

IN THE MATTER OF

ANNE ARUNDEL MEDICAL CENTER

Docket No. 15-02-2360

\* BEFORE THE  
\*  
\* MARYLAND HEALTH  
\*  
\* CARE COMMISSION  
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**UNIVERSITY OF MARYLAND  
BALTIMORE WASHINGTON MEDICAL CENTER'S  
COMMENTS ON ANNE ARUNDEL MEDICAL CENTER'S  
CON APPLICATION PROPOSING THE ESTABLISHMENT OF  
CARDIAC SURGERY PROGRAM**

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University of Maryland Baltimore Washington Medical Center (“UM BWMC”), by its undersigned counsel and pursuant to COMAR 10.24.01.08F, submits these comments addressing the Certificate of Need Application and related materials filed by Anne Arundel Medical Center (“AAMC”), proposing to establish a cardiac surgery program. UM BWMC respectfully requests that the Maryland Health Care Commission deny AAMC’s application.

### **INTRODUCTION**

AAMC’s CON application to establish a new cardiac surgery program should be denied in favor of UM BWMC’s proposal to expand the geographic scope of the cardiac surgery program operated by the University of Maryland School of Medicine’s Division of Cardiac Surgery (“UM Division of Cardiac Surgery”). AAMC states that it will develop the proposed program in partnership with Johns Hopkins Medicine (“JHM”), but provides little information about its existing relationship with JHM.

Among other flaws, the AAMC proposal: (1) fails to document that AAMC will achieve the minimum annual volume of 200 cases by the second full year of operation; (2) would cause significant adverse impact on the existing and revitalized cardiac surgery program at Prince George’s Hospital Center (“PGHC”); (3) would not be a cost-effective method of delivering cardiac surgery services; and (4) would not be financially feasible.

On a comparative basis, UM BWMC proposes a superior cardiac surgery program. Located in Glen Burnie, Maryland, UM BWMC is a member hospital of the University of Maryland Medical System (“UMMS”). UM BWMC joined UMMS as a member institution in 2000, and it has been owned by UMMS and operated as a fully integrated UMMS hospital since then. As a part of UMMS, UM BWMC has access to the research, training, and referral network of the largest hospital system in Maryland.

Like AAMC, UM BWMC also submitted a CON application to establish a cardiac surgery program in Anne Arundel County. However, unlike AAMC's proposal, UM BWMC's proposal does not suffer from the infirmities identified above. UM BWMC proposes only to extend the reach of the existing UM Division of Cardiac Surgery, which currently provides cardiac surgery services at two UMMS affiliated hospitals – University of Maryland Medical Center (“UMMC”) and University of Maryland St. Joseph Medical Center (“UM SJMC”).<sup>1</sup>

Thus, UM BWMC proposes to serve as a new location of the well-established UM Division of Cardiac Surgery program. Most of the projected volume of cardiac surgery cases at UM BWMC will be shifted from UMMC, and the new location will have a minimal adverse impact on other cardiac surgery providers. As part of a larger program within UMMS, the cardiac surgery program at UM BWMC will achieve a sustainable volume of cases through shifting cases within UMMS, based on the convenience of patients and families. If UM BWMC's proposal is approved, residents of Anne Arundel County and the mid-shore counties will have a more convenient and lower cost option for cardiac surgery services.

By contrast, AAMC proposes to establish a new cardiac surgery program that would draw significant volume from other providers, especially MedStar Washington Hospital Center and PGHC (although AAMC does not acknowledge the adverse impact its proposed program will cause to PGHC). Moreover, relative to UM BWMC's proposal, AAMC's proposed program would generate more Maryland hospital cost per capita, which affects the State's obligations under the Maryland All Payer Model Agreement with the Centers for Medicare and Medicaid Services.

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<sup>1</sup> The UM Division of Cardiac Surgery also operates the cardiac surgery program at PGHC under an agreement with Dimensions Healthcare System (“Dimensions”).

Unlike UM BWMC, which is clinically and operationally integrated with UMMS, AAMC is an independent hospital that must bear the financial burden of a new cardiac surgery program alone. As explained below, the proposed program at AAMC, as a stand-alone program, is not financially feasible; whereas the proposed expansion of the UM Division of Cardiac Surgery is financially feasible as an overall program. The benefits and strengths that AAMC claims will occur as a result of its program, including significant case volume, staffing, clinical research, training, and education, are uncertain given that these benefits depend largely on the continuation of a loose affiliation between AAMC and JHM.

### **INTERESTED PARTY STATUS**

UM BWMC is an “interested party” within the meaning set forth in COMAR § 10.24.01.01B(20) because (1) it is an applicant in this comparative review; and (2) approval of AAMC’s application would adversely affect UM BWMC in an issue area over which the Commission has jurisdiction.

### **ARGUMENT**

#### **I. AAMC’S CON APPLICATION DOES NOT MEET THE STATE HEALTH PLAN REVIEW STANDARDS FOR CARDIAC SURGERY PROGRAMS.**

##### **A. AAMC CANNOT DEMONSTRATE COMPLIANCE WITH THE STANDARDS BECAUSE AAMC HAS NOT DISCLOSED THE TERMS OF ITS STRATEGIC ALLIANCE AGREEMENT WITH JOHNS HOPKINS MEDICINE.**

AAMC touts its relationship with JHM and purports to propose its cardiac surgery program “in partnership” with JHM. However, AAMC is not a member of JHM (or of any other JHM entity), nor is JHM an applicant in the CON review. Yet, AAMC relies heavily upon key contributions from JHM to comply with a number of CON standards and review criteria.

JHM’s involvement in the AAMC proposal is instrumental in at least the following ways:

- Minimum Volume and Need – To show that it will achieve a minimum volume of 200 cases by the second full year of operation, AAMC relies upon an undocumented expectation that 50% of the cardiac surgery cases performed at Johns Hopkins Hospital (“JHH”) for patients who reside in the AAMC proposed service area will be shifted to AAMC. (AAMC Appl. at pp. 80-81, 146.)
- Financial Feasibility – In attempting to demonstrate financial feasibility, AAMC not only relies upon a significant volume of cases shifting from JHM to generate revenue, it also depends upon JHM for providing surgeons and perfusionists in connection with its expense projections. (AAMC Appl. at pp. 59-63.)
- Education, Research, and Training – AAMC promotes JHM’s research and training initiatives, including ongoing clinical trials in cardiac surgery and a residency program in thoracic surgery. (AAMC Appl. at pp. 197-199.)

AAMC has not sufficiently explained and documented its supposed partnership with JHM to warrant the Commission’s reliance upon the partnership to find compliance with the required standards and review criteria to establish a new cardiac surgery program at AAMC.

AAMC describes the partnership in vague terms:

In 2007, AAMC and JHM entered into a relationship in recognition of their mutual commitment to patient-centered care and improved access to the highest quality, affordable, health care in the region. As part of this ongoing alliance, AAMC will partner with JHM to bring renowned cardiac surgeons to AAMC to establish its cardiac surgery program.

AAMC Appl. at p. 15. A letter submitted by JHM President Ronald R. Peterson provides little more detail about the existing “affiliation” between JHM and AAMC, mentioning the co-development of a medical office building in Odenton, Maryland and the joint identification of



access issues for pediatric sub-specialties in the contiguous service areas of the two institutions. AAMC Appl. at Appendix 3(c).

AAMC has not submitted any written agreement with JHM as part of its CON application, although AAMC's website contains a January 3, 2012 report stating that a five-year "strategic alliance agreement" with JHM was renewed. *See* <http://www.aahs.org/news/?p=1102> (last accessed July 22, 2015). In short, AAMC has revealed very little about the exact nature of its affiliation with JHM, the specific initiatives covered by the agreement, the term of the relationship, any financial arrangements (such as a licensing or similar fee), the relative obligations of the parties under the agreement, and the parties' intentions and commitments about the future of the relationship.

A strong, integrated, and long-term relationship with JHM is critically important to implementing and successfully maintaining a cardiac surgery program at AAMC. If the Commission awarded a CON to establish the cardiac surgery program described in the AAMC application and the affiliation between AAMC and JHM ended, then the actual program would be vastly different from the one approved by the Commission. Given that the approval of another cardiac surgery program in the Baltimore / Upper Shore Region would not be permitted for at least three years after the program began operating (*See* COMAR § 10.24.17.04A(1)(d)), it is risky for the Commission to grant a CON to an applicant that depends upon uncertain key support from another party, particularly when there is an alternative applicant.

As a fully integrated member hospital of UMMS, UM BWMC presents a proposal that will be implemented within the UM Division of Cardiac Surgery exactly as it is described in the UM BWMC application, with no risk that the affiliation will terminate or materially change after the program is approved.

**B. AAMC'S CON APPLICATION DOES NOT MEET THE MINIMUM VOLUME STANDARD (COMAR § 10.24.17.05A(1)) BECAUSE AAMC DOES NOT DOCUMENT THAT IT WILL ACHIEVE A VOLUME OF AT LEAST 200 CASES IN THE SECOND FULL YEAR OF OPERATION.**

AAMC has not documented that it will be able to achieve a volume of at least 200 cases in the second full year of operation of the proposed cardiac surgery program. As set forth below, AAMC's response to this standard relies on undocumented statements and aspirational assumptions.

- i. AAMC does not meet the minimum volume standard on the basis of referral sources, because AAMC relies on undocumented referrals, and does not include discounts for severity of illness and patient preference.**

AAMC states that its existing referral base can, by itself, support a cardiac surgery program that will meet the minimum volume standard, but has not provided sufficient documentation that AAMC can reasonably expect to receive referrals from each practice. (AAMC Appl. at pp. 77-80; AAMC March 30, 2105 Response to Completeness Questions, p. 18.) AAMC provided no documentation that it may reasonably expect to receive any referrals from Cardiology Associates, a cardiology practice owned by MedStar Health. Instead, AAMC asks the Commission to rely on unsupported assertions that are insufficient to comply with this standard.

In addition, even for practices from which AAMC received letters of support, AAMC has not provided sufficient documentation of the number of estimated referrals it can reasonably expect to receive from those cardiology practices. AAMC again simply asserts that it calculated the number of referrals that these practices made for cardiac surgery in FY 2014, without providing documentation that would support these calculations. For example, although AAMC states that AAMC Cardiology Specialists made 105 referrals for cardiac surgery in FY2014, the

letters of support from that practice only document 50 referrals. (AAMC March 30, 2015 Response to Completeness Questions, Exh. 17(a).) The only attestations AAMC provides to support its assertions are from CEO Victoria Bayless (AAMC Appl. at Exh. 14) and CFO Robert Reilly (March 30, 2015 Responses, p. 116), who are unlikely to have personal knowledge of the number of referrals made by these cardiology practices.<sup>2</sup>

Table 1, following, demonstrates the total number of referrals that AAMC has documented through letters of support from any cardiology practice group, including each group’s referrals to hospitals other than AAMC.

**Table 1  
Cardiology Referrals by Cardiology Group**

Cardiology Practices	<u>FY 2014 Cases, Practice Total</u>	
	<b>AAMC Assertion</b>	<b>Documented Referrals<sup>(1)</sup></b>
AAMC Cardiology Specialists	105	50
Annapolis Cardiology Consultants LLC	105	110
Chesapeake Cardiac Care, PA	27	32
Bay Cardiology	10	10
Chestertown Cardiology	55	58 <sup>(2)</sup>
Cardiology Associates	120	0
<b>Total, 6 practices</b>	<b>422</b>	<b>260</b>

Note 1: AAMC March 30, 2105 Response to Completeness Questions, Exhibit 17(a)

Note 2: Includes 8 referrals attributed to Dr. Juan M. Cordero’s estimated referral of 5-10 patients yearly.

