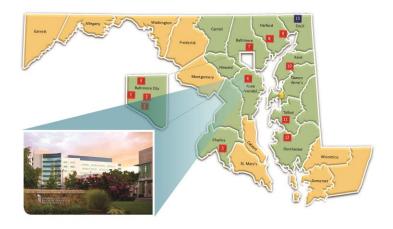
BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF BALTIMORE / UPPER SHORE CARDIAC SURGERY REVIEW

Anne Arundel Medical Center Docket No. 15 02 2360

University of Maryland
Baltimore Washington Medical Center
Docket No. 15 02 2361



Baltimore Washington Medical Center, Inc. t/a University of Maryland Baltimore Washington Medical Center

EXCEPTIONS TO RECOMMENDED DECISION

January 11, 2017

IN THE MATTER OF	*	
BALTIMORE / UPPER SHORE CARDIAC	*	BEFORE THE
	*	
SURGERY REVIEW	*	MARYLAND HEALTH
	*	
Anne Arundel Medical Center	*	CARE COMMISSION
Docket No. 15-02-2360	*	
	*	
University of Maryland	*	
Baltimore Washington Medical Center	*	
Docket No. 15-02-2361	*	
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UNIVERSITY OF MARYLAND BALTIMORE WASHINGTON MEDICAL CENTER'S EXCEPTIONS TO RECOMMENDED DECISION

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University of Maryland Baltimore Washington Medical Center ("UM BWMC"), by its undersigned counsel and pursuant to COMAR § 10.24.01.09B, submits these exceptions to the Reviewer's Recommended Decision.

INTRODUCTION

UM BWMC respectfully requests that the Commission reject the Recommended Decision because it misconstrues and misapplies several review standards and criteria in reaching an unjustifiable recommendation to approve a new cardiac surgery program at Anne Arundel Medical Center ("AAMC") and deny UM BWMC's proposal. The Recommended Decision includes the following serious errors:

- The Recommended Decision concludes that UM BWMC does not meet a threshold minimum volume requirement, and thus that the preference in comparative review standard need not be applied, premised solely on a faulty and unsupportable model that is inconsistent with the applicable State Health Plan and is based on data either entered into the record 45 minutes before the issuance of the decision, or not part of the record at all, leaving the parties with no meaningful opportunity to review and contest the conclusions drawn from it.
- The Recommended Decision is inconsistent with the applicable State Health Plan's goal of protection of existing programs and disregards the serious adverse impact AAMC's proposed program would have on PGHC, which the Commission recently approved to build a new replacement regional medical center with more than \$400 million in investments from the State of Maryland and Prince George's County.
- The Recommended Decision finds AAMC's program would be in compliance with the financial feasibility standard of the applicable State Health Plan on the basis that the program will not jeopardize the financial viability of the hospital; however, the applicable standard requires that an applicant demonstrate that revenue would exceed expenses for cardiac surgery, and AAMC has not done that.

The Recommended Decision's analysis of the threshold minimum volume requirement disregards important evidence presented by the applicants and instead employs a completely new approach to forecasting whether the applicants would achieve a minimum volume of 200 cardiac

surgery cases in the second full year of operation. The new model is premised entirely on the population size of an applicant's 85% MSGA service area, which does not correlate with cardiac surgery volumes. This approach is so fundamentally flawed it constitutes an arbitrary method of assessing minimum volume. Worse, the model is based on certain data and assumptions that have not been disclosed to the parties. On the sole basis of this defective model, the Recommended Decision determines that UM BWMC's Certificate of Need ("CON") application does not comply with five review standards and criteria.

To the extent that the Recommended Decision states that AAMC has presented the stronger application, a conclusion that appears largely based on AAMC's geographic location and the size of its MSGA service area, that conclusion violates the applicable State Health Plan chapter, which sets forth the factors to be applied to determine preference in a comparative review. The relevant preference standard was not applied, because of the erroneous finding that UM BWMC did not meet the minimum volume standard under the new model. The application of the new model did not eliminate AAMC's proposal from consideration, but the Reviewer should have recommended denial of AAMC's application based on lack of financial feasibility and adverse impact on existing cardiac surgery programs, among other grounds.

UM BWMC's proposal is to open another cardiac surgery location of the UM Division of Cardiac Surgery, principally to shift appropriate patient volume within the University of Maryland Medical System ("UMMS") to UM BWMC for the convenience of patients and to reduce the cost of cardiac surgery. UM BWMC's proposed program would have little adverse impact on other existing cardiac surgery programs. UMMS already provides high-quality

cardiac surgery services in Towson and in Baltimore City.¹ The proposed Glen Burnie location is a logical complement to the existing UMMS network of cardiac surgery locations and outpatient surgery clinics for pre- and post-operative care, especially for serving patients in Anne Arundel County and in the State's mid-Shore counties. The new location at UM BWMC would be part of the UMMS merged asset system of hospitals and health care facilities, which are completely integrated, clinically and administratively.

UM BWMC demonstrated that it will achieve more than 200 cardiac surgery cases by the second full year of operation, largely by shifting suitable UMMS cases to a more convenient and cost effective location. The Reviewer incorrectly underestimated UMMS's ability to ensure that cardiac surgery cases are performed in the right place for the benefit of patients and payers.

UM BWMC's proposed new location is consistent with national and state health care goals to reduce the cost of care and enhance patient experience.

The cardiac surgery program proposed by AAMC relies entirely on shifting volume from existing unaffiliated hospitals with cardiac surgery programs. (DI #3AA, p. 92.) But, the Recommended Decision and AAMC give short shrift to the adverse impact AAMC's proposed program would cause on existing cardiac surgery programs. In particular, AAMC largely ignored the impact that its proposed program would have on PGHC, which the Commission

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Also, the UM Division of Cardiac Surgery serves the Metropolitan Washington region in partnership with Dimensions Healthcare at Prince George's Hospital Center ("PGHC"). The UM Division of Cardiac Surgery is currently supporting three locations with strong quality measures. Moreover, the resurgence of the cardiac surgery program at PGHC is well underway and progressing positively.

recently approved to build a new replacement regional medical center with more than \$400 million in investments from the State of Maryland and Prince George's County.

During the past two and half years, the cardiac surgery program at PGHC has undertaken a revitalization with the leadership and staffing of the UM Division of Cardiac Surgery. The volume of cardiac surgery cases at PGHC has grown substantially to more than 100 cases in the last fiscal year (FY 2016). Also, the program now ranks within the top 10% of cardiac surgery programs nationally in terms of quality measures. The resurgence of the cardiac surgery program at PGHC is an important component of the success of the newly approved regional medical center in Largo Town Center. This new facility is critical to the transformation of the health care delivery system in Prince George's County, which is the most racially diverse and second most populous jurisdiction in Maryland. The success of the PGHC program is critical to addressing the racial disparities in cardiac surgery. For far too long, the residents of Prince George's County have been underserved by the health care delivery system – many residents have sought care outside of the County. The approval of AAMC's application threatens the PGHC program at a time when it is just beginning to reemerge, and it is inconsistent with the goals of the State Health Plan Chapter for Cardiac Surgery and Percutaneous Coronary Intervention Services (the "SHP" or "State Health Plan"), which protect existing programs from adverse impact.

Moreover, AAMC utterly failed to demonstrate that its proposed program would be financially feasible within the meaning of the applicable standard in the State Health Plan, *i.e.*, by showing that revenue would exceed expenses <u>for cardiac surgery</u>. The Recommended Decision, however, finds AAMC to be in compliance by misconstruing and ignoring the plain

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meaning of the standard, finding instead only that the program would not jeopardize the financial feasibility of the hospital.

The Recommended Decision should be rejected for these and other reasons, as described below. The Commission should deny AAMC's application and approve UM BWMC's application. Alternatively, the Commission should require the Reviewer to reopen the record for the purpose of reevaluating the applicants' compliance with the minimum volume, adverse impact, and financial feasibility standards and related review criteria.

EXCEPTIONS

Minimum Volume, COMAR § 10.24.17.05A(1)

I. <u>EXCEPTION NO. 1</u>: THE ALTERNATIVE MODEL FOR ASSESSING MINIMUM VOLUME IS FUNDAMENTALLY FLAWED, VIOLATES UM BWMC'S RIGHT TO DUE PROCESS, AND SHOULD BE REJECTED. (COMAR § 10.24.17.05A(1)).

The memorandum summarizing the Recommended Decision, as well as the "Reviewer's Recommendation" that closes the decision, suggests that the Recommended Decision is based on a comparative review of the applications and that AAMC was found to be the stronger applicant. That is an incorrect and misleading summary of this review. The Recommended Decision recommends eliminating UM BWMC's application from a comparative review analysis based solely on the finding that UM BWMC supposedly did not meet the 200-case threshold minimum volume requirement. The Recommended Decision then uses this finding as the sole basis for concluding that UM BWMC did not meet four other review standards and criteria. As a result, the Recommended Decision does not address the comparative review factors, again on the basis

of the Reviewer's faulty conclusion that UM BWMC did not meet the initial minimum volume threshold.

Thus, any comparative statements made in the Recommended Decision suggesting that AAMC's application is stronger are made wholly outside of the framework this Commission has established for the comparative review of cardiac surgery programs. The decision does not address or apply the "preference in comparative reviews" standard that defines the criteria upon which a preference may be based.

The Reviewer's minimum volume analysis itself is severely flawed and inconsistent with the State Health Plan. The Recommended Decision does not address the significant evidence put forth by either applicant during this two year review. Instead, the Reviewer advances an Alternative Model of analyzing minimum volume that is inconsistent with and not set forth in the State Health Plan chapter, and has never before been applied by the Commission. As explained below, it is also mathematically and logically flawed, and is based on data that is not part of the record in this review and not readily available to the applicants — leaving the applicants without the ability to independently recreate and assess the Reviewer's methodology. If adopted by the full Commission, the application of this Alternative Model as a basis for eliminating UM BWMC from a comparative review would be not only inconsistent with the State Health Plan chapter governing this review, but would also violate UM BWMC's right to due process.

The Commission should see the Alternative Model for what it is – a seriously flawed methodology for excluding UM BWMC's application from a meaningful comparative review – and should reject it.

A. The Alternative Model Creates an Arbitrary Threshold Inconsistent with the State Health Plan Minimum Volume Standard.

COMAR § 10.24.17.05A(1), the Minimum Volume Standard ("Standard .05A(1)"), provides, in relevant part:

An applicant proposing establishment or relocation of cardiac surgery services shall document that the proposed cardiac surgery program will meet the following standards:

(a) For an adult cardiac surgery program, demonstrate the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation; the program shall attain a minimum annual volume of 200 cardiac surgery cases by the end of the second year of operation.

. . .

(d) The applicant's demonstration of compliance with the Minimum Volume and Impact standards of this chapter shall address the most recent published utilization projection of cardiac surgery cases in Regulation .08 for the health planning region in which the applicant hospital is located and any other health planning regions from which it projects drawing 20 percent of more of its patients. The applicant shall demonstrate that its volume projections and impact analysis are consistent with the projection in Regulation .08 or, alternatively, demonstrate why the methods and assumptions employed in the Regulation .08 projections are not reasonable as a basis for forecasting case volume.

<u>Id</u>.² For more than two years, each applicant submitted many filings detailing its assumptions regarding its minimum volume analysis, but in the end the Reviewer failed to seriously evaluate the analyses submitted by the applicants. Instead, the Reviewer created a

The Recommended Decision's quotation of this standard includes a reference to Regulation .10, instead of Regulation .08. Recommended Decision, pp. 15-16. The Recommended Decision appears to be relying up on the version of the State Health Plan chapter as amended on November 9, 2015, which inserted new subsections and renumbered former subsection .08 to .10. The August 18, 2014, version of the State Health Plan chapter is the version applicable to this review. However, the reliance on the new version does not appear to affect the substance of this review.

"simple alternative forecast model" (the "Alternative Model") for analyzing minimum volume.

The Alternative Model takes the following steps:

- 1. Identify the Zip Codes, ranked by highest to lowest frequency, that contributed to 85% of the hospital's MSGA service area ("SA");
- 2. Apply population and utilization projections to 85% MSGA SA to identify projected number of cardiac surgery discharges in 85% MSGA SA in CY 2020;
- 3. Assume that hospital will have 18-20% normative market share with maximum 25% market share to determine number of cardiac surgery discharges hospital will have in CY 2020 from 85% MSGA SA;
- 4. Assume hospital receives 66% of its cardiac volume from its 85% MSGA service area to project total number of cardiac surgery discharges for hospital in CY 2020;
- 5. Apply a 94% adjustment factor to project number of open heart surgery discharges.

Regardless of the strength of its strategy, system affiliations, referral relationships, or any other circumstances, a hospital applicant can only achieve minimum volume under the Alternative Model if there will be at least 701 cardiac discharges in its 85% MSGA service area in the relevant year.

