected cases are based on two primary "methods": (1) "expected referrals" from AAMC medical staff and surrounding cardiology practices and (2) volume shifts, chiefly from Johns Hopkins Hospital and MWHC. (AA App. pp. 60-61, 78-79, and 88). For its part, BWMC also turns to a cardiologist survey and simply assumes that its cardiac surgery market share will equal its "cardiology" market share. (BW App. p. 43-45, revised at BW Supp. #1 p. 8). To the extent that both applications rely on volume projections based on "letters from cardiologists", they rest upon a very dubious source of support. In this case, reliance on cardiologists as a source for estimating "cardiac surgery" volume is risky.

Simply put, cardiologists do not decide whether or not cardiac surgery will ultimately occur – surgeons do. The applications' assumptions for "shifting market share" are also suspect. From AAMC's perspective, both Johns Hopkins and MWHC operate well-established cardiac surgery programs set in well-developed systems of cardiac care delivery. Each provides the full gamut of cardiac surgery services including the ability to treat very high risk surgical patients –

AAMC and BWMC likely would not have the same ability to do so. Taking significant market share from MWHC in particular is unlikely.

Based on the Suburban Hospital experience, it is not implausible that an applicant for new cardiac surgery services would overestimate volume. During the Suburban CON review and approval, Suburban Hospital did not face the pressure and focus on payment reform or on improving the cardiac surgery volumes as did PGHC. In this environment, Suburban projected that it would perform 410 cardiac surgeries by its third year of operation (FY 08). After nearly ten years of operation it has yet to come close to this projection and is barely meeting the 200 case minimum volume. (See Chart 4 and AA App. at 24-25).

**CHART 4 - Suburban Hospital Cardiac Surgery Discharges**



\*FY15 annualized based on Q1-Q3 discharges (n=162)  
 Source: DC Hospital Association inpatient database ; patient ages 15+; Maryland Health Care Commission ICD-9 procedure codes for cardiac surgery.  
 200 = Minimum cases required per the State Health Plan  
 405 = Suburban CON projected cases

As Suburban Hospital did previously with its own CON application, both AAMC and BWMC are relying on the same over-exuberance in projecting future volumes at their proposed cardiac surgery services.

AAMC's calculations of market share are also suspect. AAMC estimates a 25% market share in the first year, which is assumed would increase to 40% by the third year of operation. (AA App. p. 83). AAMC bases this assumption on its market share of "bariatric surgery and joint replacement surgery." The analogy is not applicable. Bariatric surgery and joint replacement surgery are not corollaries to cardiac surgery; they are not tertiary/quaternary level services or regional services. AAMC already has a reputation for offering quality bariatric surgery and joint replacement, but AAMC has no expertise in cardiac surgery. It would struggle to attain the expertise of existing high volume cardiac surgery providers. Therefore, we believe that AAMC's market share estimates are overstated.

Both BWMC and AAMC have sought to "verify" their rate/market share volume projection by "informally polling" certain cardiologists who "refer for surgery". (BW App. p. 79; BW Supp. #1 p. 14-20; AA Supp. #1 p. 78). This is an oxymoron. Polling physicians on "how many patients they will refer" to a brand new service is a dangerous and risky planning model and unlikely to be reliable.

Of even greater concern here, cardiologists do not "refer for surgery." Cardiologists refer to cardiac surgeons their potential surgical cases. Surgeons – not cardiologists – ultimately decide whether – and, importantly, where – surgery is to be performed. AAMC seeks to rectify this weakness in its methodology. AAMC stated on p. 20 of its first supplemental response that

50% of cardiologist referrals for surgery are likely to result in surgery. If true, then the 422 FY 19 “referral cases” would translate to only 211 surgical cases at best, not the 387 it projected to the Commission. AAMC then applies a seemingly arbitrary estimated percentage of their referrals that would be expected to be seen at the new AAMC program – ranging from 25% to 90% (fourth column), with no explanation for this wide variation (AA App. 15), with an average of 80% of the estimated referrals being performed at AAMC (bottom of fourth column). This assumes, however, that only 20% of patients would constitute “high risk patients” whom AAMC would not be qualified to treat. AAMC offers no support for this “unable to treat” estimate of high risk patients. Ironically, AAMC would still need to transfer a good chunk of its patients to existing providers.

Finally, AAMC tries to verify the use rate/market share volume projection with an approach based on its current inpatient and outpatient transfers generally for cardiac surgery or referred for evaluation for surgery in FY 14 (AA App. p. 80, AA Supp. #1 p. 19). The analysis of transfers out for cardiac surgery or evaluation for cardiac surgery was done by “clinicians” (*Id.* p. 80). There is no indication of who these clinicians are and how they performed this analysis. These unknown clinicians were apparently tasked to identify patients that were transferred from AAMC to any facility providing cardiac surgery for evaluation for surgery. However, Chart 48 of AAMC’s first supplement to its CON application identifies 76 inpatients transferred for cardiac surgery and 19 outpatients transferred “for surgery,” for a total of 95 patients. The chart also identified 128 inpatients and 79 outpatients transferred “for evaluation for surgery,” totaling 207 patients (applying a 50% rate to outpatients). AAMC’s conclusion is

that 234 “surgical cases” could be identified as cardiac surgery cases, based on its current experience.

This is an inaccurate estimate. Chart 48 applies a 95% “assumption of surgery” to the 79 outpatient referrals, rather than the 50% assumption of surgery applied elsewhere. Using AAMC’s own 50% assumption of surgeries emanating from this group, rather than 95%, would result in only 199 assumed surgical cases in FY 2014.