Table 2 below projects the total number of referrals that AAMC has documented from any cardiology practice for FY 2014, projected for FY 2017 and FY 2018 using the same methodology that AAMC used in its projections, which incorporates the Commission’s cardiac surgery need methodology.

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<sup>2</sup> AAMC also provides an attestation for its May 6, 2015 Responses to Completeness Questions from Director of the AAMC Heart Institute, Jerome Segal. These responses do not indicate the number of referrals made by the six cardiology practices cited by AAMC.

**Table 2**  
**Total Documented Practice Group Referrals for Cardiac Surgery**  
**FY 2014 Actual, FY 2017 and FY 2018 Projected<sup>(1)</sup>**

<b>Cardiology Practices</b>	<b>FY14</b>	<b>FY17</b>	<b>FY18</b>
AAMC Cardiology Specialists	50	48	48
Annapolis Cardiology Consultants LLC	110	106	105
Chesapeake Cardiac Care, PA	32	31	31
Bay Cardiology	10	10	10
Chestertown Cardiology	58	56	55
Cardiology Associates	0	0	0
<b>Total, 6 practices</b>	<b>260</b>	<b>251</b>	<b>249</b>

Note 1: % market change applied based on MHCC projection used by AAMC (FY17:-3.56%, FY18: -0.89%)

Table 3, following, applies AAMC’s assumptions regarding the percentage of referrals these cardiology practices will refer to AAMC to project total patient volume based on referrals.

**Table 3**  
**Projected AAMC Volume Based on Documented Referrals**

<b>Cardiology Practices</b>	<b>Total Projected Practice Referrals</b>			<b>AAMC Share<sup>(1)</sup></b>		<b>AAMC Projected Volume</b>	
	<b>FY14</b>	<b>FY17</b>	<b>FY18</b>	<b>FY17</b>	<b>FY18</b>	<b>FY17</b>	<b>FY18</b>
AAMC Cardiology Specialists	50	48	48	90%	90%	43	43
Annapolis Cardiology Consultants LLC	110	106	105	90%	90%	95	95
Chesapeake Cardiac Care, PA	32	31	31	50%	75%	16	23
Bay Cardiology	10	10	10	75%	90%	8	9
Chestertown Cardiology	58	56	55	25%	50%	14	28
<b>Total, 5 practices</b>	<b>260</b>	<b>251</b>	<b>249</b>			<b>176</b>	<b>197</b>

Note 1: Based on percentages applied by AAMC in March 30, 2105 Response to Completeness Questions, p. 17.

AAMC however, did not sufficiently document even this reduced volume. AAMC assumed that it would perform cardiac surgery for 90% of patients referred by cardiologists whose letters of supported indicated that he or she would refer “all,” “nearly all” or “likely all” patients to AAMC. (AAMC May 6, 2015 Response to Completeness Questions, pp. 6-8.<sup>3</sup>)

<sup>3</sup> The cited responses have two conflicting page numbers. The cited page numbers refer to the number marked “Page [x] of 50 in AAMC’s responses.”

This assumption fails to discount referral volume for patients requiring surgery at an academic medical center due to severity of illness (“SOI”). In FY 2014, 17% of the cardiac surgery cases for all hospitals in Maryland had an SOI rating of “Extreme.” (FY 2014 MSA Database). AAMC admits that it will not take “the most complex cases, and those procedures restricted to a limited number of approved sites.” (AAMC Appl. at p. 80).<sup>4</sup>

At a minimum, AAMC should account for SOI by assuming that no more than 83% of the documented referrals from those practices will result in discharges at AAMC. Such an assumption would result in the volumes demonstrated in Table 4, below.

**Table 4  
AAMC Projected Volume Based on Documented Referrals  
Excluding 17% minimum for SOI**

Cardiology Practices	Total Projected Practice Referrals			AAMC Share, with min. 17% excl. for SOI		AAMC Projected Volume	
	FY14	FY17	FY18	FY17	FY18	FY17	FY18
AAMC Cardiology Specialists	50	48	48	83%	83%	40	40
Annapolis Cardiology Consultants LLC	110	106	105	83%	83%	88	87
Chesapeake Cardiac Care, PA	32	31	31	50%	75%	16	23
Bay Cardiology	10	10	10	75%	83%	8	8
Chestertown Cardiology	58	56	55	25%	50%	14	28
<b>Total, 5 practices</b>	<b>260</b>	<b>251</b>	<b>249</b>			<b>165</b>	<b>186</b>

Even if AAMC will treat some patients with an “Extreme” SOI, AAMC also failed to discount its projections for other factors, as described below. While these factors would result in a relatively small decrease in projected volume, AAMC’s failure to account for them further underscores the inflation of AAMC’s projected volumes.

<sup>4</sup> If AAMC’s proposed cardiac surgery program will treat patients with “Extreme” SOI, AAMC should clarify its proposal to explain what cases will be excluded as “the most complex cases, and those procedures restricted to a limited number of approved sites.”

Surgery Assumption: AAMC assumes that 100% of referred patients will have surgery. This assumption fails to account for patients who are ultimately determined not to need surgery, are too clinically unstable for surgery or die before surgery can be performed.

Patient Preference: Cardiac surgery cases are usually elective rather than urgent, which often allows patients the ability to seek out care from their preferred providers. Patients may choose to have surgery at another facility for a myriad of reasons, including established relationships within a medical system, previous experiences of friends and family, convenience of outpatient clinic locations, and other factors.

Comparatively, UM BWMC's projected cardiac surgery case volume, based upon its documented current cardiologist referral base, can support a cardiac surgery program within the program's first year of operation. *See* Exhibit 1. As further described in UM BWMC's application and responses to completeness questions, UM BWMC's proposed cardiac surgery program will be sustainable due in large part to the strength of the integration within the UM Division of Cardiac Surgery and with the local cardiologist community, as well as the demonstrated support for UM BWMC's proposed cardiac surgery program. These strong relationships will assure maintenance of a strong referral volume necessary to sustain a cardiac surgery program, in excess of 200 cases per year. AAMC does not demonstrate a comparable level of integration and documented support.

**ii. AAMC cannot meet the minimum volume standard on the basis of its inpatient transfers, outpatient transfers, and expected volume from JHH.**

AAMC's assertion that its existing patient based is sufficient to meet the minimum volume standard is misleading because that patient base is well below the minimum volume

standard once AAMC’s retention assumptions are applied to the patient base as projected for the first two years of operation.

AAMC states that it transferred 303 cardiac care patients to an accepting hospital for cardiac surgery in FY 2014. (AAMC Appl. at pp. 77-78; AAMC March 30, 2015 Response to Completeness Questions, pp. 19-20.) AAMC then applied a surgery assumption based on the reason for transfer, resulting in an assumed 234 patients that AAMC assumed had surgery. (*Id.*) AAMC then assumed that 80% of the patients who actually had surgery would have chosen to have their surgery at AAMC if a cardiac surgery program existed there. (*Id.*) This results in an assumed 187 cases for FY 2014. As shown in Table 5, applying the assumptions underlying the Commission’s projections, which AAMC relies upon elsewhere in its application, results in a volume of only 181 cases in FY 2017 and 179 cases in FY 2018 – both insufficient to meet the minimum volume standard.

**Table 5**  
**AAMC Cases Based on Inpatient and Outpatient Transfers**  
**FY 14 based on AAMC Appl., FY 17-18 Adjusted based on MHCC Projections**

Recorded Reason for Inpatient Transfer	Total Cases	AAMC Surg. Assumption	Total Surg. Cases	Total Projected Cases		AAMC Share (80%)	
				FY17	FY18	FY17	FY18
CABG	52	100%	52	50	50	40	40
Unspecified surgery	15	100%	15	14	14	12	11
Surgery (Valve)	9	100%	9	9	9	7	7
Evaluation for valve surgery	3	50%	2	1	1	1	1
Cardiac Cath for cardiac surgical eval.	95	50%	48	46	45	37	36
Evaluation for cardiac surg. based on dx	25	50%	13	12	12	10	10
Eval. for cardiac cath/Valve	4	50%	2	2	2	2	2
Evaluation for cardiac cath/CABG	1	50%	1	0	0	0	0
N/A	1	0%	0	0	0	0	0
<b>Total, Inpatient Transfers</b>	<b>205</b>		<b>140</b>	<b>135</b>	<b>134</b>	<b>108</b>	<b>107</b>
<b>Outpatient Transfers</b>	<b>19</b>	<b>100%</b>	<b>19</b>	<b>18</b>	<b>18</b>	<b>15</b>	<b>15</b>
<b>Outpatient Referrals for Surgery</b>	<b>79</b>	<b>95%</b>	<b>75</b>	<b>72</b>	<b>72</b>	<b>58</b>	<b>57</b>
<b>TOTAL, TRANSFERS AND REFERRALS</b>	<b>303</b>		<b>234</b>	<b>226</b>	<b>224</b>	<b>181</b>	<b>179</b>

Source: AAMC Appl. at pp. 77-78; AAMC March 30, 2015 Response to Completeness Questions, pp. 19-20  
Percent market change applied based on MHCC projection as used by AAMC (FY17:-3.56%, FY18: -0.89%)

Furthermore, AAMC’s surgery assumptions may be overstated. For example, AAMC does not identify which patient or surgery types are included in several categories, including “Outpatient Transfers,” “Outpatient Referrals for Surgery,” and “Cardiac Cath for cardiac surgical eval.,” leaving UM BWMC and the Commission without a meaningful way to evaluate the appropriateness of AAMC’s surgery assumptions. Also, AAMC’s assumptions, especially those at 100%, may not account for patients who will be too unstable for surgery, become deceased prior to surgery, or who are ultimately determined not to need surgery. As shown in Table 6, even a slight reduction of five percentage points in AAMC’s surgery assumptions for the three vague categories would bring AAMC’s volume even further below the minimum volume standard.

**Table 6  
AAMC Cases Based on Inpatient and Outpatient Transfers  
with Adjusted Surgery Assumptions**

Recorded Reason for Inpatient Transfer	Total Cases	AAMC Surg. Assumption	Total Surg. Cases	Total Projected Cases		AAMC Share (80%)	
				FY17	FY18	FY17	FY18
CABG	52	100%	52	50	50	40	40
Unspecified surgery	15	100%	15	14	14	12	11
Surgery (Valve)	9	100%	9	9	9	7	7
Evaluation for valve surgery	3	50%	2	1	1	1	1
Cardiac Cath for cardiac surgical eval.	95	45%	43	41	41	33	33
Evaluation for cardiac surg. based on dx	25	50%	13	12	12	10	10
Eval. for cardiac cath/Valve	4	50%	2	2	2	2	2
Evaluation for cardiac cath/CABG	1	50%	1	0	0	0	0
N/A	1	0%	0	0	0	0	0
<b>Total, Inpatient Transfers</b>	<b>205</b>		<b>135</b>	<b>130</b>	<b>129</b>	<b>104</b>	<b>103</b>
<b>Outpatient Transfers</b>	<b>19</b>	<b>95%</b>	<b>18</b>	<b>17</b>	<b>17</b>	<b>14</b>	<b>14</b>
<b>Outpatient Referrals for Surgery</b>	<b>79</b>	<b>90%</b>	<b>71</b>	<b>69</b>	<b>68</b>	<b>55</b>	<b>54</b>
<b>TOTAL, TRANSFERS AND REFERRALS</b>	<b>303</b>		<b>224</b>	<b>216</b>	<b>214</b>	<b>173</b>	<b>172</b>

AAMC should further explain these categories and the underlying assumptions.

AAMC attempts to bolster its volume from current direct transfers by claiming that it also expects a total of 50% of patients in its proposed cardiac surgery service area who had surgery at The Johns Hopkins Hospital (“JHH”) in FY 2014 to shift to AAMC. (AAMC App. at p. 81.)