Table 1 Alternative Model Minimum Required Cardiac Volume in 85% MSGA SA

Cardiac Discharges in 85% MSGA SA	701 ³
Adj. for 20% Market share in 85% MSGA SA	140
Adj. for 66% MSGA Cardiac Volume from 85% MSGA SA	212
Adj. for 94% Open Heart Surgery	200

The reduction of the 701 cases by even one discharge would place a hospital under the minimum volume threshold of 200 cases. This model oversimplifies the complex nature of the health care delivery system for cardiac surgery services which, by the Commission's design, are provided on a regional basis.

Had the Commission intended to apply this simplistic and rigid threshold to a new cardiac surgery program, it should have done so as a matter of rulemaking by replacing the State Health Plan's current minimum volume standard with a standard that incorporates the above methodology. The relevant State Health Plan chapter has been amended twice in recent years, on August 18, 2014, and November 9, 2015, both the result of a planning process that provided an opportunity for public comment. There is no support in the State Health Plan or the Recommended Decision to reject the applicable minimum volume standard in favor of a different, arbitrary cut off. The Alternative Model threshold should be rejected in favor of the

identified "normative market range" of 18-20%. At 22% market share, the Alternative Model would require that there be at least 637 cardiac surgery cases in the applicant hospital's 85%

MSGA service area, rather than 701.

As explained more fully below, application of the Alternative Model to AAMC in fact requires AAMC to achieve a 22% market share in its 85% MSGA service area, despite the

actual requirement in the State Health Plan chapter – demonstration of the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation.⁴

Furthermore, as set forth in greater detail below, the Alternative Model is fundamentally flawed at each step. The Commission should reject the Alternative Model, apply the State Health Plan chapter minimum volume standard, and find that UM BWMC meets the standard because it "demonstrate[d] the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation" and "address[ed] the most recent published utilization projection of cardiac surgery cases." COMAR § 10.24.17.05A(1).

- B. The Alternative Model is arbitrary and relies upon the flawed assumption that MSGA service area is the relevant market to assess, rather than the cardiac surgery service area proposed by either applicant or the State Health Plan.
- (i) The Alternative Model rewards a hospital for weak MSGA market share and penalizes a hospital with strong MSGA market share.

The Alternative Model's reliance on the MSGA service area as the starting point for cardiac surgery volume is flawed and arbitrary because, as demonstrated below, its methodology could possibly assign greater cardiac volume to hospitals with weaker MSGA market share – a hospital's anticipated cardiac surgery volume under the Alterative Model will increase as its market share per Zip Code decreases. To understand how this impacts the analysis as applied to

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In the last cardiac surgery CON review considered by the Commission, which was completed in 2005, the Commission found that each of the applicants – Suburban Hospital, Southern Maryland Hospital, and Holy Cross Hospital – complied with the minimum volume standard on the strength of referral relationships. <u>In re Metropolitan Washington Open Heart Surgery Review</u>, Docket Nos. 04-15-2133, 04-15-2134, and 04-15-2135, Recommended Decision, p. 53.

UM BWMC and AAMC, it is first necessary to examine the MSGA volume, population size, and market share of each hospital in its MSGA service area.

UM BWMC has stronger market share in its MSGA service area than AAMC

UM BWMC sits in a more densely populated area and has a stronger market share in its surrounding Zip Codes than AAMC. As a result of its strong market share and the dense population of its surrounding Zip Codes, UM BWMC's MSGA service area is relatively small – only 15 Zip Codes.

Table 2 UM BWMC, 85% MSGA Service Area, CY 2014 Zip Codes, Population and Market Share

	Baltimore Washington Medical Center							
		BWMC		Total MSGA	BWMC	MSGA		
		MSGA	Running	Discharges in	MSGA	Population		
<u>#</u>	ZIP	Discharges	Total %	Zip (All Hosp)	Market Share	(Age 15+)		
1	21061	3,311	20.79%	5,235	63.25%	44,824		
2	21122	2,992	39.57%	4,773	62.69%	50,919		
3	21060	1,988	52.05%	3,187	62.38%	25,267		
4	21144	1,164	59.36%	2,040	57.06%	26,465		
5	21146	750	64.07%	1,910	39.27%	22,437		
6	21113	691	68.40%	1,637	42.21%	25,917		
7	21108	619	72.29%	1,112	55.67%	14,310		
8	21225	488	75.35%	3,948	12.36%	25,873		
9	21076	391	77.81%	799	48.94%	11,108		
10	21090	355	80.04%	881	40.30%	8,329		
11	21226	222	81.43%	754	29.44%	6,084		
12	21054	207	82.73%	755	27.42%	8,700		
13	21227	174	83.82%	3,173	5.48%	27,248		
14	20794	153	84.78%	1,036	14.77%	12,749		
15	21114	147	85.71%	1,148	12.80%	20,513		
	Total	13,652	85.71%	32,388	42.15%	330,743		

Zip Codes with under 10% market share highlighted

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014⁵

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⁵ UM BWMC relies on two data sources that have not been entered into the record in this review – the HSCRC Maryland Discharge Database for CY 2014, and DC Hospital Discharge

In contrast, AAMC's MSGA service area is a less densely populated area and AAMC has a weaker market share in it. Thus, 85% of AAMC's MSGA service area is defined by 41 Zip Codes.

Table 3
AAMC 85% MSGA Service Area, CY 2014
Zip Codes, Population and Market Share

	Anne Arundel Medical Center						
				Total MSGA		MSGA	
		AAMC MSGA	Running	Discharges in	AAMC MSGA	Population	
<u>#</u>	ZIP	Discharges	Total %	Zip (All Hosp)	Market Share	(Age 15+)	
1	21401	2,549	13.37%	3,259	78.21%	32,469	
2	21403	1,689	22.23%	2,166	77.98%	25,618	
3	21037	1,005	27.50%	1,301	77.25%	17,247	
4	21012	828	31.84%	1,232	67.21%	17,599	
5	20715	811	36.10%	1,785	45.43%	21,145	
6	21409	760	40.08%	1,007	75.47%	16,564	
7	21146	674	43.62%	1,910	35.29%	22,437	
8	21114	666	47.11%	1,148	58.01%	20,513	
9	21666	566	50.08%	935	60.53%	10,236	
10	20716	519	52.80%	1,314	39.50%	16,986	
11	21113	382	54.81%	1,637	23.34%	25,917	
12	21054	367	56.73%	755	48.61%	8,700	
13	21032	344	58.54%	594	57.91%	7,646	
14	21122	340	60.32%	4,773	7.12%	50,919	
15	21035	334	62.07%	450	74.22%	6,654	
16	21619	294	63.61%	511	57.53%	5,062	
17	20711	281	65.09%	555	50.63%	5,382	
18	21617	261	66.46%	716	36.45%	8,367	
19	20721	250	67.77%	1,686	14.83%	23,312	
20	20774	239	69.02%	3,037	7.87%	37,677	

Database for CY 2014. As explained for more fully in Exception No 3, new data and analyses based on such data were entered into the record 45 minutes before the issuance of the Recommended Decision, and some data relied upon was not entered into the record at all. All tables in these Exceptions are based on the two cited databases, which appear to have been relied upon by the Reviewer, and/or data entered into the record. UM BWMC reserves its right to object to the entry and use of such data based on the grounds described more fully in Exception No. 3. Because these Exceptions rely on two databases outside of the record, an affirmation is attached to this filing.

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	Anne Arundel Medical Center					
<u>#</u>	ZIP	AAMC MSGA Discharges	Running Total %	Total MSGA Discharges in Zip (All Hosp)	AAMC MSGA Market Share	MSGA Population (Age 15+)
21	20764	233	70.24%	321	72.59%	3,113
22	20772	229	71.45%	2,754	8.32%	36,608
23	20776	210	72.55%	277	75.81%	3,580
24	21061	204	73.62%	5,235	3.90%	44,824
25	20720	201	74.67%	1,130	17.79%	19,155
26	20733	187	75.65%	253	73.91%	2,616
27	21108	183	76.61%	1,112	16.46%	14,310
28	21144	180	77.56%	2,040	8.82%	26,465
29	21638	149	78.34%	388	38.40%	4,137
30	21140	140	79.07%	188	74.47%	2,826
31	21601	135	79.78%	2,604	5.18%	20,342
32	20751	132	80.47%	183	72.13%	2,046
33	20736	122	81.11%	585	20.85%	7,412
34	21658	117	81.73%	272	43.01%	3,228
35	20639	115	82.33%	867	13.26%	11,946
36	21620	102	82.86%	1,365	7.47%	11,229
<i>37</i>	20732	92	83.35%	597	15.41%	8,157
38	20778	92	83.83%	118	77.97%	1,816
39	20754	88	84.29%	415	21.20%	5,799
40	21060	87	84.75%	3,187	2.73%	25,267
41	20706	83	85.18%	2,509	3.31%	30,493
	Total	16,240	85.18%	57,171	28.41%	665,819

Zip Codes with under 10% market share highlighted

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

As these tables demonstrate, while the population of AAMC's MSGA service area is over twice that of UM BWMC, the number of MSGA discharges AAMC draws from that much larger population is only 19% higher than BWMC's MSGA discharges.

The market share figures in these tables demonstrate that in its respective 85% MSGA service area, UM BWMC possesses a 42.15% MSGA market share while AAMC possesses 28.41% in its service area. There is only one Zip Code included in BWMC's 85% MSGA service area where it has less than 10% market share, and it has greater than 25% in 11 of the 15

Zip Codes. In contrast, AAMC's service area includes 9 Zip Codes where its market share is below 10% - including six of the seven largest Zip Codes in its service area.

The Alternative Model Rewards AAMC for Weaker MSGA Market Share per Zip Code

The reliance of the Alternative Model on the 85% MSGA service area size is critical (and misplaced) because it is the starting point for all volume adjustments. Under the model, a hospital with a greater population size in its 85% MSGA SA will have more cardiac surgery discharges in that service area, and thus will be more likely to reach the required 701 cardiac discharges that would result in 200 open heart surgery cases at the relevant hospital.

A hospital with weaker market share penetration will have more Zip Codes included in its 85% MSGA service area than a hospital with stronger market share. As a hospital service area reaches out to more Zip Codes to make up 85% of its MSGA volume, the Alternative Model will reward the hospital for the entire population in those Zip Codes, irrespective of the applicant's market share there.

As demonstrated below, UM BWMC has an MSGA market share well above the 18-20% flat cardiac surgery market share of the Alternative Model in 73% of its MSGA service area population. AAMC has a market share of less than half the normative range in 56% of its MGSA service area population. Yet, both hospitals get full credit for the population size of each MSGA Zip Code, and have a flat 18-20% market share applied.

UM BWMC's MSGA service area is defined by 15 Zip Codes, representing 330,743 adult (15+) population. Table 2, *supra*. AAMC's MSGA service area is defined by 41 Zip Codes, representing 665,819 adult population. Table 3, *supra*. The following tables show all Zip Codes in each applicant's 85% MSGA service area in which the applicant has a market share

below 22%. Thus, the Zip Codes below are those which the Alternative Model will assign a flat market share percentage to AAMC that is much higher than its MSGA market share.

Table 4
AAMC MSGA Market Share by Zip Code
Selected Zip Codes (<22%), CY 2014

	Anne Arundel Medical Center							
<u>#</u>	ZIP Code	AAMC MSGA Discharges	Total MSGA Discharges in Zip (All Hosp)	AAMC MSGA Market Share	MSGA Population (Age 15+)			
14	21122	340	4,773	7.12%	50,919			
19	20721	250	1,686	14.83%	23,312			
20	20774	239	3,037	7.87%	37,677			
22	20772	229	2,754	8.32%	36,608			
24	21061	204	5,235	3.90%	44,824			
25	20720	201	1,130	17.79%	19,155			
27	21108	183	1,112	16.46%	14,310			
28	21144	180	2,040	8.82%	26,465			
31	21601	135	2,604	5.18%	20,342			
33	20736	122	585	20.85%	7,412			
35	20639	115	867	13.26%	11,946			
36	21620	102	1,365	7.47%	11,229			
37	20732	92	597	15.41%	8,157			
39	20754	88	415	21.20%	5,799			
40	21060	87	3,187	2.73%	25,267			
41	20706	83	2,509	3.31%	30,493			
	Total	2,650	33,896	7.82%	373,915			

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

As Table 3 and Table 4 demonstrate, 56% of the adult (15+) population in AAMC's 85% MSGA service area (373,915/665,819) live in Zip Codes where AAMC currently has an average MSGA market share of 7.82%. While the utilization projection will differ slightly based on the

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Twenty-two percent was selected as the relevant data point because, while the Alternative Model purports to apply an 18-20% "normative market share," as discussed more fully in the following pages, it in fact requires that AAMC reach at least a 22% cardiac surgery market share in its 85% MSGA service area.

defined cardiac region of each Zip Code, and the projected population of each Zip Code in CY 2020, this means that about 56% of the cardiac surgery discharges the Alternative Model uses as a starting point for AAMC's projected volume are in the Zip Codes above. Even though AAMC has only a small market share (under 8%) in these Zip Codes, the Alternative Model assigns the benefit of the entire Zip Code population to AAMC by assigning a flat 18-20% market share.