AAMC also did not apply the generous 80% caseload limiting factor it used itself elsewhere to account for those patients that are either high-risk, complex cases which AAMC would not be able to handle, or prefer having cardiac surgery at a high volume at an experienced provider. Even ignoring all trends showing decreasing utilization and increasing supply as shown in Chart 2, AAMC’s own self-serving assumptions grossly overestimate the projected number of cardiac surgery cases it would see. We submit that AAMC has not met its burden of demonstrating it would achieve 200 minimum procedures. It is therefore not consistent with this standard.

When assessing each applicant’s cardiac surgery caseload projections, we also assert that the experience of the most recently approved cardiac surgery program – that of Suburban Hospital – is instructive and adds further doubt as to what AAMC and BWMC would achieve the projected volumes within three years, if at all.

**B. Providers of Cardiac Surgery in the Health Planning Region and Adjacent Regions Would be Negatively Affected by the Approval of New Services.**

Under COMAR 10.24.17.05A(2)(b)(i), CON applicants must demonstrate that other providers of cardiac surgery in the “health planning region” or an adjacent region will not be negatively affected to a degree that will compromise the financial viability of cardiac surgery

services at an affected hospital. In relation to this standard, we ask that the Commission consider our arguments regarding the purported cost-effectiveness of both proposals discussed at Sections II.C and III.C in these written comments.

**C. The Costs of the Proposed Programs Significantly Outweigh Any Benefit.**

This plan standard requires a cost/benefit analysis to determine if “the benefits of (the) proposed cardiac surgery program to the health care system as a whole exceed the cost to the health care system.” COMAR 10.24.17.05A(4). BWMC claims the benefits of its proposal would outweigh the costs to the system through a \$2.4 million “savings in payments.” (BW App. p. 55). AAMC claims “\$8.2 million savings” in payments for services (App. at p. 109) and states that it would provide a lower cost/charge alternative to other facilities. There has not been – and cannot be – the showing of need; thus any additional cost would be unnecessary. In this context, it is impossible for any addition of new services to be “cost effective.”

As we detail in the cost-effectiveness discussion at Section II.C, each CON applicant overestimates revenues and underestimates its expenses. Specifically, we 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.

**D. The Applications Refutable Allegations Regarding Travel Times and Patient Transfer Problems Do Not Amount to “Access Barriers” as Defined Under COMAR 10.24.17.05A(5)(a)(i).**

Because the SHP concludes that geographic access is not a problem with respect to patient travel time and survival in Maryland, there is no need for an additional cardiac surgery

program. (See, COMAR 10.24.17.03 – Access to Care). See Section II.B.v for our full discussion about the deficiencies in the applicants’ arguments regarding access barriers to cardiac surgery services, which shows that neither application has demonstrated any access barriers exist.

**E. Neither of the CON Proposals Are Financially Feasible Because the True Expenses of the Proposed Programs Are Unknown.**

Neither applicant has reasonably demonstrated that the proposed new service would generate revenues that would exceed its expenses as required under COMAR 10.24.17.05A(7)(iv). This is chiefly because neither of the applications are based on realistic utilization projections or expense estimates.

As discussed at length in Section III.A, over-exuberant volume projections have caused the applicants to overestimate revenues. As a result, revenues based on such volumes are highly likely to be exaggerated. Second, both applications provide incomplete analyses of staffing costs. BWMC’s application admits that “[a]s a stand-alone cardiac surgery program,” the proposed project would not achieve excess revenue over total expenses within three years. (BW App. p. 61). In fact, even based on its own assumptions, the BWMC program would operate at a loss for FY 16-FY 21, and likely beyond. (BW App. p. 62). AAMC simply does not provide enough detail to allow an accurate assessment of their staffing costs, as we state in Sections II.D.ii through II.D.iv. Thus, until the full staffing costs are known, the Commission cannot determine whether either of the proposed CON projects are financially feasible.

**F. Neither Proposal Should Be Afforded Preference by the Commission as Both Must be Denied.**

Neither applicant meets “all policies and standards” established by the CON laws and regulations as required by COMAR 10.24.17.05A(8). Therefore, neither applicant’s CON proposal can merit preference from the Commission over the other.

**IV. NEITHER APPLICANT MEETS KEY RELEVANT STANDARDS SET FORTH IN THE ACUTE CARE HOSPITAL SERVICES STATE HEALTH PLAN.**

Not only must the CON applicants meet the requirements set forth in the CON review criteria and the Cardiac Surgery Services chapter of the SHP, they must also meet the relevant standards articulated in the Acute Care Hospital Services SHP set forth at COMAR 10.24.10 because their services are delivered in hospitals.

**A. The Proposed Projects Are Not the “Most Cost-Effective Approach” to Meeting an Identified Need.**

“A proposed hospital capital project should represent the most cost effective approach to meeting the needs that the project seeks to address.” COMAR 10.24.10.04B(5). There is no need for these projects. For the same reasons we articulate in Section III.C above, we assert that the CON applications cannot meet this standard. Maintaining the status quo option is clearly the more cost-effective alternative for both CON applicants and the state’s health care system to pursue. If there is no need, no benefit can arise from the addition of a new cardiac surgery program.

**B. There is No Demonstrable Need for the Proposed Projects.**

The Acute Care Hospital Services chapter of the SHP explicitly states that “[a] hospital project shall be approved only if there is demonstrable need.” COMAR 10.24.10.04B(6). As we indicate in our discussion at Sections II.A and III.B, the question of “need” – absent any other

consideration – is singularly dispositive. Under this standard alone, the Commission must deny both applications.

**V. CONCLUSION**

For all the reasons stated above, the applications are not consistent with the general regulations criteria at COMAR 10.24.01.08G, the Cardiac Surgery Services or the Acute Care Hospital Services chapters of the SHP. Therefore, both CON applications must be denied.