AAMC states that 163 patients in its service area had surgery at JHH in CY 2013, which, applying a 50% shift, would result in 82 patients in CY 2013 volume. (*Id.*) According to AAMC, 37 of these 82 patients are counted in the direct transfer analysis, leaving an additional 45 patients who AAMC expects will shift to it in CY 2013 volume. (*Id.*)

AAMC provides no documentation or analysis as to why or how it can expect these additional JHH patients to have cardiac surgery at AAMC. Because this patient volume relies solely on undocumented assertions, it cannot be considered documentation of AAMC's ability to achieve the minimum volume standard.

Furthermore, AAMC's assumptions regarding the shift from JHH are inconsistent throughout AAMC's application. Table 7, below, collects volume projections as stated by AAMC in its application. The rows labeled 3, 4, and 5 apply projections used elsewhere in AAMC's application to numbers as stated by AAMC (shaded in blue) to reveal further inconsistencies. There is inconsistency even in the numbers AAMC cites directly. For example, in response to the minimum volume standard, AAMC states that "[i]n CY 2013, a total of 163 service area residents had cardiac surgery at the JHH." (AAMC Appl. at p. 82.) Elsewhere in its application, AAMC estimates a volume shift of 85 cases from JHH based on CY 2013 data, which would be 170 total JHH cases in CY 2013. (*See* Row 4.) In its need analysis, AAMC projects JHH's total volume in AAMC's service area at 163, and the shift to AAMC less direct transfers from AAMC to JHH as 45, for FY 2014 rather than for CY 2013 as stated previously. (*Compare* Rows 1 and 3.)

**Table 7  
Inconsistencies in AAMC Application of JHH Volume Shift to AAMC**

	AAMC Appl. Cite	CY 2013			FY 2014			FY 2017			FY 2018		
		Total JHH	AAMC Shift	AAMC direct transf.	Total JHH	AAMC C Shift	AAMC direct transf.	Total JHH	AAMC Shift	AAMC direct transf.	Total JHH	AAMC Shift	AAMC direct transf.
1	p. 81, 138, <sup>(1)</sup> 146	163	82	45									
2	pp. 88, <sup>(2)</sup> 92-93		85								69		
3	p. 148				163	45			43			42	
4	applying 50% assump.	170	85										
5	a applying MHCC proj. (FY17: -3.56%, FY 18: -.89%)				163		157				156		
	b applying 50% assump.							79			78		
6	a applying AAMC projection (CY13 to FY19: -18.14%) <sup>(3)</sup>	163	82	45							67	37	
	b applying MHCC proj. (FY17 = FY18+.089%)							68	37				
	c applying 50% assump.						135			134			

Note 1: Page 88 cites only the FY 2014 impact of 69 cases.

Note 2: Page 138 cites CY 2013 total cases of 163.

Note 3: Chart 11 in AAMC’s application projected FY 2018 volume based on CY 2013 data. The percent decrease from CY 2013 to FY 2018 was different for each hospital. Excluding percentages based on CY 2013 volumes of less than 10, AAMC projected an average volume decline from CY 2013 to FY 2018 of 18.14%. See Exhibit 2.

AAMC’s volume analysis may therefore be overstated. If AAMC projected that JHH would have 163 cases in FY2014, then the impact on JHH should be 78 cases in FY 2018 and 79 cases in FY 2017. (See Row 5b.) Instead, AAMC projects that there will be a total shift from JHH of 69 cases in FY 2018. (See Row 2.) Assuming the correct volume is 163 cases at JHH in CY 2013, and applying projections AAMC uses elsewhere in its application, results in a volume shift of 67 cases in FY 2018 and 68 cases in FY 2019. (See Rows 6a-b.) Applying the same assumptions to a shift of 45 cases after accounting for direct transfers would result in only 37 additional cases shifting to AAMC in FY 2017 and FY 2018. (*Id.*)

Because AAMC’s projections of the volume shift from JHH are inconsistent throughout the application, these projections should not be considered documentation of AAMC’s ability to achieve minimum volume. AAMC should be required to explain these inconsistencies, update

its projections, and provide documentation supporting its assumptions concerning minimum volume.

**iii. AAMC's market share projections are unrealistic and do not constitute documentation of AAMC's ability to achieve the minimum volume standard.**

AAMC cannot meet the minimum volume standard by relying upon unsupported, aspirational market share projections. AAMC assumes that it will have a 25% cardiac surgery market share in its defined service area in the first year of operation, 35% in the second year, and 40% in the third year. As set forth below, AAMC's market share assumptions are not documented, and are not reasonable.

AAMC assumes a current market share equivalent of cardiac surgery of 19% based on its surgery and retention assumptions regarding its existing base of hospital transfers and hospital referrals. AAMC argues that the reasonableness of these assumptions is reinforced by its nearly 20% market share for PCI. AAMC next assumes it will achieve an additional 4%-5% market share (bringing its total market share to 23%-24%) based on its assumption that it will treat 50% of referral patients in AAMC's service area currently treated at JHH. As previously discussed, AAMC has not provided sufficient documentation to support these assumptions.

AAMC attributes the remainder of its 25% market share to its assertion that it has newly affiliated physician practices in Kent County. Kent County had an average of 11 residents discharged for cardiac surgery in FY 2013-FY 2015, and UMMS hospitals had a 60.1% share of Maryland hospital discharges of Kent County residents for cardiac surgery during the same period. (See Exhibit 3.) AAMC's undocumented new relationship with unnamed physician practices in this county does not constitute documentation of AAMC's ability to achieve the

minimum volume standard, or demonstrate a reasonable foundation for its assumed 25% market share.

Next, AAMC projects that its market share will grow within two years from 25% to 40% (a 60% increase) based on seriously flawed rationale. (AAMC Appl. at p. 83.)

First, AMMC notes that its overall inpatient market share in the region is only 24%, but it assumes that it can achieve a much greater market share in cardiac surgery because it has a 40% market share in joint replacement and a 32% market share in bariatric surgery. AAMC does not explain why its market shares in such dissimilar programs as joint replacement and bariatric surgery are reliable markers for projecting market share in cardiac surgery. A more reliable surrogate for the cardiac surgery market share would be AAMC's Adult Medical Cardiology Market share, which AAMC disclosed as 18.9% in its proposed service area for CY 2013. (AAMC Appl. at p. 139.)

Second, AAMC attempts to justify its leap of market share by claiming that it "will be the only cardiac surgery provider within a 60 minute drive for thousands of area residents." AAMC does not identify what percentage of its service area population lives in the area it identifies as more than 60 minutes away from an existing program, (AAMC Appl. at p. 122), but 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). Notably, while a drive time map AAMC provided identifies portions of Kent, Cecil, Harford, Queen Anne's, and Caroline Counties as being more than 60 minutes from an existing program, AAMC did not include Christiana Hospital as an existing program. (AAMC Appl. at p. 122.)

Finally, AAMC asserts that its greatly increased market share will result from payer-provider contracts, but it provides no detail about these alleged arrangements that will supposedly dramatically change the marketplace in AAMC’s favor.

In addition to making assertions and assumptions that do not support a 40% market share, AAMC fails to consider the strength of PGHC and UMMS in AAMC’s proposed cardiac surgery service area. As discussed more in PGHC’s interested party comments, although AAMC attributed almost no service area volume to PGHC, PGHC had 58 cardiac discharges from Zip Codes that overlap with AAMC’s proposed cardiac surgery services area in the last 6 months, which would be an annual 116 cases even if PHGH’s rapidly reviving program experiences no further upward trend in growth. Furthermore, recent cardiac surgery case volumes originating from the mid-shore counties show an overwhelming preference for UMMS-affiliated cardiac surgical programs. Table 8 below shows the relative market shares for cardiac surgery services in the mid-shore counties of the Baltimore / Upper Shore health planning region.

**Table 8**  
**Adult Cardiac Surgery Distribution of Discharges from Maryland Hospitals**  
**Residents of 4 Mid-Shore Counties in Baltimore/Upper Shore Region**  
**FY13, FY14, FY15 Q1-Q3**

<b>County of Patient Origin</b>	<b>UMMS</b>	<b>JHHS</b>	<b>PRMC</b>	<b>Other</b>
Caroline	52.3%	5.8%	39.5%	2.3%
Kent	60.0%	36.7%	3.3%	0.0%
Queen Anne's	55.1%	37.2%	2.6%	5.1%
Talbot	68.2%	12.7%	17.3%	1.8 %
All Mid-Shore Counties in Cardiac SA	59.5%	19.4%	18.4%	2.6%

Source: MSA database, HSCRC discharge data, see Exhibit 3

Despite the UMMS member hospitals being over an hour driving time away, UMMS has a combined 59.5% market share in the mid-shore counties. (*See also* Exhibit 3.)

AAMC does not provide convincing evidence that it will be able to shift a significant percentage of UMMS’ volume to AAMC. This preference exists despite that the other programs

are closer or a comparable drive time for Eastern Shore residents. AAMC's own application claims that the JHM affiliation will help drive volume growth; however, JHM is clearly not a preferred provider for Eastern Shore patients. AAMC has not demonstrated that it can sufficiently reduce UMMS' majority market share in the Eastern Shore, which it has achieved through offering a continuum of cardiac care services at three hospitals, and several outpatient centers and physician practices on the Eastern Shore. In short, there is no reasonable basis for AAMC to assume it can establish a market share of 40% by the third year of operation, and AAMC has failed to document that it can achieve the minimum volume standard.

**C. AAMC'S CON APPLICATION DOES NOT MEET THE IMPACT STANDARDS (COMAR § 10.24.17.05A(2) AND COMAR 10.24.01.08G(3)(f)) BECAUSE AAMC DID NOT ADEQUATELY ADDRESS THE IMPACT ON PGHC AND BECAUSE AAMC WILL NEGATIVELY IMPACT PGHC, ACCESS TO SERVICES IN PRINCE GEORGE'S COUNTY, AND COSTS OF OTHER PROVIDERS**

- i. AAMC did not meet its burden of projecting the impact of its proposal on PGHC, and its proposal will cause PGHC's volume to drop below 100 discharges, and will decrease access for an underserved population.**

In assessing the impact of its proposed new cardiac surgery program on existing providers, AAMC failed to consider the growing volume in cardiac surgery at PGHC. AAMC states: "this analysis does not address the impact of a new program on Prince George's Hospital Center, which has served fewer than 20 cases/year in CY 2012 and CY 2013." (AAMC Appl. at pp. 93-94.) AAMC's failure to account for the growing cardiac surgery volumes at a neighboring hospital with an overlapping service area results in a seriously flawed impact analysis.

The proposed AAMC cardiac surgery service area overlaps extensively with the existing service area for PGHC (an overlap of 15 zip codes), and a new cardiac surgery program at

AAMC will significantly impact PGHC's existing program. AAMC has not demonstrated that its proposed program would not result in reducing the volume at PGHC below the volume benchmarks set forth in COMAR § 10.24.17.05A(2)(b). In fact, as explained in the comments submitted by PGHC, the proposed program at AAMC would cause such adverse impact at PGHC.<sup>5</sup> PGHC demonstrates that in FY 2015 it had a volume of 85 cardiac surgery cases, and the volume is growing.

While the Commission should consider significant adverse impact of a new program on any existing provider, the PGHC cardiac surgery program deserves special protection because substantial resources have been invested to revitalize the cardiac surgery program at PGHC. Prince George's County, a county that is underserved, has no cardiac surgery provider other than PGHC.