In contrast, the population in the Zip Codes in UM BWMC's 85% MSGA SA in which it has less than a 22% market share comprises only 26% of its total 85% MSGA SA population (86,383 / 330,743).

Table 5
BWMC MSGA Market Share by Zip Code
Selected Zip Codes (<22%), CY 2014

	Baltimore Washington Medical Center							
			Total MSGA	BWMC's	MSGA			
		BWMC MSGA	Discharges in	MSGA	Population			
#	ZIP	Discharges	Zip (All Hosp)	Market Share	(Age 15+)			
8	21225	488	3,948	12.36%	25,873			
13	21227	174	3,173	5.48%	27,248			
14	20794	153	1,036	14.77%	12,749			
15	21114	147	1,148	12.80%	20,513			
	Total	962	9,305	10.34%	86,383			

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

The result is that if UM BWMC had weaker market share in the Zip Codes within its 85% MSGA service area, it would extend to more Zip Codes to reach its 85% service area, would have greater population size within the service area, and it would have more cardiac surgery discharges within the service area to draw from in order to meet the Alternative Model.

The best example of the serious flaw in the Alternative Model's reliance on MSGA service area population without consideration of MSGA market share is seen in the results of the model as applied to Zip Code 21122. That Zip Code had a population size of 50,919 in CY 2014 – the largest Zip Code by population size in both applicants' 85% MSGA service area.

UM BWMC has a market share of 62.69% in the Zip Code, and AAMC a market share of 7.12% . Under the Alternative Model, both AAMC and UM BWMC receive credit for the entire population of Zip Code as part of the population of its service area, and a flat 18-20% assumption is applied to both, even though UM BWMC's market share is almost nine times higher than AAMC's. This effect is compounded because each step of the Alternative Model is built off of the MSGA service area population size.

There can be no serious question that a low market share in an MSGA service area does not correlate with a strong cardiac surgery program. Yet that is the logical result of the Alternative Model methodology employed by the Reviewer. It should be rejected for this reason alone.

(ii) There is no correlation between a hospital's MSGA service area population size and open heart surgery discharges.

No evidence has been put into the record in this review that cardiac surgery discharges are correlated with the population size of a hospital's 85% MSGA service area, yet that is the driving factor in the Alternative Model. Maryland has 47 acute care hospitals across the state with different geographic inpatient service areas.⁷ In contrast, it has only 10 cardiac surgery

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Based on the MHCC Annual Report on Selected Maryland General and Special Hospital Services, FY 2016, available at http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_hospital/documents/acute_care/chcf_acute_care_license_rpt_2016_20151130.pdf.

programs. Thus, cardiac surgery programs necessarily have different and larger cardiac service areas than their MSGA service areas. Indeed, the State Health Plan Chapter recognizes that "For specialized services, the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base." COMAR § 10.24.17.03, p.6.

In order to determine whether there is truly a relationship between the population size of a hospital's 85% MSGA service area and its total count of open heart surgeries, UM BWMC performed a linear regression analysis. For the purposes of this analysis, UM BWMC examined eight Maryland hospitals with cardiac surgery programs, excluding UMMC and JHH due to their cardiac program size and the population size within their 85% MSGA, both of which are more than 200% greater than the experience of any other Maryland program. See Table 6, below. UM BWMC analyzed the total population of each hospital's 85% MSGA service area and each hospital's CY 2014 total open heart surgery volume.

The analysis demonstrates that there is no significant statistical correlation between the population in a hospital's service area and its number of open heart surgery cases. Primarily, this conclusion is drawn from both the intercept and population coefficient having P-values well above the statistically significant benchmark of 0.05 (0.14 and 0.34, respectively). Furthermore, the residuals squared value of 0.150 suggests that the data points are not closely associated with their trend line. Residuals squared values fall between 0 and 1, with more closely fitting data points equaling a result closer to 1. The graphical and summary output of this analysis are attached as Exhibit 1.

- C. The Alternative Model makes several assumptions that are inconsistent with the actual experience of Maryland hospitals, including UM BWMC, are not applied in a mathematically sound manner, or are otherwise unsupportable by any fact in the record.
- (i) There is no reasonable support for the Alternative Model's assumption that 66% of cardiac surgery discharges will come from within applicants' 85% MSGA SA.

Based on Maryland hospital experience, the range of cardiac volume outside of a hospital's 85% MSGA service area ranges from 3.4% to 50.5%. The Alternative Model assumes that 66% of the volume from the applicant hospitals will be within their 85% MSGA service area, based on the experience of Washington Adventist Hospital ("WAH"), UM St. Joseph's Medical Center, and Suburban Hospital with little analysis.

Table 6
Maryland Cardiac Surgery Programs
MSGA SA Discharges by Hospital, CY 2014

Hospital Name	Population	Cardiac Surgery Discharges			Open H	Open Heart Surgery Discharges		
			Outside	% Outside		<u>Outside</u>	% Outside	
	MSGA (Ages 15+)	<u>85% SA</u>	<u>SA</u>	<u>SA</u>	<u>85% SA</u>	<u>SA</u>	<u>SA</u>	
Maryland hospitals with	h cardiac surgery pr	ograms						
AAMC	665,819	-	-	0.0%	-	-	0.0%	
BWMC	330,743	-	-	0.0%	-	-	0.0%	
JHH	4,945,459	1,017	164	13.9%	823	142	14.7%	
PGHC	770,160	28	1	3.4%	28	3 1	3.4%	
PRMC	160,459	341	90	20.9%	332	2 88	21.0%	
Sinai	1,338,031	245	137	35.9%	243	3 137	36.1%	
St. Joseph's	1,219,141	308	140	31.3%	306	140	31.4%	
Suburban	1,401,045	191	53	21.7%	186	5 52	21.8%	
UMMC	3,715,797	816	149	15.4%	682	118	14.8%	
Union Mem.	1,535,290	535	101	15.9%	450	89	16.5%	
WAH	1,023,776	149	152	50.5%	145	146	50.2%	
Western MD RMC	77,705	140	30	17.6%	138	30	17.9%	
Maryland subtotal		3,770	1,017	21.2%	3,333	943	22.1%	

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

While the Recommended Decision suggests WAH's experience is analogous because it is in a suburban area (Recommended Decision, p. 29, fn 23), WAH's significant out of MSGA service area cardiac surgery volume appears to be largely driven by referrals from its affiliated hospital in Shady Grove. Of its 301 cardiac surgery cases in CY 2014, WAH drew 85 cases (or 28%) from the GBR service area of Adventist HealthCare Shady Grove Medical Center ("Shady Grove"). (Nielsen Population Projections (DI #97GF), HSCRC MD Discharge Database.)⁸

If the Alternative Model had instead applied the average out of service area discharge rate of all Maryland hospitals, even without removing WAH, a clear outlier that drives up the average, neither applicant hospital would achieve minimum volume under the Alterative Model. Table 7 below applies the Alternative Model methodology, using a 20% market share (the high end of the "normative range" identified in the Recommended Decision) and adjusts the model with an assumption that 78.8% of the hospital's volume will be within the 85% MSGA service area based on the average experience of all Maryland hospitals.

Table 7
Alternative Model at 20% Market Share
Adjusted for 78.8% Cardiac Volume in MSGA SA

	CY 2	2020
	AAMC	BWMC
Cardiac Discharges in 85% MSGA SA	668	330
Adj. for 20% Market share in 85% MSGA SA	134	66
Adj. for 78.8% MSGA Cardiac Volume from 85% MSGA SA	170	52
Adj. for 94% Open Heart Surgery	159	49

Source: Recommended Decision, Table 5.

⁸ GBR service area of Adventist HealthCare Shady Grove Medical Center determined based on the hospital's GBR agreement, available at http://www.hscrc.maryland.gov/gbr-tpr.cfm.

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To be clear, this conclusion is not intended to suggest that neither hospital can achieve minimum volume. As stated above, there is no correlation between cardiac surgery volume and the population size of a hospital's 85% MSGA service area. Rather, this result demonstrates yet another reason why the Alternative Model is arbitrary and not based reasonable assumptions.

(ii) There is not sufficient data in the record to test the assumption that the applicants will be able to achieve only 18-20% cardiac surgery market share in their 85% MSGA service areas.

The Alternative Model's application of an 18%-20% as the normative range for expected cardiac surgery market share within a hospital's 85% MSGA service area is problematic for several reasons.

First, as discussed above, the assumption makes no distinction between an applicant such as UM BWMC with a market share of well over 20% in 74% of its 85% MSGA service area, and an applicant like AAMC, which has less than an 8% market share in more than half of its 85% MSGA service area population.

Second, the assumption is driven, in part, by the experience of WAH. Recommended Decision, p. 29, FN 23. Twenty-eight percent of WAH's cardiac discharges come from the GBR service area of Shady Grove. (Nielsen Population Projections (DI #97GF), HSCRC MD Discharge Database.)⁹ One can reasonably assume, based on this fact and the fact that WAH's experience is a clear outlier from the experience of other Maryland hospitals (see Table 6, *supra*), that WAH's market efforts are focused in part on developing the service area around

GBR service area of Adventist HealthCare Shady Grove Medical Center determined based on the hospital's GBR agreement, available at http://www.hscrc.maryland.gov/gbr-tpr.cfm.

Shady Grove. In addition, WAH, Suburban, and St. Joseph's Medical Center all have competing cardiac programs in close proximity.

Table 8
Suburban, UM SJMC, WAH, AAMC, BWMC
Cardiac Surgery Programs within 10 miles (straight line)

	JHH	MUM	PGHC	Sinai	Suburban	UMMC	WAH	WHC
Suburban							5.9	7
UM SJMC	6.2	4		3.5		6.9		
WAH			5.8		5.9			4
AAMC								
BWMC								

Source: ArcGis

In contrast, either applicant would be the only cardiac surgery program in Anne Arundel County, and no cardiac surgery program is within 10 miles of either applicant.

These factors could reasonably cause the market share of these so-called analogous hospitals to be quite different than the experience of the applicants, and, despite the substantial evidence entered into the record by both applicants, the Alternative Model and Recommended Decision do not indicate what weight, if any, was given to such factors.

Third, the application of an assumption that each applicant will achieve a 18%-20% cardiac surgery market share in its 85% MSGA service area fails to account for the significant difference in UM BWMC's demonstrated ability to achieve significantly more MSGA market share in that service area than the other hospitals used in the comparison.

Table 9
Market Share in 85% MSGA SA, CY 2014
Hospitals Used in Alternative Model

Hospital	MSGA Discharges in 85% MSGA SA	Total MSGA Discharges in 85% MSGA SA	MSGA Market Share ⁽¹⁾
UMBWMC	13,652	32,388	42.15%
AAMC	16,240	57,171	28.41%
Suburban Hospital	10,377	100,318	10.34%
WAH	6,908	91,979	7.51%
UM St. Joseph	11,211	140,925	7.96%

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

UM BWMC has a significantly higher market share in its 85% MSGA service area than the three comparison hospitals – a fact that is given no weight in the model, which instead relies on MSGA service area population size and the experience of three Maryland hospitals.

UM BWMC also has a higher market share in its MSGA service area than AAMC, yet the two are given the same, flat 18-20% market share in the alternative model.

As Table 9 demonstrates, the failure to consider MSGA market strength in a model premised on MSGA service area is a serious logical flaw. The three comparison hospitals achieve a cardiac market share in their 85% MSGA service area that ranges from about two to three times *higher* than their MSGA market share in the same Zip Codes. This makes sense, because there are fewer cardiac surgery hospitals than acute care hospitals. Yet, despite the experience of the very hospitals used as a comparison, the Alternative Model assumes UM BWMC will have a cardiac surgery market share that is 51% lower than its MSGA market share in the same geographic area. The Alternative Model states the experience of these hospitals in their cardiac and MSGA service areas should be used as a comparison, yet it cherry

picks only certain aspects of those hospitals' experience without adequate analysis, explanation, or support, and without any support from the State Health Plan chapter.

(iii) The 94% adjustment factor is logically unsound.

The Alternative Model applies, at the end of the analysis, a 94% adjustment factor. This adjustment combines three unrelated data points that are melded together to form an unsupportable assumption.