**ii. AAMC understates the impact its program would have on other hospitals.**

In addition to having an adverse financial impact on PGHC, AAMC's cardiac surgery program would cause an unfavorable financial impact on other hospitals, to a greater extent than stated in its Application. AAMC assumes hospitals' costs are 50% fixed and 50% variable, (AAMC Appl. at pp. 220-221). Therefore, AAMC assumes that a revenue shift at 50% has no impact on operating income as a reduction in revenue is offset by an equal reduction in variable expenses. This is not a realistic assumption, as hospital experience has proven the difficulty of controlling expenses during periods of declining volume. In reality, if the affected hospitals are

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<sup>5</sup> Like the proposed cardiac surgery program at UM BWMC, PGHC's cardiac surgery program is operated by the UM Division of Cardiac Surgery. Thus, UM BWMC is aware that PGHC is submitting written comments that will address the adverse impact of AAMC's proposed cardiac surgery program on PGHC's recently revitalized program. UM BWMC adopts those comments for purposes of challenging the validity AAMC's purported impact analysis.

unable to reduce costs, the impact of the decline in volume on revenues would fall directly to operating income. Thus, the potential adverse impact on existing providers could reach \$10.1 million in FY 2018. This assumes a market share adjustment to revenue equal to 50% of the \$20.2 million, or \$60,221 estimated average payment per case for all 337 relocated cases presented by AAMC. (AAMC Appl. at p. 109, Chart 14.)

AAMC's implicit assumption that hospitals operate with a 50% variable cost structure is inconsistent with its own financial projections. Total AAMC uninflated expenses from FY 2017 – FY 2018 and FY 2018 – FY 2019 are projected to grow with 38.5% and 39.0% expense variability, for an average of 38.8% expense variability with growth in volume. If AAMC's own expense variability assumption is used to determine its impact on other providers, the removal of \$10.1 million in revenue (50% of \$20.2 million) combined with an assumption of providers reducing costs at 39%, or \$7.8 million, would still result in a negative impact of \$2.3 million on existing providers.

In contrast to AAMC, UM BWMC relies primarily on volumes already in the UMMS system. Thus, its expected impact under the same 50% revenue variability and 39% expense variability assumptions is about one fifth of AAMC's impact, or \$469,000. As shown in Table 9 below, of the 228 cases expected to transfer to UM BWMC in Year 3, 66%, or 151 cases, are transfers from UMMC.



**Table 9  
UM BWMC Net Projected Impact on Other Providers**

Hospital	Yr 3 Cases to Transfer	Charge Per Case	Net Payment Per Case at 90.7% <sup>(1)</sup>	Net Payments
UMMC	151	\$ 66,211	\$ 60,053	\$ 9,068,060
Hopkins	21	57,279	51,952	1,090,993
Union Memorial	11	61,076	55,396	609,355
Sinai	2	62,624	56,800	113,600
Peninsula	4	46,792 <sup>(2)</sup>	42,440	169,761
Washington Adventist	2	51,086	46,335	92,670
UM SJMC	7	55,688	50,509	353,563
Total Maryland				\$ 11,498,003
DC Hospitals	30		\$ 58,681 <sup>(3)</sup>	\$ 1,760,430
Total Payments shifted to UM BWMC				\$ 13,258,433
Less: UMMC <sup>(4)</sup>				\$ 9,068,060
Total Net Revenue from Other Providers				\$ 4,190,373
50 % Variability				\$ 2,095,186
39% Expense Reduction				\$ (1,625,865)
<b>Net Impact on Existing Providers</b>				<b>\$ 469,322</b>

Note (1): Based on 90.7% average net-to-gross ratio in BWMC Financial Projections for FY 2017-2019.

Note (2): FY 2014 Charge per case for Cardiac Surgery services per Inpatient data tapes.

Note (3): Based on AAMC Chart 14, which provides DC Hospital estimated payment per case.

Note (4): Removed from impact calculation as revenue shifts within UMMS are transferred at 100%.

**D. AAMC'S PROPOSAL IS NOT COST-EFFECTIVE UNDER COMAR § 10.24.17.05A(4).**

**i. AAMC low charge per case results in part from maintaining certain outpatient services as rate-regulated, which is not a cost-effective practice.**

In projecting revenue, AAMC assumes a baseline charge per case of \$10,962, equal to its FY 2014 hospital-wide charge per case at a case mix of 1.0. (AAMC Appl. at p. 162.)

While AAMC is presented as a hospital with a low charge per case at a CMI of 1.0, one reason AAMC appears efficient is that it has a broad base of rate-regulated outpatient services to which it can allocate its overhead costs. As UM BWMC and other hospitals have shifted certain outpatient services to an unregulated setting, they reduce the regulated outpatient services to which they can allocate overhead costs. For example, most of the UM BWMC physician practice services are provided in space that is not rate-regulated.

AAMC provides more outpatient services in rate-regulated space, which allows AAMC to allocate its overhead and thereby reduce AAMC's charge per case to appear more price

competitive. However, providing these outpatient services in a regulated setting typically results in higher charges to payers and patients, and is not the most cost effective way to deliver health care services.

**ii. AAMC projects that its proposed cardiac surgery program would have an unfavorable \$5.8 million impact on the All-Payer Waiver Test.**

Although AAMC asserts that its proposed cardiac surgery program will reduce costs to payers for those cases shifted from the District of Columbia (principally from Washington Hospital Center), AAMC concedes that its proposed strategy will have an unfavorable impact on the requirement that Maryland maintain an annual limit on the all-payer total hospital revenue growth (the “All Payer Waiver Test”). (Maryland All-Payer Model Agreement, Section 8(a).) AAMC projects that the impact will be in excess of \$5.8 million in the first two years of operation of the program. (AAMC Appl. at p. 171.)

**E. AAMC HAS NOT ESTABLISHED THAT ITS PROPOSED PROGRAM CAN BE JUSTIFIED ON THE BASIS THAT THERE EXISTS INADEQUATE ACCESS TO SERVICES (COMAR § 10.24.17.05A(5)).**

**i. Geographic access to cardiac surgery services is not a problem in Maryland with respect to patient travel time.**

The Maryland Health Care Commission recognizes that “[g]eographic access to cardiac surgery services . . . is not a problem in Maryland, with respect to patient travel time or survival.” COMAR 10.24.17.03 at p. 11. Cardiac surgery cases are usually elective, not urgent, which allows patients the ability to seek out care from their preferred providers. Patient preference is influenced by current provider networks, prior experiences, and other individualized factors, including the availability of convenient pre- and post-operative care. Accordingly, the access standard does not focus on geographic access but on other barriers to access, requiring applicants that seek to justify a program on the basis of this standard to

demonstrate that such barriers exist and explain how its program will remedy those barriers. COMAR § 10.24.17.05A(5).

Despite this, AAMC includes a discussion that spans eight pages and 10 maps of the travel time cardiac surgery patients currently face. AAMC fails to present any evidence that travel time is a barrier to access for cardiac surgery, and fails to disprove the express regulation governing AAMC's application that travel time is "not a problem."<sup>6</sup>

**ii. UM BWMC is better positioned than AAMC to provide a continuum of cardiac care to a greater number of patients.**

AAMC argues that even though geographic access is not a barrier to cardiac surgery itself, AAMC's program will improve the continuum of care for residents of Anne Arundel County and the Eastern Shore. (AAMC Appl. at pp. 110-112.) AAMC has not put forth any evidence demonstrating that there is an existing barrier in accessing a full continuum of cardiac care in these regions. Even if true, however, UM BWMC, as a part of UMMS, is in a far better position to provide this continuum of care to more residents in the region. AAMC's application proposes only an outpatient clinic on its Annapolis campus. AAMC only has one affiliated cardiologist practice with an Eastern Shore location that has a documented referral projection. AAMC does not offer an affiliated cardiac rehabilitation practice on the Eastern Shore.

Comparatively, UM BWMC's program will offer patients greater options for their care and maximize patient and family convenience. The UM Division of Cardiac Surgery, which

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<sup>6</sup> Although UM BWMC briefly addressed travel time in its application, it did so in the context of cost effectiveness. (See UM BWMC Appl. at p. 57.) UM BWMC recognizes that a program in Anne Arundel County would make cardiac surgery more convenient for residents of the County, and hopes to remedy the current inconvenience some patients face through the development of a third UM Division of Cardiac Surgery location at UM BWMC. However, UM BWMC denies that the current inconvenience some patients face is an actual barrier to care.

would include UM BWMC if the CON is granted, currently offers outpatient clinics in Queenstown, Baltimore, Towson, and Bel Air and hospitals in Glen Burnie, Chestertown, and Easton. This will allow Eastern Shore patients and others the flexibility to choose an outpatient location that is convenient to their homes or work places, while being able to have their surgery at UM BWMC. UMMS-owned and UMMS-affiliated cardiology practices are located in Easton, Cambridge, and Queenstown on the Eastern Shore and in the northern Anne Arundel County and Baltimore regions. Additionally, cardiopulmonary rehabilitation programs accredited by the American Association of Cardiovascular and Pulmonary Rehabilitation are available at a number of UMMS locations including UM BMWC, UM Shore Regional Health Centers at Chestertown, Dorchester, and Easton, and UM Shore Medical Pavilion at Queenstown. This clinically integrated system of care allows for streamlined care delivery and a shared medical record, prevents duplication of effort, increases collaboration and communication between providers, and ultimately promotes improved quality of care, patient safety, patient satisfaction and better health outcomes.

In addition, AAMC's argument that mid-shore residents currently face barriers to accessing "comprehensive pre-operative procedures, urgent pre- and post-operative care, coordinated follow-up care and effective care management" as a result of the distance to a cardiac surgery program is flawed. (AAMC Appl. at p. 115.) Mid shore residents have all of these available without leaving the Eastern Shore, through the UMMS services described above.

**iii. The UM Division of Cardiac Surgery is in a better position to improve geographic access to cardiac surgery services for a greater number of Maryland residents than AAMC.**

Even if AAMC had proven that geographic access were a barrier to access to cardiac surgery, AAMC's geographic access argument is flawed because, as throughout its application,

AAMC fails to consider the cardiac surgery program in neighboring Prince George's County. As an initial matter, AAMC's program would negatively impact the resurgence of PGHC's cardiac surgery program. (See Section I.C(i), *supra*.) Thus, AAMC's proposed increase in access for the more affluent residents of Anne Arundel County comes at a risk of negative impact on the access of minority and lower-income residents in neighboring Prince George's County.

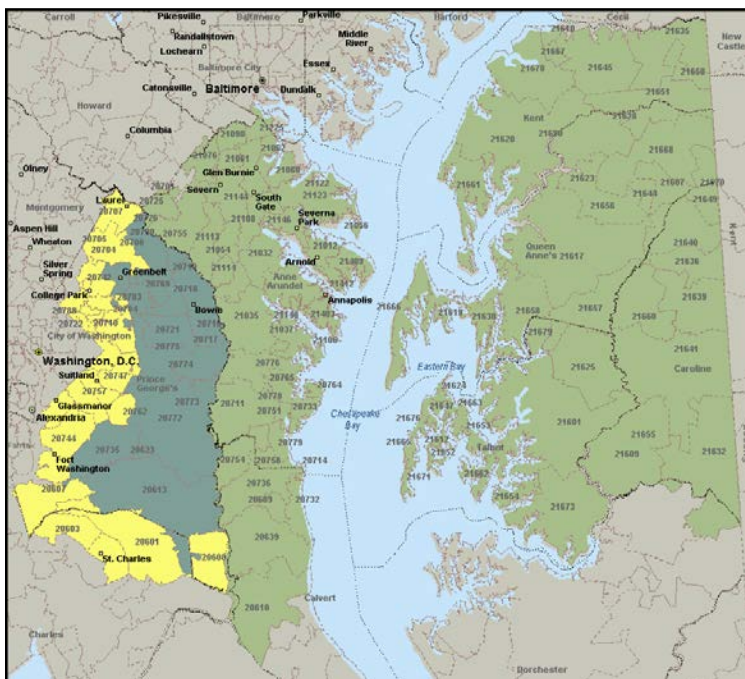
In addition, the UM Division of Cardiac Surgery can provide improved geographic access to a greater number of Maryland residents. PGHC's revived, high quality cardiac surgery program currently provides convenient geographic access to care for residents in Southern Maryland, and its service area overlaps significantly with the western portion of AAMC's proposed cardiac surgery service area. (See Figure 1 below.)<sup>7</sup> Furthermore, while Anne Arundel County is largely outside of the PGHC cardiac surgery service area, the drive time between PGHC and AAMC from the five Zip Codes in the southernmost portion of Anne Arundel County differs by at most 4 minutes.<sup>8</sup> UM BWMC's proposed cardiac service area overlaps with the northern and eastern portion of AAMC's proposed cardiac service area. (See Figure 2 below.) Thus, between UM BWMC and PGHC, the UM Division of Cardiac Surgery can provide access to all of AAMC's service area, including more convenient access for the northern and southern portions of AAMC's service area, and comparable access for others. These results are depicted in Figures 1 and 2 on the following pages. Full size versions are available as Exhibit 4.