The Recommended Decision refers first to the fact that the Alternative Model forecasts cardiac surgery discharges, not open heart surgery discharges, which make up 90% of cardiac surgery discharges based on the average results of the last five years for which data is available. Recommended Decision, p. 31. The Recommended Decision also states that "[i]n 2015, over 97% of the cardiac surgery cases at the three hospitals used as a "peer" group for purposes of estimating a normative market share assumption range for the MSGA were open heart surgery cases." Id., 30-31. This second data point suggests that the peer group hospitals' open heart surgery market share in their SA may be larger than their cardiac surgery market share in their service areas. It does not suggest that in those hospitals' service areas there was a

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The Recommended Decision does not state which five years were used or the source of the data. There is no indication of whether this is based on Maryland hospitals only, or also includes cardiac surgery discharges of Maryland residents from Washington, D.C. hospitals. This is just one of many examples of where the Alternative Model uses data not placed in the record and does not give sufficient data for the applicants, or the Commissioners, to review and test the Model.

greater proportion of open heart to non-open heart cases than experienced by Maryland hospitals overall.¹¹

The Recommended Decision then introduces a third point - that the hospitals affiliated with the applicants may shift "less complex <u>open heart surgery</u> cases" to the applicants. <u>Id.</u>, 31. Again, this has no bearing on whether these hospitals' service areas have a greater proportion of open heart to cardiac surgery cases than the state average. The shift of additional open heart surgery cases from affiliated hospitals may justify an assumption regarding an applicant's likely market share. It has no bearing on what percentage of the cardiac surgery cases in the hospital's service area will be open heart surgeries.¹²

The Recommended Decision combines these three, unrelated data points to suggest that it is appropriate to adjust the projected cardiac surgery case volume for each hospital – which is based on cardiac surgery, not open heart surgery, by only 94% instead of 90%. The Decision states, "Applying this 90% adjustment to the total service area cardiac surgery caseload serving as a base of this analysis but also recognizing that the case shifts facilitated by the applicant's partner hospitals will tend to result in a higher proportion of less complex open heart surgery

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Or than experienced by Maryland patients discharged from Maryland or Washington, D.C. hospitals – the data source is not defined.

This brief reference to referral relationships, which the parties addressed at great length in their filings, should be a part of a model that assesses likely volume. But this adjustment factor is made because the Alternative Model projects total cardiac surgery cases and, until this point, fails to account for the state average experience that only 90% of these surgeries are open heart surgeries. Up until this point in the Reviewer's analysis, the volume is based on geography and population size alone. Referral relationships have no bearing on whether the cardiac surgery discharges in the service areas of the applicants exceed the state average of 90% open heart surgeries.

cases being shifted to these new programs, an adjustment factor of 94% is reasonable to use in this case."

The data points on which this conclusion is based do not suggest that the percentage of cardiac surgery discharges that are open heart surgeries in the relevant 85% MSGA service area is somehow higher than the 90% state average. And, no explanation is given as to why 94% was selected from the range between 90% and 97%. By applying only a 94% adjustment factor, the Alternative Model in fact assigns a higher market share of cardiac surgery discharges to the applicants than stated.

Table 10 94% Adjustment applied to AAMC Volume

	@20%	@ 25%
AAMC OHS Volume	191	238
AAMC Service Area Volume (66% of Total)	126	157
Total Cardiac Surgery Volume in Service Area	668	668
Total OHS Volume in Service Area (90% of Cardiac Surgery)	601	601
AAMC Implied Market Share of OHS Cases	20.9%	26.1%

Source: Recommended Decision, pp. 26-32.

The 94% adjustment relies on unsupported and unstated assumptions, and should be rejected.

(iv) AAMC does not meet the minimum volume standard under the Alternative Model when the 94% adjustment is applied.

While these exceptions demonstrate that the Alternative Model should be wholly rejected rather than applied in this review, the application of it results in AAMC having below the minimum volume threshold of open heart surgery cases if all of the assumptions are applied – a fact left out of the Recommended Decision. The Alternative Model assumes a "normative

cardiac surgery market share of 18% to 20%" for cardiac surgery cases originating in each applicant's 85% MSGA service area. A 25% maximum "best case scenario" share is then portrayed. Recommended Decision, p. 29.

In modeling AAMC's projected volume under the Alternative Model, the Recommended Decision suggests that AAMC achieves 200 cases in CY 2020 when within the normative market share of 18-20%. That is incorrect. Although each adjustment made until the final 94% adjustment for open heart surgery cases is accompanied by table showing the volume at each level of market share, no such table accompanies the final adjustment factor of 94%. Instead, the Recommended Decision states that after application of the adjustment, AAMC's volume would be reduced to 171-238 cases. Recommended Decision, p. 31. What that summary leaves out is that AAMC, after the final adjustment in the Alternative Model, only achieves greater than 200 cases if it exceeds the "normative range" identified by the Alternative Model.

Table 11
94% Adjustment Factor Applied to Recommended Decision Table 10 (AAMC only)

Market Share	2017		2020		
Assumption	AAMC	BWMC	AAMC	BWMC	
N1 – 18%	178	88	171	84	
N2 -20%	198	99	191	94	
Max – 25%	248	122	238	118	

Source: Recommended Decision, pp. 26-32.

Moreover, had the Alternative Model applied the correct adjustment factor to adjust cardiac surgery cases to open heart cardiac surgery cases, AAMC's volume would have further decreased.

Table 12 Adjustment for 90% Open Heart Surgery Experience

Market Share	20	17	20	20
Assumption	AAMC	BWMC	AAMC	BWMC
N1 – 18%	160	80	154	75
N2 - 20%	179	89	172	85
Max – 25%	223	110	214	107

Source: Recommended Decision, pp. 26-32.

Because the Alternative Model assumes that 66% of the applicants' volume comes from the applicant's 85% MSGA service area, AAMC would need to have 132 open heart surgery cases in its 85% MSGA service area (200 x 66%). That means, at a minimum, AAMC must achieve a 22% market share of open heart surgery cases in its MSGA to meet the minimum volume standard – a percentage that the Alternative Model states is outside of the "normative range" of the experience of the hospitals used to create the model. Thus, under the very assumptions of the Alternative Model, AAMC does not achieve minimum volume under the defined normative range. Instead, it achieves 200 cases only if an arbitrary maximum market share is applied. Yet, the Recommended Decision relies upon the model to find only that UM BWMC does not meet the minimum volume standard, and thus that the Preferences in comparative reviews standard need not be applied.

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While the Alternative Model shows each applicant at a "maximum" market share of 25%, it does conclude that AAMC is likely to exceed the normative range. The decision to include this maximum range above the normative experience of the three comparison hospitals is also curious, as no range above the normative experience of the comparison hospitals was included for the assumption that 66% of the applicants' cardiac volume would come from their 85% MSGA service areas.

UM BWMC does not suggest that the Alternative Model should exclude AAMC, but that even if an alternative method is applied, it should be consistent with the State Health Plan, based on reliable data which are consistent with experience, and be impartial to both applicants. The Alternative Method applied in the Recommended Decision is not. Each applicant submitted lengthy filings regarding their minimum volume assumptions and the assumptions of the other applicant. The Commission should reject the Alternative Model, which is inconsistent with the State Health Plan and is based on unsupportable assumptions. The Commission should instead refer to the parties' filings.

- II. <u>EXCEPTION NO. 2</u>: THE RECOMMENDED DECISION'S DETERMINATION THAT UM BWMC'S APPLICATION FAILS TO MEET THE MINIMUM VOLUME STANDARD (COMAR § 10.24.17.05A(1)) SHOULD BE REJECTED.
 - A. UM BWMC documented that it would achieve minimum volume consistent with the minimum volume standard.

In response to the minimum volume standard, UM BWMC demonstrated the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation, and its projections were consistent with the most recent published utilization projection of cardiac surgery cases. COMAR § 10.24.17.05A(1). UM BWMC summarized its minimum volume and need analysis in a document identified in the review as Exhibit 44 (DI #8BW, Exhibit 44), attached here as Exhibit 2. The Recommended Decision recognizes that "BWMC's approach to evaluating the demand it would likely experience as a cardiac surgery hospital was also practical

and sufficiently documented."¹⁴ Recommended Decision, p. 26. UM BWMC's response to this standard was stated as follows:

Table 2
Summary of Projections of Volume of
Cardiac Surgery Cases at UM BWMC (FY 2016 – FY 2021)

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Shift from UMMC	64	145	151	157	154	150
Shift from Other Maryland Hospitals	12	36	47	57	67	74
Shift from D.C. Hospitals	8	23	30	36	43	46
TOTAL	81	204	228	250	264	270

Source: Detailed volume projections contained in Exhibit [44]. 15

The projected volumes are based on the following methodology and assumptions:

- 1. FY 2014 baseline cardiac surgery volumes for the defined UM BWMC cardiac surgery service area were obtained from the Maryland MSA Database. All patients with an extreme severity were excluded as it was assumed the majority of the extreme cases would continue to be referred to larger tertiary/quaternary facilities, such as UMMC. To complete FY14 baseline, volumes that out-migrated to Washington DC hospitals were added. The out-migration information was obtained from the CY2011 DC Inpatient Database.
- 2. The FY14 baseline volumes were segmented into two categories: (1) those that were discharged from UMMC; and (2) those that were discharged from other hospitals in Maryland and Washington DC.
- 3. Year to year decline from the FY14 baseline market volumes were calculated based on the percentage decline as projected by the Commission's projected utilization of cardiac surgery services for the Baltimore / Upper Shore Health Planning Region.

Based on this finding alone, UM BWMC complied with the minimum volume standard. The standard of proof in this contested case is the preponderance of evidence. Md. Code, State Government, § 10-217.

DI #8BW, Exhibit 44.

4. Assumptions were made year by year as to the percentage of volumes that would shift to a UM BWMC cardiac surgery program. It was assumed since the UM BWMC program would be part of the larger University of Maryland program, a much larger percentage shift would occur in these patients than those patients being discharged at non University of Maryland hospitals. As the years progress, the percentage of the market volumes shifting to a UM BWMC program gradually increased.

The reliability of the volume projections is verified and corroborated by letters of support from several cardiology practices which estimate that they will refer a combined total of 312 cardiac surgery cases based on their referral of cases in CY 2014. Copies of the letters are attached collectively as Exhibit 24. Table 3 below shows a breakdown of the estimated referred cases. While UM BWMC does not expect that every referral will result in a surgical procedure performed in the new program, the number of referrals supports the reasonableness of the volume projections.

Revised Table 3
Estimated Referrals of Cardiac Surgery Cases
to UM BWMC by Cardiology Practice

Cardiology Practice	Estimated Total Referred Cardiac Cases	Estimated Referred Cardiac Cases Excluding Extreme SOI ¹	
Arundel Heart Associates, P.A.	71	59	
The Heart Center of Northern Anne Arundel County, P.A.	89 ²	74	
Chesapeake Cardiology at Shore Health	57	47	
UM SOM Division of Cardiovascular Medicine	54 ³	45	
Maryland Heart Associates, LLC	41	34	
TOTAL	312	259	

- The referrals from each source were reduced by 17% to account for extreme cases, which will continue to be performed at UMMC.
- The estimated surgery referrals of the Heart Center of Northern Anne Arundel County, P.A. are based on the FY14 actual referrals plus an expected 10% increase based on the projected addition of another physician to the practice.
- In FY14, 200 patients were referred directly from the UM SOM Division of Cardiovascular Medicine to the UM Division of Cardiac surgery, resulting in a cardiac surgery discharge. While Zip Code origin data are not available for these patients, Dr. Rajagopolan, Chief of Cardiovascular Medicine (see Exhibit 24) stated that patients in this category who live in UM BWMC's service area would be patients whose surgery

could be done at UM BWMC by the same faculty cardiac surgeons. In FY14, of the 828 cardiac surgery discharges at UMMC, 27% originated from UM BWMC's service area (224) (Source: UM BWMC volume projection detail). Applying this same patient origin ratio to the 200 cardiac surgery referrals from the UM SOM Division of Cardiovascular Medicine results in another 54 cardiac surgery discharges that could be performed at UM BWMC.

(DI #2BW, pp. 44-45; DI #8BW, p. 2.) UM BWMC provided additional information regarding its minimum volume assumptions in response to requests for additional information from Commission staff, in response to comments from interested parties, and in its comments on the application of AAMC.

As recognized by the Recommended Decision, UM BWMC's approach to demonstrating minimum volume was "practical and sufficiently documented." Recommended Decision, p. 26. The Recommended Decision further acknowledges that "[b]oth applicants forecast the ability to reach a level of cardiac surgery that should allow compliance with the adult open heart surgery part of this standard, given the high proportion of these community hospital total cardiac surgery case load that would be open heart procedures." Id., pp. 26-27. Yet, the decision concludes that UM BWMC did not comply with the minimum volume standard.