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<sup>7</sup> PGHC does not have a defined cardiac surgery service area. The maps that follow use the cardiac surgery service area defined by Dimensions for the relocated Prince George's Regional Medical Center ("PGRMC"). The PGRMC location is 6 miles southeast of PGHC. (See PGRMC Modified Application.) Given the location of other cardiac surgery programs in the State, this six mile difference is not likely to have a significant impact on the cardiac surgery service area of PGHC versus PGRMC.

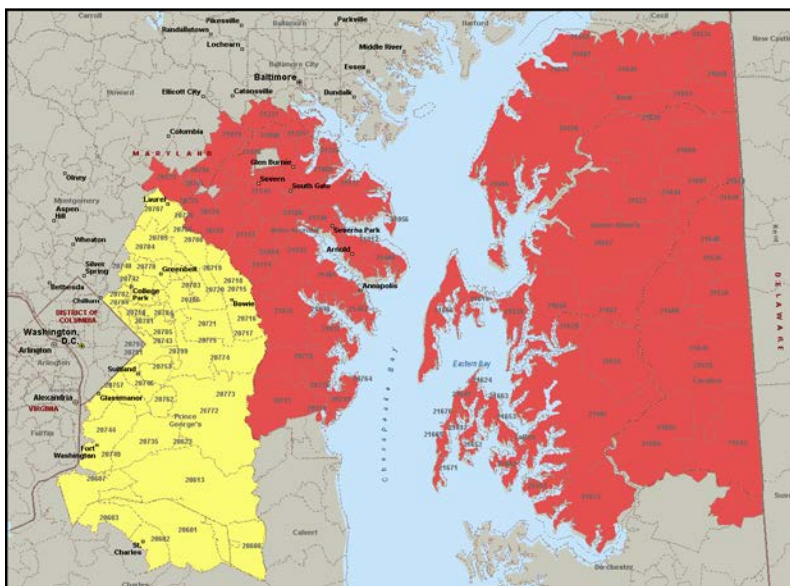
<sup>8</sup> Zip Codes: 20736, 20714, 20758, 20754, 20779. Source: Google Maps, without traffic.

**Figure 1**  
**AAMC Cardiac Service Area and PGHC/PGRMC Service Area**



PGRMC only
  PGRMC and AAMC
  AAMC Only

**Figure 2**  
**UM BWMC Cardiac Service Area and PGHC/PGRMC Service Area**



PGRMC
  UM BWMC

**F. AAMC'S CON APPLICATION DOES NOT MEET THE FINANCIAL FEASIBILITY STANDARD (COMAR § 10.24.17.05A(7)).**

AAMC cannot show that its proposed cardiac surgery program will generate excess revenues over total expenses within three years or less, as required by COMAR § 10.24.17.05A(7)(iv).

AAMC's revenue projections "assume that AAMC's GBR will 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 Appl. at 82.) The HSCRC finalized a policy for market shift adjustments to revenue on July 17, 2015 (Exhibit 5) that uses a 50% revenue variability factor for incremental volumes. AAMC even acknowledges this, stating, "[w]hile the HSCRC's policies for applying and calculating the market share adjustments (MSAs) are not fully established in the context of CON funding, the discussions and precedents regarding MSAs as of the preparation of the AAMC CON suggest that the MSAs for each of the JHH and the University of Maryland Medical Center will be calculated as 50% of the allowable charges of the relocated cases." (AAMC Appl. at p. 219.) As such, the 85% variable cost factor is outdated and should not be used in projections for a new program.<sup>9</sup>

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<sup>9</sup> AAMC's reliance on an 85% variable cost factor is also curious given that AAMC criticized Dimensions for relying on an 85% variable cost factor in its own revenue projections for cardiac surgery at the relocated PGRMC. (*See* AAMC's May 4, 2015 Comments on PGRMC Application at 6.) AAMC's criticism of Dimensions was unfounded not only because it contradicts AAMC's own projections, but because Dimensions did not in fact rely on an 85% variable cost factor. Dimensions used a 50% variable factor, as AAMC argued it should. (*See* Dimensions' Response to Completeness Questions, filed March 13, 2015, Exhibit 50, Financial Projection Assumptions.)

Holding all of AAMC’s assumptions constant with the exception of revenue variability, and changing the 85% to 50%, renders the AAMC cardiac surgery program financially unfeasible with operating losses in each year, as shown in Table 10 below.

**Table 10  
AAMC  
Impact of 50% vs. 85% Revenue Variability**

	FY17	FY18	FY19
CON Net Operating Revenue	\$5,712,862	\$8,627,925	\$10,279,621
Net Operating Revenue @ 50%	\$3,360,507	\$5,075,250	\$6,046,836
<b>Impact of Variability</b>	<b>\$(2,352,355)</b>	<b>\$(3,552,675)</b>	<b>\$(4,232,785)</b>
Operating Income / (Loss) per CON	\$(1,436,872)	\$242,764	\$1,257,875
Impact of Variability	\$(2,352,355)	\$(3,552,675)	\$(4,232,785)
<b>Operating Loss @ 50% Revenue Variability</b>	<b>\$(3,789,227)</b>	<b>\$(3,309,911)</b>	<b>\$(2,974,910)</b>

Given the significant operating loss, the analysis in Table 11 below was performed to determine the volumes required in FY 2019 in order for the AAMC cardiac surgery program to achieve a break-even operating margin. The underlying assumptions regarding revenues, deductions, and variability of expenses are based on AAMC’s financial projections included in the AAMC CON application.

**Table 11  
Anne Arundel Medical Center  
Cardiac Surgery Breakeven Analysis**

	FY2019 50% Revenue Variability
AAMC CON Volume	387
<b>AAMC Operating Income</b>	<b>\$ (2,974,910)</b>
Breakeven Volume	1,601
<b>AAMC Operating Income</b>	<b>\$ -</b>

Given that the proposed AAMC cardiac surgery service area is projected to have a total of only 883 cases in FY 2019, (AAMC Appl. at p. 136), AAMC will not be able to achieve the 1,601 cases required to break even and its proposed program is, therefore, not financially feasible.



**II. UM BWMC IS ENTITLED TO PREFERENCE UNDER THE PREFERENCE IN A COMPARATIVE REVIEW STANDARD (COMAR § 10.24.17.05A(8)).**

**A. UM BWMC PROPOSES A MORE COST EFFECTIVE CARDIAC SURGERY PROGRAM (PREFERENCE CRITERION .058(A)).**

AAMC assumes 85% revenue variability associated with the growth in cardiac surgery cases while it expects that the HSCRC will reduce revenue at other Maryland hospitals related to the loss of volume with a 50% market share adjustment. AAMC acknowledges that these assumptions will result in a net increase in revenue in the State and will, therefore, result in erosion in the All Payer Waiver Test. (AAMC Appl. at p. 172).

UM BWMC assumes that revenue will be shifted at 50% for both the receiving hospital and the loss at other hospitals. Thus, except for the shift of a small number of cases from the District of Columbia, the UM BWMC proposal will produce no negative impact on the All-Payer Waiver Test. As UM BWMC assumes revenue neutrality within the State rather than an erosion of the All-Payer Waiver Test, it should be given preference under the comparative review standard. Also, UM BWMC will not have any significant impact on existing providers.

UM BWMC, not AAMC, should receive preference under the cost-effectiveness comparative review standard.

**B. UM BWMC AND AAMC HAVE COMPARABLE ESTABLISHED RECORDS OF CARDIOVASCULAR DISEASE PREVENTION AND EARLY DIAGNOSIS PROGRAMMING IN THE GENERAL COMMUNITY (PREFERENCE CRITERION .058(B)) AND WITH PARTICULAR OUTREACH TO MINORITY AND INDIGENT PEOPLE (PREFERENCE CRITERION .058(C)).**

There is no doubt that both UM BWMC and AAMC have established records of cardiovascular disease prevention and early diagnosis programming, including provisions for educating patients about treatment options. Both hospitals have had substantial cardiovascular outreach programs, including outreach efforts focused on minority and indigent residents. In

FY 2014, UM BWMC identifies 403 events and more than 4,643 encounters (plus another 254 events and 4,613 encounters including UM Shore Regional Health's programs). (UM BWMC Appl. at pp. 81-82.) AAMC identifies 83 events and 3,089 encounters (excluding Tobacco Cessation and Obesity Prevention & Reduction programs at AAMC, apparently work force initiatives, which UM BWMC specifically excluded from its outreach programs). (AAMC Appl. at pp. 178-90.) However, UM BWMC's programs are generally held in an area of the County with more high risk populations than the County as a whole. (UM BWMC Appl. at pp. 94-99.)

Each hospital holds programs both on the hospital campus and in the community. However, UM BWMC's campus is located in Glen Burnie zip code 21061, which has a higher than average percentage of minority residents, a higher Medicaid enrollment rate, a higher uninsured rate, and higher rates of chest pain, hypertension, and diabetes than the County average, and UM BWMC serves as a center for community health education, early detection, and treatment. (UM BWMC Appl. at pp. 71-72.) Both hospitals have community partners. Both hospitals have established records of cardiovascular disease prevention and early diagnosis programming that includes provisions for educating patients about treatment options.

The one additional program that AAMC states it will initiate if it obtains a CON is participation in The Johns Hopkins Center to Eliminate Cardiovascular Health Disparities. (AAMC Appl. at pp. 176-177). However, a cardiac surgery program is not required to participate in this program. AAMC could participate in this program regardless of whether it receives a CON.

In sum, neither hospital deserves a preference under these comparative review standards.

**C. UM BWMC PROPOSES A PROGRAM WITH STRONGER RESEARCH, TRAINING, AND EDUCATION COMPONENTS (PREFERENCE CRITERION .05A(8)(d)).**

UM BWMC is a fully integrated member institution of UMMS. As a proposed extension of the existing UM Division of Cardiac Surgery, a new location at UM BWMC would offer superior research, training, and education components as compared to a new cardiac surgery program at AAMC. UM BWMC's Application details the strong research, training, and education programs within the UM Division of Cardiac Surgery as well as the prospects for including UM BWMC patients in future clinical trials, which will offer these patients cutting edge treatments. (UM BWMC Appl. at pp. 105-11.)

The key to UM BWMC's inclusion in the strong clinical research programs of the UM Division of Cardiac Surgery is the clinical and operational integration of UM BWMC within UMMS. Through this complete integration, the UM Division of Cardiac Surgery will have the control it needs to ensure that clinical research performed at UM BWMC is high-quality, properly managed administratively, and financially feasible.

AAMC relies upon its relationship with JHM to show strength in education, research, and training. However, as discussed above, AAMC has not sufficiently explained and documented its supposed partnership with JHM to warrant the Commission's reliance upon JHM for research, training, or education programs within a new cardiac surgery program at AAMC.

Without a strong and lasting affiliation with JHM, it is unlikely that AAMC will be a preferred site of long-term clinical trials administered by JHM, especially since JHM has another community hospital option for cardiac surgery research within its system (Suburban Hospital).

AAMC's boast of "current ongoing clinical trials in which Johns Hopkins Cardiac Surgery, Cardiology and Cardiac Anesthesia faculty are participating and which will be

immediately available for AAMC patients after Institutional Review Board (IRB) approval,” (AAMC Appl. at p. 197), oversimplifies the lengthy process for opening a clinic site for an existing clinical trial.<sup>10</sup> Exhibit 6 addresses the steps and procedures that UMMS undertakes to ensure regulatory compliance, clinical success, and Institutional Review Board approval. Also, if clinical research is conducted at AAMC and the ill-defined partnership between AAMC and JHM terminates, the continuation of the trials at AAMC will be called into question.

### **III. AAMC FAILS TO COMPLY WITH COMAR 10.24.10.04A(3) (QUALITY OF CARE).**

To comply with the general acute care services standard for quality of care, hospital applicants are required to disclose any Quality Measure in the most recent update of the Maryland Hospital Performance Evaluation Guide (the “Guide”) for which the hospital’s score was within the bottom quartile of all hospitals’ reported performance and also falls below a 90% level of compliance with the Quality Measure. COMAR § 10.20.10.04A(3)(b). For each such disclosure, the hospital is required to document its action for improving performance on the applicable Quality Measure.

The Commission recently implemented a new and significantly re-designed Guide. Under the new Guide, quality measure performance within the bottom quartile of all hospitals, which the standard requires an applicant to assess, is not readily apparent. However, UM BWMC complied with the standard by calculating the bottom quartile scores for each of the measures and reporting its performance. (UM BWMC Appl. at p. 42 and Exhibit 22.) AAMC failed to comply with the standard and instead discussed its performance relative to data reported

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<sup>10</sup> A list of these current trials, which AAMC states is attached as Exhibit 9(a), is either not included in AAMC’s application or is mislabeled.

on the Centers for Medicare and Medicaid Services: Hospital Compare. (AAMC Appl. at pp. 36-37.)

**CONCLUSION**

For the reasons set forth above, UM BWMC respectfully asks that the Commission deny AAMC's Application proposing to establish a cardiac surgery program.

Respectfully submitted,



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Thomas C. Dame  
Ella R. Aiken  
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Baltimore MD 21201  
(410) 727-7702

*Attorneys for University of Maryland Baltimore  
Washington Medical Center*

July 27, 2015

### Table of Exhibits

Exhibit	Description
1	UM BWMC cardiologist referral projections discounted for SOI, patient preference, and clinical trial need
2	AAMC Chart 11—Number of Discharges Projected to Shift to AAMC, by Hospital with average volume decline
3	Table 8: Adult Cardiac Surgery Distribution of Discharges from Maryland Hospitals Mid-Shore Counties in Baltimore/Upper Shore Cardiac Surgery Planning Region—FY2013, FY2014, FY2015 Q1-Q3
4	Full-size Figures 1 & 2
5	HSCRC memo re Global Budget Market Shift Adjustments for Rate Year 2016
6	6/19/15 letter from UM Division of Cardiac Surgery

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Table	Description
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3	Projected AAMC Volume Based on Documented Referrals
4	AAMC Projected Volume Based on Documented Referrals Excluding 17% minimum for SOI
5	AAMC Cases Based on Inpatient and Outpatient Transfers—FY 14 based on AAMC Appl., FY 17-18 Adjusted based on MHCC Projections
6	AAMC Cases Based on Inpatient and Outpatient Transfers with Adjusted Surgery Assumptions
7	Inconsistencies in AAMC Application of JHH Volume Shift to AAMC
8	Adult Cardiac Surgery Distribution of Discharges from Maryland Hospitals Residents of Four Mid-Shore Counties in Baltimore/Upper Shore Region (FY13, FY14, FY15 Q1-3)
9	UM BWMC Net Projected Impact on Other Providers
10	AAMC Impact of 50% vs. 85% Revenue Variability
11	Anne Arundel Medical Center Cardiac Surgery Breakeven Analysis

### Table of Figures

Figure	Description
1	AAMC Cardiac Service Area and PGHC/PGRMC Service Area
2	UM BWMC Cardiac Service Area and PGHC/PGRMC Service Area

## CERTIFICATE OF SERVICE

I hereby certify that on the 27<sup>th</sup> day of July 2015, a copy of the foregoing Comments on AAMC's CON Application was sent via email and first-class mail to:

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---


Ella R. Aiken

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

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Date



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Janet Petit  
Clinical Program Administrator,  
Division of Cardiac Surgery  
UMMS



I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
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July 24, 2015

Date



Scott Tinsley-Hall

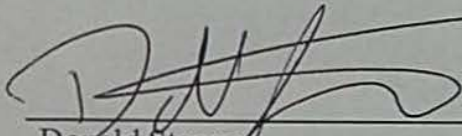
Director of Strategy and Program  
Development

UMMS

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July 24, 2015

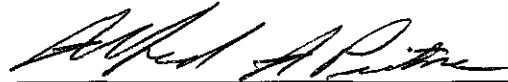
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Donald Steacy  
Planning Project Manager  
UMMS

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

\_\_\_\_\_  
Date



\_\_\_\_\_  
Alfred Pietsch  
Senior Vice President and CFO  
UM BWMC

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

Date

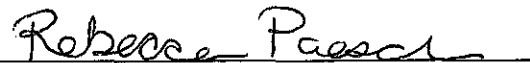


Kathy McCollum  
Senior Vice President, Clinical  
Integration and COO  
UM BWMC

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

Date



Rebecca Paesch

Vice President, Strategy and Business  
Development  
UM BWMC

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

Date



Daniel Donaldson

Director of Finance Decision Support

UM BWMC

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

Date



Laurie Fetterman  
Strategic Planning Project Manager  
UM BWMC

I hereby declare and affirm under the penalties of perjury that the facts stated in  
UM BWMC's Comments on Anne Arundel Medical Center's CON Application  
Proposing the Establishment of Cardiac Surgery Program and its attachments are true and  
correct to the best of my knowledge, information, and belief.

July 24, 2015

---

Date



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Andrew L. Solberg

A.L.S. Healthcare Consultant Services



# **EXHIBIT 1**

UM BWMC cardiologist referral projections  
Discounted for SOI, patient preference, and clinical trial need

UM BWMC-affiliated Cardiology Practices	Actual Referrals	Total Projected Practice Referrals			UM BWMC Estimated Share			UM BWMC Projected Volume		
	FY14	FY17	FY18	FY19	FY17	FY18	FY19	FY17	FY18	FY19
Arundel Heart Associates, P.A.	71	68	68	67	90%	90%	90%	62	61	61
The Heart Center of Northern Anne Arundel County, P.A.	89	86	85	85	90%	90%	90%	77	77	76
Chesapeake Cardiology at Shore Health	57	55	54	54	90%	90%	90%	49	49	49
UM SOM Division of Cardiovascular Medicine	54	52	52	51	90%	90%	90%	47	46	46
Maryland Heart Associates, LLC	41	40	39	39	50%	65%	75%	20	25	29
<b>Total, 5 practices</b>	<b>312</b>	<b>301</b>	<b>298</b>	<b>297</b>				<b>255</b>	<b>259</b>	<b>261</b>
<b>Total, excluding 17% SOI</b>	<b>271</b>	<b>262</b>	<b>259</b>	<b>258</b>				<b>222</b>	<b>225</b>	<b>227</b>

Note: Market change percentage applied based on MHCC projection used by AAMC (FY17:-3.56%, FY18: -0.89%, FY19: -0.56%). UM BWMC referral share of affiliated cardiologists was conservatively set at 90% due to existing clinical integration between Arundel Heart, Heart Center and UMMS affiliated practices.

# **EXHIBIT 2**

AAMC Chart 11  
Number of Discharges Projected to Shift to AAMC, by Hospital  
with average volume decline

HOSPITAL	Estimated Volume Shift Based on CY 2013	Proj. volume shift, with use rate FY 2018	<i>(added to AAMC Chart 11 by UM BWMC)</i>  <b>Use rate appl. by AAMC</b>	
Washington Hospital Center	271	221	<b>-18.45%</b>	<b>-18.45%</b>
Johns Hopkins Hospital	85	69	<b>-18.82%</b>	<b>-18.82%</b>
University of Maryland Medical Center	35	29	<b>-17.14%</b>	<b>-17.14%</b>
George Washington University Med Center	7	6	<b>-14.29%</b>	
Washington Adventist	7	6	<b>-14.29%</b>	
Sinai Hospital	3	3	<b>0.00%</b>	
Union Memorial Hospital	2	2	<b>0.00%</b>	
UM St Joseph Med Center	1	1	<b>0.00%</b>	
Prince George's Hospital Center	0	0	-	
<b><i>Average use rate % decline applied by AAMC</i></b>			<b>-10.37%</b>	<b>-18.14%</b>

# **EXHIBIT 3**

**Table 8**  
**Adult Cardiac Surgery Distribution of Discharges from Maryland Hospitals**  
**Mid-Shore Counties in Baltimore/Upper Shore Cardiac Surgery Planning Region**  
**FY2013, FY2014, FY2015 Q1-Q3**

<b>County</b>	<b>FY13</b>	<b>FY14</b>	<b>FY15 (9 Mo)</b>	<b>Total</b>
<b>Caroline County</b>	<b>27</b>	<b>31</b>	<b>28</b>	<b>86</b>
UMMC	13	17	14	44
PENINSULA REGIONAL	8	12	14	34
JOHNS HOPKINS	4	1		5
UNION MEMORIAL	1			1
UM SJMC		1		1
SINAI	1			1
<b>Kent County</b>	<b>11</b>	<b>12</b>	<b>7</b>	<b>30</b>
UMMC	5	7	5	17
JOHNS HOPKINS	5	4	2	11
UM SJMC		1		1
PENINSULA REGIONAL	1			1
<b>Queen Anne's County</b>	<b>29</b>	<b>27</b>	<b>22</b>	<b>78</b>
UMMC	13	16	11	40
JOHNS HOPKINS	14	7	8	29
UNION MEMORIAL	2	1	1	4
UM SJMC		2	1	3
PENINSULA REGIONAL		1	1	2
<b>Talbot County</b>	<b>34</b>	<b>47</b>	<b>29</b>	<b>110</b>
UMMC	22	32	18	72
PENINSULA REGIONAL	6	10	3	19
JOHNS HOPKINS	5	3	5	13
UM SJMC		1	2	3
SUBURBAN			1	1
WASHINGTON ADVENTIST	1			1
UNION MEMORIAL		1		1
<b>Grand Total</b>	<b>101</b>	<b>117</b>	<b>86</b>	<b>304</b>

Source: MSA database, HSCRC discharge data, FY13, FY14, FY15Q1-Q3

**Table 8**  
**Market Share by Hospital/System**  
**Adult Cardiac Surgery Discharges from Maryland Hospitals**  
**Mid-Shore Counties in Baltimore/Upper Shore Cardiac Surgery Planning Region**  
**FY2013, FY2014, FY2015 Q1-Q3**