The finding that UM BWMC did not meet the standard is primarily based on three factors. First, the Alternative Model, as applied to UM BWMC, does not show that UM BWMC would achieve minimum volume. The many faults with the Alternative Model are discussed above, and it should be rejected. Furthermore, the Recommended Decision states that the Alternative Model "is not a rejection of the applicants' response to this standard." Id., p. 27. Yet, the Recommended Decision does just that – it fails to meaningfully analyze the evidence submitted by UM BWMC and relies instead on the results of the Alternative Model. Based on the Recommended Decision's own statement that the model is not a rejection of the applicants'

response, the Commission should find that UM BWMC's practical, well documented response complies with the standard.

The second factor that appears to lead to the conclusion that UM BWMC has not met the minimum volume standard is the finding that UM BWMC's assumptions regarding market share shift from hospitals other than UMMC are not sufficiently conservative. The decision states, "both applicants took reasonable approaches to the development forecasts but there is a basis for concluding that some assumptions about the market share levels they forecast, especially with respect to market share outside the collaborative framework which is proposed by both applicants to 'steer' case volume to their new programs, are not assumptions that can be described as 'conservative.'" Id. Yet, UM BWMC's assumptions regarding market share shift from hospitals other than UMMC are conservative when compared to UM BWMC's MSGA market share, the very assumptions in the Alternative Model, and UMMS's and UM BWMC's cardiovascular market share.

The third factor that resulted in the finding that UM BWMC did not meet the minimum volume standard results from the Recommended Decision's failure to consider or address in any meaningful way UM BWMC's ability to shift cardiac surgery discharges in its proposed service area from UMMC to UM BWMC. This volume comprises 66% of UM BWMC's projected cases in the second full year of operation. Yet, the Recommended Decision's analysis of minimum volume touches on this only to acknowledge that the Alternative Model "did not account for the impact of collaborative initiatives to shift case volume to BWMC, from UMMC." Recommended Decision, p. 31.

As the Recommended Decision acknowledges, UM BWMC put forth practical, well documented, and supportable assumptions regarding its expected market share shift from hospitals other than UMMC, and its expected ability to shift cases from its proposed service area currently being performed at UMMC. Nevertheless, the Recommended Decision summarily rejects these assumptions without analysis or explanation other than the faulty Alternative Model. As explained in greater detail below, UM BWMC's assumptions are reasonable.

B. UM BWMC's market shift assumptions were similar to those applied by the Alternative Model.

UM BWMC projected a cardiac surgery service area that would have a total of 548 cases during its proposed program's second full year of operation. (DI #8BW, Exhibit 44.)

UM BWMC projected that it would perform 228 open heart cardiac surgery cases from its service area that year, consistent with the minimum volume standard. <u>Id.</u> Of that volume,

UM BWMC projected shifting 151 cases from UMMC, and an additional 77 cases from other hospitals. <u>Id.</u> The shift from hospitals other than UMMC is consistent with a 20% market share.

Table 13
UM BWMC Projected Volume, Second Year of Operation

Total proposed SA Cardiac Cases	584
UMMC Cases	201
Non-UMMC Cases	383
Projected Shift non-UMMC Hospitals	77
% Market Share of Non-UMMC cases	20%

Source: DI #8BW, Exhibit 44

The Recommended Decision provides no justification for its conclusion that this 20% market share assumption is not conservative. Other data submitted in the Recommended Decision and in the review shows it is not. For example, the Recommended Decision notes that

WAH, UM St. Joseph's, and Suburban achieve an 18-20% cardiac market share in their 85% MSGA service areas. Those hospitals have an MSGA market share in the same service area of 7.51%, 7.96%, and 10.34%, respectively – meaning that in their 85% MSGA service areas, they achieve a *higher* cardiac market share than their MSGA market. UM BWMC has a 40.83% market share in its 85% MSGA service area. The experience of the comparison hospitals suggest, if anything, that UM BWMC's assumption is too conservative.

UM BWMC also demonstrated an ability to pull cases from areas outside of its MSGA service area based on its integration with UMMS. UM BWMC provided recent cardiac surgery case volumes originating from the mid-Shore counties included in the Baltimore / Upper Shore health planning region for cardiac surgery services.

Table 14
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

County of Patient Origin	UMMS	JHHS	PRMC	Other
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%
(DI #29GF, p. 17, Table 8)				

The data demonstrate an overwhelming preference for UMMS-affiliated cardiac surgical programs. 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.

This strong market share is likely due, in part, to referrals from physicians affiliated with UMMS member hospitals without cardiac surgery programs, such as UM Shore Regional Health.

Indeed, WAH's ability to draw 28% of its cardiac surgery volume from the Shade Grove GBR service area suggests UM BWMC would have greater success than stand-alone programs in achieving substantial market share outside of its MSGA service area. UM BWMC reasonably expects that the addition of another UMMS member cardiac program would strengthen UMMS market share in UM BWMC's proposed cardiac surgery service area by attracting additional mid-shore patients who would otherwise go to hospitals other than UMMC.

C. The Alternative Model fails to provide any adjustment for case volume that affiliated hospitals may drive to a new program, and thus rejects, without any explanation, the entire premise of UM BWMC's program.

The Recommended Decision improperly disregards the strongest evidence of generating cardiac surgery volume at UM BWMC. The primary driver of cardiac case volume under UM BWMC's proposal is the deliberate shifting of cases from UMMC to UM BWMC, which are both member hospitals within the UMMS merged asset system and are current or proposed locations of the fully integrated UM Division of Cardiac Surgery.

The cardiac surgery cases that UM BWMC projects will shift from UMMC are a portion of the cases for patients living in the UM BWMC proposed cardiac surgery service area. There is no reason to believe that a significant number of patients who live closer to UM BWMC will not agree to have their cardiac surgical procedures performed at UM BWMC, a more convenient and cost effective environment than UMMC, especially since the UM Division of Cardiac Surgery will staff both UMMC and UM BWMC. (DI #2BW, UM BWMC Application, p. 8.) UM BWMC projects that it will capture an increasing percentage of the UMMC cases from within the UM BWMC proposed cardiac surgery service area. In the second full year of operation, FY 2018, UM BWMC projected that 75% of such cases will shift to UM BWMC,

totaling 151 cases or approximately 66% of the expected volume at UM BWMC for that year. (DI #8BW, Exhibit 44.) The 75% assumption is based on the number of UMMC cases that would qualify for transfer to UM BWMC's program, and thus already excludes UMMC cases that have a severity or complexity level that exceeds the level of services UM BWMC expects to provide. Id.

As discussed above, the Recommended Decision supplants the applicants' evidence and assertions regarding minimum volume in favor of the invented Alternative Model, which is based on established MSGA inpatient service areas. Recommended Decision, p. 27. The Recommended Decision admits that the Alternative Model does "not account for the impact of collaborative initiatives to shift case volume to BWMC, from UMMC, and to AAMC, from JHH." In other words, it disregards the support for two-thirds of the UM BWMC cardiac surgery volume.

In addition to not giving deserved credit to UM BWMC's case shift justification for establishing minimum volume, the Recommended Decision seems to offer AAMC additional support for its case volume by stating that "it is theoretically possible that JHH and AAMC could shift a higher number of Anne Arundel residents who seek cardiac surgery at JHH to a program at AAMC than AAMC has assumed in its CON application (50%)." Recommended Decision, p. 31. The Recommended Decision's incongruous treatment of the two applicants on this issue of case shift from their respective sponsor hospitals is illogical for at least two reasons.

First, UMMC and UM BWMC are member hospitals in a merged asset system and they would become part of the same cardiac surgery program. AAMC and JHH are independent hospitals that share a "Licensing and Program Agreement" concerning possible cardiac surgery

services at AAMC. (DI #45GF, Exhibit 24.) Thus, the relationship between UMMC and UM BWMC is far more stable, lasting, and integrated than the relationship between JHH and AAMC. As a result, the case volume shift between UMMC and UM BWMC is more certain. Second, UMMC has much more cardiac surgery case volume in UM BWMC's service area than JHH has in AAMC's service area. As shown in the following tables, in CY 2014, UMMC had 176 open heart surgery cases in UM BWMC's MSGA service area, while JHH had just 114 in AAMC's much larger MSGA service area. Thus, there are many more cases available for UMMC to shift to UM BWMC than JHH may be able to shift to AAMC.

Table 15
UMMC Cardiac Discharges in Applicant MSGA Service Areas
85% MSGA Service Area for UM BWMC, CY 2014

BWMC MSGA Service Area		UMMC		
		Cardiac	Open Heart	
	CY14 MSGA	Surgery	Surgery	
Zip Codes	Population	Discharges	Discharges	
21061	44,824	34	33	
21122	50,919	45	43	
21060	25,267	23	21	
21144	26,465	13	11	
21146	22,437	15	14	
21113	25,917	7	7	
21108	14,310	6	6	
21225	25,873	10	10	
21076	11,108	2	2	
21090	8,329	4	4	
21226	6,084	4	2	
21054	8,700	7	5	
21227	27,248	12	10	
20794	12,749	7	6	
21114	20,513	2	2	
Total	220 742	101	176	
Total	330,743	191	176	

Table 16 JHH Cardiac Discharges in Applicant MSGA Service Areas 85% MSGA Service Area for AAMC, CY 2014

AAMC MSGA	AAMC MSGA Service Area		The Johns Hopkins Hospital Cardiac Open Heart		
	CY14 MSGA		Open Heart Surgery		
Zip Codes	Population	Surgery Discharges	Discharges		
21401	32,469	8	7		
21403	25,618	8	8		
21037	17,247	4	4		
20715	21,145	4	3		
21012	17,599	7	7		
21409	16,564	6	6		
21114	20,513	6	5		
21146	22,437	11	9		
21666	10,236	3	3		
20716	16,986	5	4		
21113	25,917	5	5		
21054	8,700	2	2		
21122	50,919	8	8		
21035	6,654	3	3		
20711	5,382	2	1		
21032	7,646	2	2		
21619	5,062	1	1		
21617	8,367	1	1		
20764	3,113	3	3		
20774	37,677	2	1		
20721	23,312	-	-		
20772	36,608	1	1		
21061	44,824	5	5		
20720	19,155	1	1		
21108	14,310	-	-		
20776	3,580	2	2		
21144	26,465	5	5		
20733	2,616	-	-		
21638	4,137	3	3		
20736	7,412	1	-		
21601	20,342	5	5		
21140	2,826	-	-		
20639	11,946	-	-		
21658	3,228	-	-		
20751	2,046	-	-		
20706	30,493	-	-		
21060	25,267	6	6		
20732	8,157	2	1		
20778	1,816	1	1		
20754	5,799	-	-		
21620	11,229	1	1		
Total	665,819	124	114		
	555,515				

Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

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III. EXCEPTION NO. 3: THE RECOMMENDED DECISION RELIES ON DATA THAT WAS NOT PART OF THE RECORD AT A TIME WHEN THE PARTIES COULD MEANINGFULLY REVIEW, QUESTION, AND CONTEST THE DATA, ASSUMPTIONS, AND ANALYSIS.

This review has been pending before the Commission since AAMC and UM BWMC first filed Letters of Intent on December 8, 2014. (DI #1AA, DI #1BW.) Over the past two years, the applicants and interested parties have compiled an extensive administrative record consisting of argument and evidence in support of their applications and questioning the assumptions of opposing parties. On December 30, 2016, more than two years after the review first began, the Reviewer made a ruling to open the record and enter new evidence into it. (DI #97GF, #98GF.) The Recommended Decision was issued 45 minutes later, and incorporated an analysis that raises genuine issues of fact presented to the parties without meaningful opportunity to respond and comment. This introduction of new facts and analyses at the close of a two year review not only undermines the goals of the review process, it also violates the parties' right to due process.

A. The Recommended Decision relies upon data entered into the record 45 minutes prior to its issuance, and data that is not a part of the record.