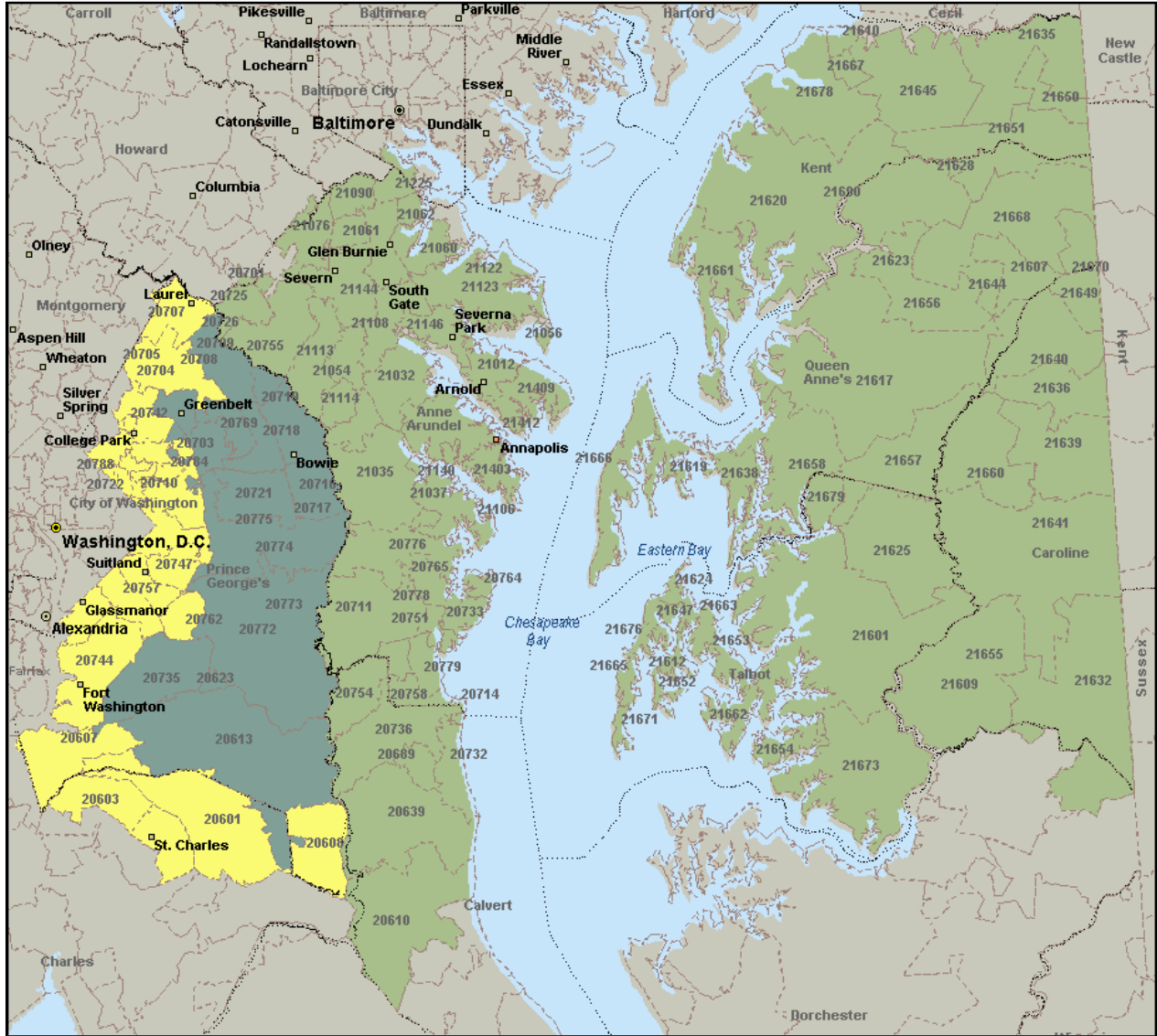
County	FY13	FY14	FY15 (9 Mo)	Total	% Market Share
<b>Caroline County</b>	<b>27</b>	<b>31</b>	<b>28</b>	<b>86</b>	
UMMS	13	18	14	45	52.3%
PENINSULA REGIONAL	8	12	14	34	39.5%
JHHS	4	1	0	5	5.8%
OTHER	2	0	0	2	2.3%
<b>Kent County</b>	<b>11</b>	<b>12</b>	<b>7</b>	<b>30</b>	
UMMS	5	8	5	18	60.0%
PENINSULA REGIONAL	1	0	0	1	3.3%
JHHS	5	4	2	11	36.7%
OTHER	0	0	0	0	0.0%
<b>Queen Anne's County</b>	<b>29</b>	<b>27</b>	<b>22</b>	<b>78</b>	
UMMS	13	18	12	43	55.1%
PENINSULA REGIONAL	0	1	1	2	2.6%
JHHS	14	7	8	29	37.2%
OTHER	2	1	1	4	5.1%
<b>Talbot County</b>	<b>34</b>	<b>47</b>	<b>29</b>	<b>110</b>	
UMMS	22	33	20	75	68.2%
PENINSULA REGIONAL	6	10	3	19	17.3%
JHHS	5	3	6	14	12.7%
OTHER	1	1	0	2	1.8%
<b>Grand Total</b>	<b>101</b>	<b>117</b>	<b>86</b>	<b>304</b>	
UMMS	53	77	51	181	59.5%
PENINSULA REGIONAL	15	23	18	56	18.4%
JHHS	28	15	16	59	19.4%
OTHER	5	2	1	8	2.6%

Source: MSA database, HSCRC discharge data, FY13, FY14, FY15Q1-Q3

# **EXHIBIT 4**

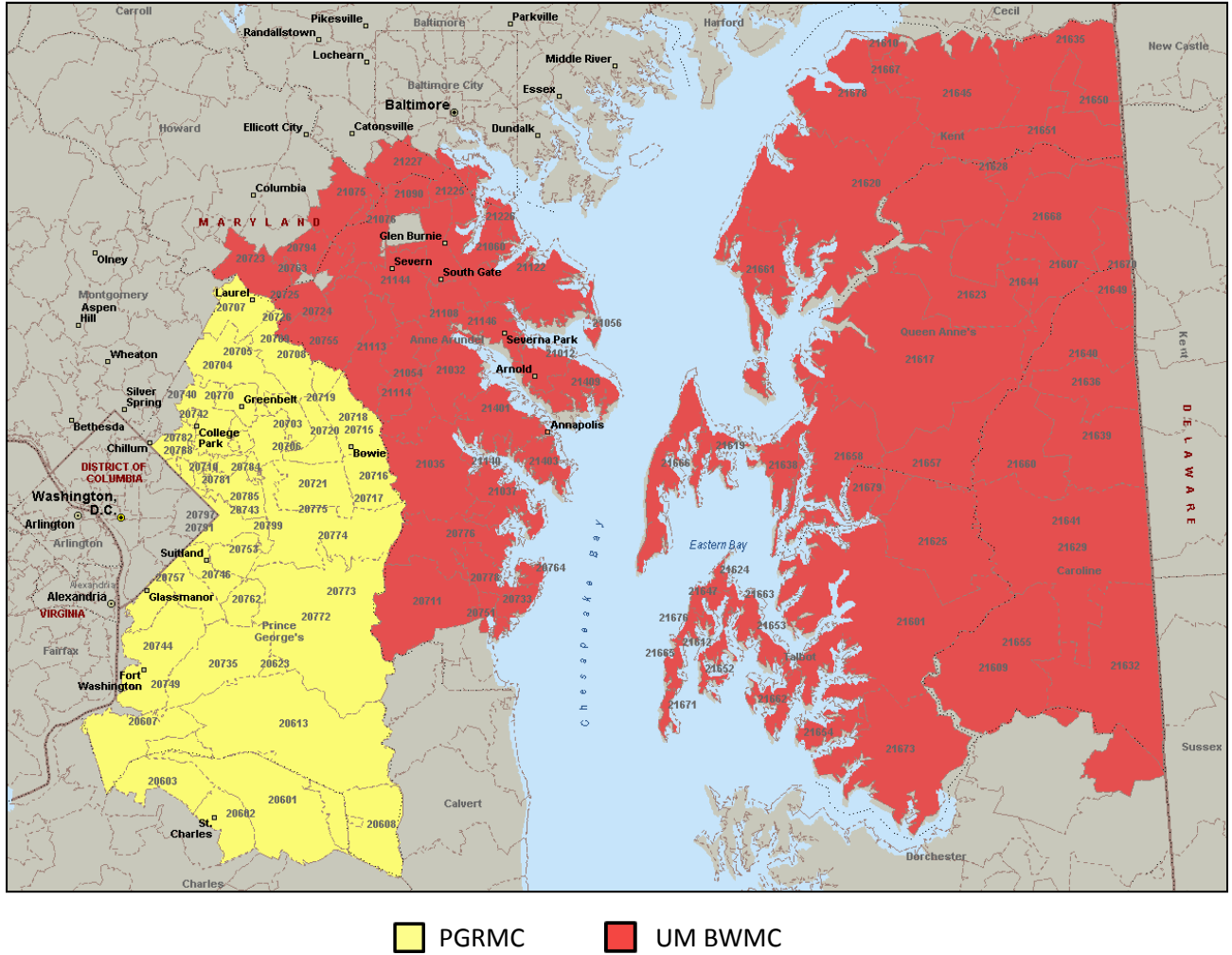


**Figure 1**  
**AAMC Cardiac Service Area and PGHC/PGRMC Service Area**



PGRMC only
  PGRMC and AAMC
  AAMC Only

**Figure 2**  
**UM BWMC Cardiac Service Area and PGHC/PGRMC Service Area**



# **EXHIBIT 5**

**State of Maryland  
Department of Health and Mental Hygiene**



**John M. Colmers**  
Chairman

**Herbert S. Wong, Ph.D.**  
Vice-Chairman

**George H. Bone,**  
M.D.

**Stephen F. Jencks,**  
M.D., M.P.H.

**Jack C. Keane**

**Bernadette C. Loftus,**  
M.D.

**Thomas R. Mullen**

**Health Services Cost Review Commission**

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Phone: 410-764-2605 · Fax: 410-358-6217  
Toll Free: 1-888-287-3229  
hsrc.maryland.gov

**Donna Kinzer**  
Executive Director

**Stephen Ports**  
Principal Deputy Director  
Policy and Operations

**David Romans**  
Director  
Payment Reform  
and Innovation

**Gerard J. Schmith**  
Deputy Director  
Hospital Rate Setting

**Sule Gerovich, Ph.D.**  
Deputy Director  
Research and Methodology

To: Hospital CFOs

Cc: Hospital Case-mix Liaisons, MHA

From: Sule Gerovich, Ph.D. SC

Date: July 17<sup>th</sup>, 2015

Re: Global Budget Market Shift Adjustments for Rate Year 2016

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The purpose of this memo is to inform hospitals that the Health Services Cost Review Commission (HSCRC) finalized the calculations for global budget revenue (GBR) market shift adjustments for all inpatient and outpatient services, except for radiation therapy, infusion and chemotherapy, for inclusion in rate year 2016 global budgets. Staff is still developing an appropriate weighting methodology for the remaining service lines and is planning to include this service line adjustment in RY 2016 GBRs.

The Market Shift Adjustments (MSAs) mechanism is part of a much broader set of tools that links global budgets to populations and patients under the State's new All-Payer Model. The specific purpose of MSAs is to provide criteria for increasing or decreasing the approved regulated revenue of Maryland hospitals operating under GBR rate arrangements to ensure that revenue is appropriately reallocated when shifts in patient volumes occur between hospitals. MSAs under GBR arrangements are fundamentally different from volume adjustments. Hospitals under a population-based payment system, such as GBR, have a fixed budget for providing services to the population in their service area. Therefore, it is imperative that MSAs reflect shifts in patient volume independent of general volume increases in the market.

The methodology of market shift calculations was developed through a stakeholder process during HSCRC Payment Models work group and market share subgroup. HSCRC developed an algorithm to calculate MSAs for a specific service area (e.g., orthopedic surgery) and a defined geographic location (e.g., zip code). The algorithm compares the growth in volumes at hospitals with utilization increases to the decline in volumes at hospitals with utilization decreases. Adjustments are capped at the lesser of the growth for volume gains or the decline for volume losses. This approach separates market shifts from collective changes in volume in the service area and removes incentives for driving up volume in the service area. Zip codes in rural, less populated areas of the state are consolidated to a county level. These counties include Garrett,

Allegany, Washington, Cecil, Kent, Queen Anne's, Caroline, Talbot, Dorchester, Wicomico, Somerset, Calvert, Charles, Saint Mary's, and Worcester.