The December 30, 2016 letter ruling (DI #98GF) entered into the record (i) information obtained from Nielsen Claritas on the estimated and projected populations of Zip Code areas in this review; and (ii) audited financial statements of the applicant Maryland hospitals. (DI #97GF, #98FG.) This data was used as the basis for the Alternative Model under which the Reviewer analyzed minimum volume. However, the analysis also relied upon the following data, that has not been made a part of the record. At least the following data is missing from the record:

- The source described in the Recommended Decision, p. 28, Table 5 states "Population data obtained from Nielsen. 2017 population interpolated using 2015 and 2020 projections supplied from vendor." The December 30, 2016 filing contained only 2014 and 2015 data.
- While the Recommended Decision states that certain tables in the minimum volume analysis were based only on the "HSCRC Discharge Data Base," that appears incorrect the HSCRC Discharge Data Base supplies discharge information only from Maryland hospitals. It does not supply data concerning Maryland residents discharged from Washington, D.C. hospitals. Because the Reviewer relied on Zip Code level data for hospitals with service areas near D.C., the Reviewer either relied also upon a D.C. discharge database and did not disclose it, or the data is incomplete. The distinction is relevant to UM BWMC because the HSCRC database is more readily accessible than the D.C. discharge database. However, the distinction is immaterial to consideration of the Administrative Procedures Act the Reviewer did not enter data from either into the record.
- The most recent cardiac surgery use rates entered into the record were for CY 2019. Maryland Register, Vol. 42:3 (Feb. 6, 2015). The State Health Plan requires the parties to rely upon the most recent utilization projections. COMAR § 10.24.17.05A(1). Yet, the Reviewer relied upon utilization projections for CY 2020 an analysis the parties have no ability to replicate, even applying the assumptions from the State Health Plan chapter methodology, because CY 2020 projected population data is also not entered into the record.
- Additional data that would allow UM BWMC to replicate the Reviewer's methodology is also missing, but it is not readily apparent what it is because it has not been disclosed. For example, when UM BWMC attempted to recreate the definition of AAMC's 85% MSGA service area, it came up with a total of 41 Zip Codes within the service area. The Recommended Decision refers to only 39. It is not clear why, what data was used to arrive at 39, or which Zip Codes included in UM BWMC's attempt to recreate the analysis were excluded by the Reviewer.

Because the Recommended Decision relies upon newly entered and undisclosed data,

UM BWMC has been unable to fully analyze and recreate the Reviewer's conclusions.

B. The Recommended Decision's reliance upon data newly entered into the record and missing data deprives UM BWMC of an opportunity to meaningfully contest that data.

This contested review is governed by the Administrative Procedure Act ("APA"), Md. Code, State Government, § 10-201 et seq. Parties to a contested review under the APA are entitled to a meaningful opportunity to contest any fact entered into the record. The Act provides, "[f]indings of fact must be based exclusively on the evidence of record in the contested case proceeding and on matters officially noticed in that proceeding." Id., § 10-214(a). "If the agency has any evidence that the agency wishes to use in adjudicating the contested case, the agency shall make the evidence part of the record." Id., § 10-213(b). In order to enter new evidence into the record, the agency "may take official notice of [certain] facts." Id., § 10-214(h)(1). "Before taking official notice of a fact, the presiding officer . . . shall give each party an opportunity to contest the fact." Id., § 10-214(h)(2).

Exceptions to a recommended decision do not constitute a meaningful opportunity to contest a fact. In re Clarksburg Community Hospital (Balt. City Cir. Crt, Feb 21, 2012) No. 24-C-11-001046 (Pierson, J.), attached as Exhibit 3. The Commission encountered this very issue in in the comparative review of the applications of Holy Cross Hospital Silver Spring and Clarksburg Community Hospital, Inc. to develop a new acute care general hospital. In that review, a recommended decision issued that relied upon historical, current, and projected population data and that D.C. Discharge database/Data Set. Id. at 2. The Court held on appeal that an agency must provide an opportunity to contest a fact *before* the agency takes official notice of it, and that exceptions filed in response to a recommended decision did not constitute a meaningful opportunity to contest a fact. Id. at 2. The Court's reasoning was as follows:

The issues presented in this case are of great complexity, and the record, as the Commission notes, is measured in feet rather than inches. The Reviewer's analysis of the data required a 180 page decision. Following the service of the Recommended Decision, petitioners had twenty days to file exceptions, and were allotted twenty minutes at the exceptions hearing to present all of their objections to the Recommended Decision. It is unrealistic to state that petitioners had a meaningful opportunity to contest the use of this information.

Id. at 2.¹⁶ This holding is directly applicable here. The Commission should reject the Recommended Decision and strike the data entered on December 30, 2016 from the record. The Reviewer thereafter should disclose all data that may be officially noticed, and allow the parties a meaningful opportunity to contest it before it is entered into the record and relied upon in a recommended decision.

C. The entry of new data and Alternative Model projections demonstrate a genuine issue if fact requiring an evidentiary hearing.

The use of new data as the basis for an alternative analytical model to address minimum volume demonstrates that there is a genuine issue of fact in this case – whether the parties have demonstrated an ability to reach 200 open heart surgery cases in the second full year of operation. Under the APA, "[o]n a genuine issue in a contested case, each party is entitled to: (1) call witnesses; (2) offer evidence, including rebuttal evidence; (3) cross-examine any witness that another party or the agency calls; and (4) present summation and argument." Md. Code, State Government, § 10-213. Such a hearing would allow the parties to question the sources and assumptions used in forming the Alternative Model, and argue that the underlying data is

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The explicit terms of the statute mandate that before an agency takes official notice of a fact it shall give each party an opportunity to contest that fact. Contrary to respondents' arguments, the court's review of the record convinces it that petitioners were not presented with a meaningful opportunity to contest the data relied upon by the reviewer.

misunderstood by the Commission. COMAR § 10.24.01.11 ("A party to the hearing is entitled, on timely request, to an opportunity to show that the Commission should not take administrative or official notice of specific facts and matters, or that the fact or matter to be officially noticed is inapplicable to the proceeding or is incorrect or misunderstood by the Commission.")

The Recommended Decision demonstrates that there is an evidentiary fact in this review.

The Commission should require the Reviewer to hold an evidentiary hearing.

Impact on Existing Programs, COMAR § 10.24.17.05A(2)

IV. <u>EXCEPTION NO. 4</u>: THE RECOMMENDED DECISION'S DETERMINATION THAT AAMC'S APPLICATION MEETS THE IMPACT STANDARD (COMAR § 10.24.17.05A(2)) AND THE IMPACT REVIEW CRITERION (COMAR § 10.24.01.08G(3)(f)) SHOULD BE REJECTED.

The impact standard under the cardiac surgery chapter of the State Health Plan, COMAR \$ 10.24.17.05A(2) ("Standard .05A(2)"), provides:

- (2) Impact.
 - (a) A hospital that projects that cardiac surgery volume will shift from one or more existing cardiac surgery hospitals as a result of the relocation or establishment of cardiac surgery services shall quantify the shift in open heart surgery and cardiac surgery case volume and the estimated financial impact on the cardiac surgery program of each such hospital.
 - (b) An applicant shall demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:
 - (i) Compromise the financial viability of cardiac surgery services at an affected hospital; or
 - (ii) Result in an existing cardiac surgery program with an annual volume of 200 or more open heart surgery cases and an STS-ACSD composite score for CABG of two stars or

- higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 200 open heart surgery cases; or
- (iii) Result in an existing cardiac surgery program with an annual volume of 100 to 199 open heart surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 100 open heart surgery cases.

In addition, the general review criterion on assessing impact on existing providers and the health care delivery system, COMAR § 10.24.01.08G(3)(f), states:

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

The Recommended Decision concludes, without any valid basis, that AAMC's proposed program complies with both Standard .05A(2) and the general review criterion addressing impact on existing providers.

In fact, only UM BWMC's proposal, which is based primarily on shifting appropriate cardiac surgery volume from its own affiliated hospital – UMMC – complies with Standard .05A(2) and the impact review criterion. (DI #2BW, pp. 43-45.) UM BWMC's proposal to expand the locations of the existing UM Division of Cardiac Surgery is intended to improve the ability of UMMS-affiliated hospitals to provide high-quality cardiac surgery services in the most convenient and cost effective locations. As shown in UM BWMC's impact analysis, a new cardiac surgery location at UM BWMC would have little impact on existing providers other than UMMC. The new program would not reduce any provider's volume below

the thresholds set forth in Standard .05A(2) (100 cases or 200 cases), and it would not have a significant financial impact on any other existing provider. (DI #2BW, pp. 46-47; DI #6BW, p. 11.) Therefore, the Reviewer correctly concludes that UM BWMC complies with Standard .05A(2) as well as the impact review criterion. Recommended Decision, pp. 39, 42.

By contrast, the cardiac surgery volume underlying the AAMC proposal is based on an aggressive plan to divert hundreds of cardiac surgery cases for residents of Anne Arundel County and Prince George's County from MedStar Washington Hospital Center. Aside from the obvious impact on MedStar, which is a high volume program, AAMC's plan also would cause serious damage to the ongoing revitalization of the cardiac surgery program at PGHC. AAMC and the Recommended Decision overlook this harm. Indeed, they even fail to assess the extent of the impact on PGHC.

As explained below, neither AAMC nor the Reviewer demonstrates that AAMC would not negatively affect the existing cardiac surgery program at PGHC to the extent of reducing its current annual volume of just above 100 cardiac surgery cases to below 100 cases per year. In its CON application, AAMC assumed no impact on PGHC's cardiac surgery program as a result of a new program at AAMC. (DI #3AA, p. 92.) Even after PGHC supplemented the record with its substantially increased volume (more than 100 cases in FY 2016), AAMC did not update its analysis to include PGHC as an impacted provider to the extent of even a single shifted cardiac surgery case. The only quantitative analysis on this issue was submitted by PGHC, which

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As discussed in Exception No. 1, the success of AAMC's proposed program to achieve an annual minimum volume of 200 cardiac surgery cases depends largely on its ability to pull hundreds of cases from MedStar Washington Hospital Center, including a substantial number of referrals from a cardiology practice that is owned by MedStar, Cardiology Associates, LLC.

presented data and analysis demonstrating that the likely impact of the proposed AAMC program would be to reduce PGHC's volume below 100 cases per year. (DI #62GF, pp. 8-10; DI #30GF, pp. 15-17.)

A. The Reviewer treated the existing cardiac surgery program at PGHC on an equal basis with the proposed AAMC program, rather than as an existing program to be protected.

By its express language, Standard .05A(2) affirmatively protects existing cardiac surgery programs from being negatively affected by a new program that would cause one or more of following harms to an affected existing program: (1) compromise the financial viability of cardiac surgery services; (2) cause the program's annual volume to drop below 200 cases (for a program with an annual volume that exceeds 200 cases); or (3) cause the program's annual volume to drop below 100 cases (for a program with an annual volume between 100 and 199 cases). The burden for demonstrating that the existing programs will be protected from undue impact is on the applicant.

In applying Standard .05A(2), the Recommended Decision treats the existing program at PGHC on an equal basis with AAMC's proposal, rather than as a program to be protected under the impact standard. The Reviewer's apparent "may the best program win" approach conflicts with Standard .05A(2), which would require the Commission to deny an application for a proposed cardiac surgery program unless the applicant demonstrates that it would not negatively affect an existing program in any of the ways specifically identified in the standard.

The Recommended Decision states that "the establishment of a cardiac surgery program at AAMC and/or BWMC would not be likely to cause PGHC's annual volume to drop below 100 cases." Recommended Decision, p. 41. There is no valid basis for this finding. Other

statements in the Recommended Decision reflect the Reviewer's actual approach of balancing the perceived benefits of a new cardiac surgery program at AAMC with the continued viability of the existing (and growing) program at PGHC. For example, the Reviewer states: "[u]ltimately, the public policy issue presented is one of weighing the benefits of having a viable program at PGHC [sic] and additional programs in Maryland, in terms of access, cost reduction, and quality of care, against the negative impact on these existing programs." Recommended Decision, p. 42. Moreover, in summarizing the Recommended Decision, the Reviewer again repeats that there likely would be sufficient volume for both PGHC and AAMC to achieve 200 cases, but states:

Obviously, neither program is guaranteed to succeed and it is not the objective of this review to provide such guarantees. I do not believe that Maryland stakeholders should forego the positive gains offered in the AAMC project to shelter existing competition from healthy competition.

Recommended Decision, p. 118.

These misguided statements conflict with the requirements of the State Health Plan. Applying the impact standard does not involve weighing public policy considerations. If the Commission wishes to weigh the perceived public policy benefits of a new program in assessing impact under Standard .05A(2), it must engage in rulemaking to change the standard. It may not change the standard while applying it in the context of a contested case. Contrary to the Reviewer's stated analysis, the Commission has an obligation to protect existing cardiac surgery programs from new competition, *i.e.*, a newly approved program, if the effect of approving the new program would drop the volumes of the existing program below the thresholds set forth in Standard .05A(2). The perceived merit of the proposed new program cannot be considered. The

impact standard is especially important where, as here, an existing program is engaged in an effective but fragile rebuilding period.

Ironically, the Reviewer expresses concern about protecting the proposed cardiac surgery program at AAMC from competition in the form of a potential second program at UM BWMC. In the Reviewer's transmittal memorandum dated December 30, 2016, he states:

The approval of two new cardiac surgery programs at the same time could risk the creation of two low-volume, underperforming programs that could require ongoing corrective actions by the Commission, possibly leading to closure of one or both programs. I concluded that the most prudent approach is to recommend approval of only the stronger application, that of Anne Arundel Medical Center.

Reviewer's December 30, 2016 Memorandum, pp. 2-3. However, the Recommended Decision shows no such regard for saving PGHC's cardiac surgery program from the fate described as possible if two new programs were approved.