Inpatient and outpatient observation cases of 24 or more hours are grouped into service lines using APR-DRGs and weighted using a case-mix index. The remaining outpatient service lines are created using EAPGs and converted to inpatient discharges by the ratio of average inpatient visit charge per discharge to average outpatient charge per visit (ECMAD, Equivalent Case Mix Adjusted Discharge). Potentially avoidable utilizations (PAU) (measured as 30 day readmissions and prevention quality indicators) are excluded from the market shift calculations to keep strong incentives to reduce PAUs under GBRs.

The revenue adjustments for market shifts are based on hospital's own average charge for each service line with 50% variable cost factor applied.

The rate year 2016 adjustments will be based on comparing the measurement period of July 2014 through December 2014 to a base year period of July 2013 through December 2013. After this initial measurement period, a full calendar year will be used to calculate MSAs. Accordingly, rate year 2017 adjustments will be based on January through December 2015, compared to January through December 2014.

A final report explaining the calculations in more detail will be posted next week on HSCRC's website. Excel pivot tables providing zip code level detail information are attached. Please note that due to small cell sizes, this file cannot be shared publically. The password will be send via email.

The HSCRC staff will continue to develop refinements to the approach. In particular, the staff is interested in expanding the definitions of Potentially Avoidable Utilization in an effort to better evaluate declines in utilization resulting from interventions.

We thank all those who attended the meetings and provided valuable insights and comments to develop the adjustments. If you have any questions, please contact Dr. Gerovich at [Sule.Gerovich@maryland.gov](mailto:Sule.Gerovich@maryland.gov).

Sincerely,

Sule Calikoglu Gerovich, Ph.D.  
Director, Center for Population-Based Methodologies  
Health Services Cost and Review Commission

**Table 1: The Global Budget Market Shift Adjustments for Rate Year 2016 by Hospital**

Hospital Name	Total Discharge/Visits July-Dec 2014	Total Discharge/Visits July-Dec 2015	Total Discharge/Visit Growth	ECMAD July-Dec 2014	ECMAD July-Dec 2015	ECMAD GROWTH	ECMAD Market Shift	Market Shift Adjustment
ANNE ARUNDEL	101,761	106,320	4,559	19,871	20,492	621	69	\$396,143
ATLANTIC GENERAL	42,762	44,132	1,370	2,927	3,054	127	(19)	-\$108,402
BALTIMORE WASHINGTON MEDICA	72,835	75,080	2,245	12,845	12,992	147	(117)	-\$799,826
BON SECOURS	20,431	20,184	(247)	2,681	2,475	(206)	(172)	-\$1,562,367
BOWIE HEALTH	16,340	17,544	1,204	540	583	43	14	\$97,155
CALVERT	32,783	32,992	209	4,249	4,232	(17)	(68)	-\$401,728
CARROLL COUNTY	42,128	41,377	(751)	7,259	7,028	(230)	(70)	-\$396,380
CHARLES REGIONAL	34,821	37,948	3,127	4,730	4,696	(35)	(43)	-\$37,376
CHESTERTOWN	18,295	18,532	237	1,466	1,457	(9)	(37)	-\$341,212
DOCTORS COMMUNITY	34,265	37,569	3,304	6,200	6,439	239	40	\$373,537
DORCHESTER	18,141	18,178	37	1,335	1,410	76	22	\$202,127
EASTON	28,377	29,608	1,231	5,155	5,090	(64)	(48)	-\$430,911
FRANKLIN SQUARE	90,274	89,939	(335)	15,037	15,506	469	245	\$1,420,348
FREDERICK MEMORIAL**	55,030	59,622	4,592	10,389	11,292	903	259	\$1,347,105
FT. WASHINGTON	20,464	20,299	(165)	1,463	1,396	(66)	(58)	-\$383,283
G.B.M.C.	80,801	81,477	676	14,014	13,689	(325)	(437)	-\$2,278,961
GARRETT COUNTY**	23,174	23,902	728	1,237	1,534	297	49	\$188,050
GERMANTOWN	16,232	16,446	214	618	622	3	(13)	-\$72,215
GOOD SAMARITAN	68,320	60,163	(8,157)	9,286	8,663	(623)	(518)	-\$3,085,321
HARBOR	42,157	41,499	(658)	6,102	6,038	(64)	(129)	-\$905,499
HARFORD	34,419	35,001	582	3,195	3,166	(29)	(18)	-\$125,166
HOLY CROSS	69,503	71,215	1,712	16,144	16,958	814	272	\$1,039,213
HOLY CROSS GERMANTOWN	-	6,654	6,654	-	782	782	379	\$0
HOPKINS BAYVIEW MED CTR	189,358	195,830	6,472	15,099	15,781	683	250	\$1,795,780
HOWARD COUNTY	61,847	63,850	2,003	10,395	10,752	357	38	\$395,457
JOHNS HOPKINS	299,913	320,772	20,859	36,137	38,180	2,043	921	\$7,714,776
LAUREL REGIONAL	20,109	19,637	(472)	3,308	3,096	(212)	(267)	-\$1,937,225
MCCREADY	10,000	10,417	417	423	436	13	2	-\$40,155
MERCY	135,022	133,919	(1,103)	15,632	15,513	(120)	(74)	-\$601,739
MERITUS	44,621	44,362	(259)	9,195	8,987	(208)	(124)	-\$709,616
MONTGOMERY GENERAL	25,466	26,431	965	5,112	5,261	149	(64)	-\$461,212
NORTHWEST	49,807	48,786	(1,021)	6,604	6,463	(141)	(225)	-\$1,385,014
PENINSULA REGIONAL	70,441	71,246	805	11,029	11,218	189	(3)	-\$55,102
PRINCE GEORGE	27,789	28,002	213	6,217	6,902	685	186	\$1,396,315
QUEEN ANNES	6,800	7,625	825	243	280	38	4	\$18,298
REHAB & ORTHO	20,859	20,962	103	3,468	3,374	(95)	(99)	-\$704,634
SHADY GROVE	55,371	55,979	608	13,074	12,857	(218)	(458)	-\$2,846,113
SINAI	104,282	104,965	683	18,647	18,497	(151)	(274)	-\$1,977,215
SOUTHERN MARYLAND	35,468	33,991	(1,477)	7,090	6,848	(242)	(255)	-\$1,493,265
ST. AGNES	75,264	80,905	5,641	12,031	12,413	382	104	\$656,125
ST. MARY	49,059	50,469	1,410	5,463	5,920	457	173	\$972,173
SUBURBAN	29,315	29,700	385	9,544	9,840	295	76	\$333,569
UM ST. JOSEPH*	54,895	56,203	1,308	12,027	13,304	1,277	758	\$4,161,524
UMMC MIDTOWN	42,015	56,741	14,726	4,111	4,702	591	305	\$3,249,062
UNION HOSPITAL OF CECIL COUNT	46,095	42,029	(4,066)	4,324	3,990	(334)	(140)	-\$1,041,023
UNION MEMORIAL	73,678	72,498	(1,180)	12,396	13,061	665	280	\$1,735,895
UNIVERSITY OF MARYLAND	137,529	136,820	(709)	28,506	28,361	(145)	(280)	-\$1,822,357
UPPER CHESAPEAKE HEALTH	67,086	68,901	1,815	9,608	9,193	(415)	(232)	-\$1,029,914
WASHINGTON ADVENTIST	33,359	33,668	309	7,110	7,020	(90)	(256)	-\$1,464,523
WESTERN MARYLAND HEALTH SYST	40,177	41,841	1,664	6,655	6,619	(36)	45	\$248,759
<b>Grand Total</b>	<b>2,768,938</b>	<b>2,842,230</b>	<b>73,292</b>	<b>420,192</b>	<b>428,462</b>	<b>8,270</b>	<b>0</b>	<b>-\$756,341</b>
HSCRC Casemix Data- Updated 7/7/2015								
Notes:								
Shifts within systems for service movements between system hospitals have not been reflected in these figures.								
*Market shift adjustment for St. Joseph Medical Center was implemented concurrently during FY2015.								
** Market shift adjustments will be revised due to data accuracy issues.								

# **EXHIBIT 6**

June 19, 2015

To Whom It May Concern:

It is the expressed goal of the University of Maryland Medical Center's Division of Cardiac Surgery to link our industry sponsored and investigator initiated clinical research opportunities with any of our clinical sites that offer cardiac surgery services. By doing so the University of Maryland Medical Center's Division of Cardiac Surgery will afford our patients the opportunity to become involved in industry sponsored and investigator initiated clinical research opportunities that they might otherwise not have access to or which might be geographically desirable due to issues related to treatment location preference or other barriers to care.

In order to do this a multi-step process must unfold to guarantee regulatory compliance and clinical success. The process that is detailed below is stepwise and one may not take place until the preceding step has been accomplished. For example a site may not start training or site initiation until the sponsor first agrees and the IRB agreements are in place.

**1) Institutional Authorization Agreement**

An Institutional Authorization Agreement (IAA) must be put in place between the University of Maryland IRB and the new site performing cardiothoracic surgical procedures. An IAA defers regulatory oversight and control from the existing Institutional Review Board (IRB) at the new site (whether central or satellite) to the central IRB located in the University of Maryland Baltimore Human Research Protections Office.

**2) Scientific Review Committee**

Prior to requesting the addition of the site to an existing protocol, the standing Scientific Review Committee (Or some such body) for a new site is traditionally required to review each protocol to be added and approve of its deployment at the new site. This is not a step in regulatory or sponsor approval but rather site approval to confirm clinical readiness and experience to deploy the protocol and protect patient safety and welfare, as well as to ensure the site is able to adhere to all provisions of the protocol.

**3) Sponsor Approval**

The sponsor for each protocol under consideration must approve the deployment of the protocol to the new site. This approval is not a given as most protocols are capped with the number of enrolling sites in a trial, as well as the number of enrollees a site may contribute to the overall study cohort. This process could be as simple as a dialogue and subsequent letter of approval from the sponsor or could be as complex as an entire new site review and initiation process. If approved, the sponsor will send a letter for each protocol that will be used in the submission to the IRB to obtain approval.

**4) Institutional Review Board Approval**

A modification for each individual protocol must be submitted to the central IRB at the University of Maryland adding the new site to the approved list of clinical research sites. Included in this will be the identification of the site PI and research team at the new site, as well as assurances that they have proper CITI and HIPAA training as dictated by GCP



guidelines. IRB review and approval must be obtained prior to any work being performed by the new site.

**5) Contracts and Budgets**

The contract for each protocol must be amended to add the additional clinical site, as well as identify the site PI. The budgets will need to be amended to include coordinator and PI effort hours, as well as clinical costs for patients enrolled at the new site. This will not occur until IRB approval and must be done protocol by protocol.

**6) Regulatory and Oversight Processes**

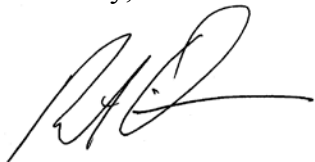
Once IRB approval is obtained each the new site must establish site-specific regulatory and oversight processes. This will included the location of all regulatory materials, study material storage, study device storage, among others.

**7) Site Initiation**

Per FDA and GCP guideline a protocol specific Site Initiation Visit must be conducted for each protocol being added to the new site. This visit will ensure that protocol specific training for those at the site is conducted, confirmation that sub-investigators at the new site understand and agree to their responsibilities, as well as the collection of all appropriate regulatory documents for the new site.

This process is not immediate and must be carried out before any clinical procedures can be initiated.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Villanueva', with a long horizontal flourish extending to the right.

Robert Villanueva, MPA  
Clinical Research Manager  
Division of Cardiac Surgery  
University of Maryland School of Medicine.