B. The protection of PGHC is essential to the delivery of health care services in Prince George's County; PGHC has established that its most recent cardiac surgery volume exceeds 100 cases per year and its STS-ACSD score is three stars.

Although the most damaging impact of the proposed AAMC program would be on the rebuilding of the cardiac surgery program at nearby PGHC, AAMC all but ignores PGHC in its evaluation of impact, incorrectly claiming that there has been insufficient case volume at PGHC to merit protection under the impact standard. (DI #3AA, pp. 87-98.)

The Commission recently approved the replacement and relocation of PGHC, to be named Prince George's Regional Medical Center ("PGRMC") (Docket No. 13-16-2351). As Commissioner Moffit described in the Decision approving that important project, PGHC has had substantial success in rebuilding a "failed" cardiac surgery program under the medical leadership

of UMMS. PGRMC Decision, p. 79. Prince George's County is the second most populous county in the State, and it is the most racially diverse. PGRMC Decision, pp. 8-9. Its residents suffer from higher rates of chronic diseases – including diabetes, heart disease, hypertension, asthma, and cancer – than those residing in neighboring jurisdictions. (DI #30GF, Exhibit 2, p 4, "Transforming Health in Prince George's County, Maryland: A Public Health Impact Study"). Today, most residents seek inpatient care outside of Prince George's County, and they have few local opportunities for primary health care services relative to the residents of neighboring jurisdictions. The replacement of PGHC in a new location as an affiliate of UMMS is critically important to the efforts to transform an under-performing health care delivery system in Prince George's County.

In its submissions, PGHC established that the revival of its cardiac surgery program is progressing impressively, and at this point it has achieved a volume of between 100 and 199 cardiac surgery cases per year. Specifically, in its June 24, 2016 Motion to Supplement its Comments, PGHC submitted information and data showing that it had achieved at least 107 cases in FY 2016. (DI #62GF, pp. 8-10.) In addition, PGHC updated its quality ratings from the Society of Thoracic Surgeons as well as its quality outcomes, showing that the cardiac surgery program at PGHC ranks among the top 9% of programs nationally in terms of quality. Id., pp. 5-7. PGHC earned a 3-Star composite quality rating for isolated CABG. For the period of July 2014, when the cardiac surgery program began its revival under the leadership of Dr. Jamie Brown, through May 2016, the cardiac surgery program at PGHC out-performed predicted quality outcomes on a number of measures, including mortality (0), stroke, infection (0), reoperation, prolonged ventilation, and new renal failure (0). Id., pp. 6-7.

Over AAMC's opposition, the Reviewer accepted PGHC's updated volume and quality information. (DI #92GF.) The Reviewer agreed with PGHC's position that the impact standard requires the Commission to consider the impact of a proposed cardiac surgery program on an existing program based on the existing program's volume and quality performance during the most recent rating cycles "prior to Commission action on an application." Id.; Recommended Decision, p. 41. Thus, the Reviewer correctly determined that although the reported data on PGHC's cardiac surgery program showed that it was weak at the beginning of the CON review, the updated reports demonstrated that it was entitled to be assessed and protected in the impact analysis. 18

Despite the Reviewer's acknowledgment that PGHC is entitled to protection as a high-quality program with at least 100 annual cardiac surgery cases, and despite PGHC's specific request that the Reviewer require AAMC to present an impact analysis showing how its proposed cardiac surgery program would impact PGHC's existing program (which analysis is required by the impact standard), the Reviewer declined to require AAMC to demonstrate its likely impact on the reviving PGHC program. The Reviewer instead closed the record on the impact issue. (DI #92GF.)

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In fact, the cardiac surgery program at PGHC was already experiencing significant increases in volume by the time AAMC and UM BWMC filed their CON applications in February 2015, but the data reporting lagged behind the progress.

C. If the same assumptions used in the Recommended Decision's minimum volume analysis were applied in an analysis of the impact of AAMC'S program on PGHC, it would demonstrate AAMC's program would cause PGHC to be unable to achieve a cardiac surgery volume of at least 200 cases annually.

While neither the Recommended Decision nor AAMC's submissions contain a quantitative impact analysis showing the likely impact on PGHC of a new cardiac surgery program at AAMC, in connection with the assessment of the applicants' compliance with the minimum volume standard, the Recommended Decision uses the Alternative Model, a new method of measuring a new program's ability to generate cardiac surgery volume. For the reasons set forth in Exception No. 1, the Alternative Model is a fundamentally flawed approach for measuring likely volume for a cardiac surgery program. However, if the Alternative Model is used to assess the impact of AAMC's proposed program on the existing program at PGHC, the result is that PGHC would not achieve and sustain at least 200 open heart surgery cases. For this reason, the Recommended Decision's unsubstantiated statement that a new program at AAMC would not have a substantial negative impact on PGHC's program is not borne out by the Alternative Model. UM BWMC directs the Commission to the Exceptions filed by PGHC for full illustration and analysis of the application of the Alternative Model to an assessment of impact on PGHC.

Under the State Health Plan, to continue its cardiac surgery program, PGHC will be required to obtain a Certificate of Ongoing Performance within three years after the relocation of the program to the newly approved Prince George's Regional Medical Center. COMAR § 10.24.17.07A(1)(b). Among other Performance Requirements, a cardiac surgery program is required to maintain an annual volume of 200 or more cases, and a program that fails to reach

100 cases per year is subject to a focused review and possible closure. COMAR § 10.24.17.07B(6). AAMC's proposed new program would place PGHC's existing program in jeopardy of possible regulatory non-compliance and closure, thereby threatening local access to cardiac surgery services for Prince George's County residents who have faced many decades of health care disparities.

The Commission should reject the Recommended Decision's conclusion that AAMC complies with Standard .05A(2) and the general review criterion for impact on existing providers. At a minimum, the Commission should require AAMC to meet its burden of proof by presenting an impact analysis that demonstrates the likely impact on PGHC of a new cardiac surgery program at AAMC using the updated PGHC volume data that the Reviewer accepted into the record.

V. <u>EXCEPTION NO. 5</u>: THE REVIEWER'S DECISION NOT TO REQUIRE AAMC TO UPDATE ITS IMPACT ANALYSIS TO ACCOUNT FOR THE SUBSTANTIALLY INCREASED CARDIAC SURGERY CASE VOLUME AT PGHC WAS ERRONEOUS.

As discussed above, Standard .05A(2) required AAMC that PGHC would not be negatively affected to a degree that will reduce its cardiac surgery volume below 100 cases per year. Also, pursuant to the standard, AAMC was obligated to quantify the shift in open heart surgery and cardiac surgery case volume from PGHC and estimate the financial impact on PGHC's cardiac surgery program.

AAMC failed to comply with any of these requirements. Through its June 24, 2016 Motion to Supplement Comments, PGHC sought relief from the Reviewer by specifically requesting that AAMC be required to present an impact analysis that quantifies the projected

shift in volume from PGHC to AAMC and estimates the financial impact on PGHC. (DI #62GF, pp. 7-10.) By letter ruling dated October 31, 2016, the Reviewer accepted PGHC's supplemental data and comments into the record, but the Reviewer declined to direct AAMC to submit an impact analysis as to PGHC. (DI #92GF, p. 2.) In fact, the Reviewer closed the record at that time and stated "I do not desire any additional filings from the parties on this issue." Id.

The Reviewer's ruling was erroneous. In the event the Commission remands this matter to the Reviewer, UM BWMC requests that the Commission require AAMC to submit an impact analysis regarding its impact on PGHC.

Financial Feasibility, COMAR § 10.24.17.05A(7)

VI. <u>EXCEPTION NO. 6</u>: THE RECOMMENDED DECISION'S DETERMINATION THAT AAMC'S APPLICATION MEETS THE FINANCIAL FEASIBILITY STANDARD FOR CARDIAC SURGERY SERVICES (COMAR § 10.24.17.05A(7)) SHOULD BE REJECTED.

The Recommended Decision erroneously determines that AAMC's proposal complies with the financial feasibility standard, COMAR § 10.24.17.05A(7) ("Standard .05A(7)").

Standard .05A(7) provides, in part:

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

. . .

(b) An applicant shall document that:

. . .

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

. . .

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

<u>Id.</u> AAMC's application and modification fail to meet this standard because AAMC has not demonstrated that its proposed cardiac surgery program "will generate excess revenues over total expenses <u>for cardiac surgery</u>." <u>Id.</u> (emphasis added). There is no valid basis for determining that AAMC's proposed cardiac surgery program, part of a stand-alone hospital, would be financially feasible under Standard .05A(7), yet the Recommended Decision manufactures grounds for finding AAMC in compliance.

UM BWMC complies with Standard .05A(7) because it demonstrated that the UM Division of Cardiac Surgery – with the proposed expansion of cardiac surgery services at UM BWMC – would be financially feasible because program revenue would exceed expenses and also that the expansion of the program at UM BWMC would not jeopardize the financial viability of the hospital. (DI #17BW, pp. 7-9.)

A. AAMC submitted multiple revenue and expense projections and none of its submissions demonstrated that its proposed cardiac surgery program would generate excess revenues over total expenses.

Struggling to establish financial feasibility of its proposed program throughout this review, AAMC relied first on unsupportable assumptions, then on unexplained assumptions, and, finally, on an inaccurate and contradictory reading of the financial feasibility standard. The only revenue and expense projections AAMC has submitted without faulty revenue reimbursement assumptions demonstrate that its proposed cardiac surgery program would have negative net

revenue for three years, and thus would not be financial feasible within the meaning of Standard .05A(7).

AAMC's Original Revenue and Expense Projections

In its CON Application, filed on February 20, 2015, AAMC based its revenue projections on the false assumption that its Global Budget Revenue ("GBR") would "be adjusted for incremental volume related to the project (incremental cardiac surgery revenue less transfer cases) at an 85% variable cost factor for the first three years of the project." (DI #3AA, p. 82; see also AAMC's original revenue and expense projection tables, DI #3AA, Exhibit 4.) As the Recommended Decision notes, this was incorrect because the HSCRC policy for market shift adjustments to revenue uses a 50% revenue variability factor for incremental volumes.

Recommended Decision, pp. 91-94. AAMC even acknowledged this fact in its original CON application, 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." (DI #3AA, p. 219.) Yet, AAMC still insisted that the HSCRC would allow AAMC to apply a variable cost factor of 85% for its market shifts.

When all of AAMC's assumptions in its original application were held constant with the exception of revenue variability, and a 50% variable cost factor was applied, the AAMC cardiac surgery program was financially unfeasible, suffering operating losses in each year. (DI #29GF, p. 28, Table 10 (UM BWMC Comments on AAMC Application).)

In its August 25, 2015 response to comments, AAMC again wrongly reasserted that it could "reasonably expect to retain 85% of the revenue generated by the AAMC's proposed program," citing the HSCRC's "flexibility to provide targeted funding through the annual update process for individual hospital budgets" and an April 8, 2014¹⁹ letter from the HSCRC to AAMC in which the HSCRC made a nonspecific commitment to consider adjustments to AAMC's GBR agreement, subject to a rate application and approval. (DI #45GF, p. 20, Ex. 30.)

The HSCRC subsequently confirmed what UM BWMC knew and repeated from the beginning of the review: that AAMC's projections for market shifts from Maryland hospitals and out-of-state providers were based on a false assumption. Its August 24, 2016 letter response to the Reviewer states:

AAMC assumed that it would be able to retain 85% of the additional revenue associated with the cardiac surgery program. Under the current HSCRC policy for market shift changes of Maryland residents, hospitals with increased volumes that are taken from other Maryland hospitals are allowed to retain 50% of the revenue associated with the additional volume while hospitals that lose volume to other Maryland hospitals are allowed to retain 50% of the revenue associated with the lost volume.

* * * * *

AAMC has projected that Maryland residents will comprise the 67% of its cardiac surgery cases that will come from D.C. and other out-of-state providers. Under the Hospital's GBR agreement, AAMC would be able to retain 50% of the cardiac surgery revenue associated with these Maryland residents.

(DI #68GF (HSCRC Letter to Commissioner Tanio, August 24, 2016 ("the HSCRC's Letter"), attached to Recommended Decision as Appendix 3, p. 1.))

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The letter is dated April 8, 2012 on page 1, and April 8, 2014 on page 4. (DI #45GF, p. 20, Ex. 30.) Based on its reference to GBR and the All-payer model, 2014 appears to be the correct date.

AAMC's October 17, 2016 Revenue and Expense Projections

Following the HSCRC's letter, the Reviewer requested "that AAMC provide revised versions of all the financial schedules previously submitted that fully conform with standard HSCRC policy with respect to retention of revenue generated from projected shifts in cardiac surgery case volume from hospitals with existing cardiac surgery programs to AAMC."

(DI #69GF.)

On October 17, 2016, AAMC submitted revised revenue and expense projections that showed revenue resulting from its cardiac surgery service line, adjusted by a 50% variable cost factor, and additional revenue that AAMC claimed would be reallocated from elsewhere in the system. ²⁰ (DI #94GF, Exhibit 4.) AAMC falsely claimed that these projections made no substantive change to its prior projections, and instead only added an additional revenue line to show that a portion of revenue was attributable to "reallocated revenue" from other resources provided in the system. <u>Id.</u> p. 4. This claim was directly contradicted by AAMC's prior filings, in which AAMC admitted that its projections assumed that its GBR would be adjusted for incremental volume at an 85% variable cost factor. ²¹ (AAMC Appl., pp. 62, 160-164.)

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AAMC's filing was stricken from this review, but is attached as Exhibit 4 to UM BWMC's Comments on AAMC's Modified CON Application. (DI #94GF, Exhibit 4.) AAMC's history of making shifting, misleading, and incorrect projections is relevant to the Commission's consideration of this matter.

Furthermore, a comparison of AAMC's October 17, 2016 projections to the projections in its initial CON application confirms that AAMC misrepresented the changes made. If AAMC's October 17 projections departed from the original application projections only by distinguishing revenue sources for its cardiac surgery service that were previously combined into a single line, then AAMC's inpatient services revenue for the entire facility should have remained constant. Instead, when AAMC adjusted its revenue to be consistent with HSCRC policy, the overall inpatient services revenue declined. AAMC's total inpatient services revenue

AAMC's Modification – November 7, 2016 Revenue and Expense Projections

The Reviewer struck AAMC's October 17, 2016 projections from the record on October 21, 2016. On October 27, 2016, the Reviewer held a Project Status Conference and requested that AAMC make a modification. The request is summarized in the Reviewer's October 28, 2016 Letter as follows:

At the project status conference, I requested that AAMC modify its application to provide revised versions of all financial schedules regarding revenues, expenses, and income for: (1) its general hospital operation; and (2) specifically, for its proposed cardiac surgery service. These revenue projections need to reflect HSCRC's current policy (stated in its August 24, 2016 memorandum to me) to assume a 50% variable cost factor. The revised financial schedules must be accompanied by a detailed statement of the assumptions used in development of the modified financial schedules. This statement of assumptions must address and detail the way in which AAMC accounts for all of the revenue and expense changes it projects to result from its provision of cardiac surgery services, across all of the hospital's departments. Anne Arundel Medical Center should also file a statement that details how and why these schedules have changed in comparison to the revenue and projections filed by AAMC prior to docketing of its application.

DI 90GF, p. 3. In response, AAMC revised its revenue projections in connection with its CON application modification filed on November 7, 2016. (DI #22AA.) AAMC filed two versions of

decreased by \$4.4 million in FY 2018 and \$5.0 million in FY 2019 (comparing Table G, line 1.a., included with AAMC's original application, attached as, and the same information included with the October 17, 2016 submission). While AAMC's cardiac surgery service revenue remained consistent with its prior projections, this was a result of AAMC admittedly reallocating revenue from elsewhere in its system to cardiac surgery. A side-by-side comparison of AAMC's revenue assumptions and projections in its original application and its October 17, 2016 submission further confirms that the original application calculated revenue based on an 85% variable cost factor, while the October 17, 2016 projections calculated revenue based on a 50% variable cost factor, as demonstrated in Table 1.

#579797 011598-0019 Table J, the revenue and expenses (uninflated) for the cardiac surgery service – Table J-1 and Table J-2. <u>Id</u>.

AAMC's Table J-1 portrayed revenue as equal to billable charges, and thus failed to comply with the Reviewer's direction to assume a 50% variable cost factor, and failed to comply with the requirement of the financial feasibility standard that "revenue estimates for cardiac surgery [be] consistent with utilization projections and account for current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, for cardiac surgery, as experienced by similar hospitals." COMAR § 10.24.17.04(A)(7)(ii).²²

AAMC's Table J-2 complied with the Reviewer's direction and COMAR § 10.24.17.04(A)(7)(ii). However, it demonstrated that AAMC's proposed cardiac surgery service line will not generate excess revenues over total expenses for cardiac surgery within three years, instead operating at losses of \$3.7, \$3.3, and \$3.0 million in FY 2017, FY 2018, and FY 2019 respectively. Thus, AAMC's modification rendered the project not approvable because it fails to meet the financial feasibility standard for cardiac surgery services.

B. The Recommended Decision misconstrues the meaning of the financial feasibility standard by requiring AAMC to demonstrate only the viability of the hospital and not the financial feasibility of the proposed cardiac surgery program.

Rather than finding AAMC's proposal to be non-compliant with Standard .05A(7), thereby making AAMC's CON application not approvable, the Recommended Decision

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AAMC's projection of revenue as billable charges is inconsistent with the financial feasibility standard. UM BWMC correctly projects revenue after applying a 50% variable cost factor. However, because the applicants are in a comparative review, if the Reviewer finds that AAMC may demonstrate revenue as projected in Table J-1, the Reviewer should similarly compare AAMC's projections to UM BWMC's program on a billable charge basis.

misconstrues the standard to fit AAMC's financial circumstances. The Commission should reject this approach. If the Commission wishes to apply a different standard, it must engage in rulemaking to change the standard. It may not change the standard in the context of a contested case.

As noted above, Standard .05A(7) requires that "[a] proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital." This general statement at the beginning of Standard .05A(7) is defined more specifically in the subparagraphs that follow. Of particular importance here, subparagraph (b)(iv) requires that "[w]ithin three years or less of initiating a new or relocated cardiac surgery program, it will generate excess revenue over total expenses for cardiac surgery." COMAR § 10.24.17.05A(7)(b)(iv) (emphasis added). Subparagraph (b)(iv) unequivocally requires a proposed cardiac surgery program, on its own, to generate excess revenue over expenses. But in considering whether AAMC's proposed cardiac surgery program satisfies Standard .05A(7), the Reviewer ignores the express language of subparagraph (b)(iv) and interpreted the financial feasibility standard as permitting an assessment at the overall hospital level. The Commission should reject the Reviewer's interpretation of the financial feasibility standard as permitting an assessment at the overall hospital level only because such an interpretation is wrong and will not withstand judicial scrutiny.²³

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[T]he State Health Plan criteria cannot be waived or ignored during this comparative review. The State Health Plan is a *bona fide* Maryland

Also, AAMC has previously argued that the express language of the SHP financial feasibility standard may not be ignored. In its August 25, 2015 comments on UM BWMC's modification, AAMC stated, in part:

The interpretation of a regulation is governed by the same principles that govern the interpretation of a statute. Maryland Comm'n on Human Relations v. Bethlehem Steel Corp., 295 Md. 586, 592–93 (1983) (collecting cases). The starting point of statutory interpretation "is the plain language of the statute, and ordinary, popular understanding of the English language dictates interpretation of its terminology." Kushell v. Dept. of Natural Res., 385 Md. 563, 576 (2005). In construing a statute's plain language, "[a] court may neither add nor delete language so as to reflect an intent not evidenced in the plain and unambiguous language of the statute; nor may it construe the statute with forced or subtle interpretations that limit or extend its application." Price v. State, 378 Md. 378, 387 (2003). It is well-established that "[i]f statutory language is unambiguous when construed according to its ordinary and everyday meaning, then [courts] give effect to the statute as written." <u>Kushell</u>, 385 Md. at 577; see also The Arundel Corp. v. Marie, 383 Md. 489, 502 (2004) (explaining that if there is no ambiguity in the statutory language, "the inquiry as to legislative intent ends; we do not then need to resort to the various, and sometimes inconsistent, external rules of construction, for the Legislature is presumed to have meant what it said and said what it meant") (internal quotation marks omitted).

regulation with the force of law. And the revision to the State Health Plan implied by BWMC would work a revolution in the CON process: merged asset systems could leverage a profitable service in one part of the system to subsidize the creation of uneconomic facilities or services in another part of the system.

(DI #46GF p. 3.) UM BWMC's CON application projects revenue for its cardiac surgery service line across the UM Division of Cardiac Surgery, of which BWMC would become a member, adding a third location to the program. That Division "will generate excess revenues over total expenses for cardiac surgery." COMAR § 10.24.17.05A(7).

Here, citing the "overarching statement of the standard set forth in .05A(7)," the Reviewer found that "the Commission's regulatory intent was to permit flexibility in its assessment of financial feasibility at the hospital level, i.e., it permits the Commission to authorize introduction of a new cardiac surgery program (or relocation of an existing program) that meets all other standards and criteria *if the financial viability of the hospital is not jeopardized by the introduction of the cardiac surgery program.*" Recommended Decision, p. 95 (emphasis added). The "overarching statement" on which the Reviewer relied provides that "[a] proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital." COMAR § 10.24.17.05A(7). The Reviewer's interpretation of the financial feasibility standard is inconsistent with the regulation, and the Commission should reject the Reviewer's proposed finding.

As a threshold matter, the Recommended Decision ignores the express language of subparagraph (b)(iv). The erroneous interpretation thus results in the implicit deletion of subparagraph (b)(iv) in its entirety, giving it no effect whatsoever. This approach is inconsistent with the proper method of statutory and regulatory construction. See Price, 378 Md. at 387 ("A court may neither add nor delete language so as to reflect an intent not evidenced in the plain and unambiguous language of the statute."). Indeed, if the Commission were to adopt the Reviewer's proposed construction of the financial feasibility regulation, it would improperly render the entirely of subparagraph (b)(iv) superfluous. See Duncan v. Walker, 533 U.S. 167, 174 (2001) ("It is our duty to give effect, where possible, to every clause and word of a statute.").

It is not enough to simply cite the general "overarching statement" set forth in Standard .05A(7) without regard to the more specific and conflicting language in subparagraph

(b)(iv) that follows. "When interpreting any statute, we must look to the entire statutory scheme, and not any one provision in isolation, to effect the statute's general policies and purposes."

Bd. of Cnty. Comm'rs of Garrett Cnty. v. Bell Atlantic-Maryland, Inc., 346 Md. 160, 178

(1997). Moreover, "[i]t is a well-settled rule of statutory interpretation that when two statutes, one general and one specific, are found to conflict the specific statute will be regarded as an exception to the general statute." J.P. DelpheyLtd. P'Ship v. Mayor and City of Federick, 396 Md. 180, 198-99 (2006). Therefore, even if the Reviewer's findings were supported by the general statement in Standard .05A(7), the more specific language in subparagraph (b)(iv) must control. As explained above, specific language in subparagraph (b)(iv) precludes the Reviewer's interpretation.

Even when separately considering only the overarching statement in Standard .05A(7), the Reviewer's findings should be rejected. The overarching statement contains two separate elements, and is as follows: "[a] proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital." COMAR § 10.24.17.05A(7) (emphasis added). The Reviewer's analysis considers only the second element of this regulation. Standard .05A(7) is written in the conjunctive, providing two distinct elements that are separated by the word "and." "It is ordinarily presumed that the word 'and' should be interpreted according to its plain and ordinary meaning and that it is not interchangeable with the word 'or.'" Comptroller of Treasury v. Fairchild Industries, Inc., 303 Md. 280, 285-86 (1985). The conjunctive term "and" can only be replaced with the disjunctive term "or" "where it is necessary to effectuate the obvious intention of the legislature." Id. at 286. But here, there is nothing that suggests the Commission intended for

this section to be interpreted other than in the conjunctive. There would have been no need for the Commission to provide several subparagraphs that set forth, in detail, the financial feasibility standards for a proposed cardiac surgery program if the controlling standard related only to the hospital's overall viability. And as explained below, if the Commission intended for the standard to be based solely on the financial viability of the hospital, it could have so stated.

The Reviewer does not—because he cannot—claim that the language of Standard .05A(7) is ambiguous, and it is undisputed that subparagraph (b)(iv) requires a proposed cardiac surgery program to generate excess revenue over expenses on a stand-alone basis. The Recommended Decision acknowledges as much, noting that "[a]ssessment at the program level, as in subparagraph's (b)(iv)'s reference to generation of excess revenues over expenses <u>for cardiac surgery</u>, is a reasonable and conventional interpretation of the standard's requirements." Recommended Decision, p. 93 (emphasis added). This should have been the end of the analysis. <u>See Crofton Convalescent Ctr., Inc.</u>, 413 Md. at 215 ("[W]hen a statute's plain language is unambiguous, we need only to apply the statute as written, and our efforts to ascertain the legislature's intent end there.").

Nevertheless, the Recommended Decision departs from the unambiguous regulatory language and improperly inquired into the Commission's regulatory intent. The Reviewer explains:

When the Commission adopted this standard as proposed permanent regulation on July 27, 2014, it could not have foreseen that later HSCRC policy would make it extremely difficult (and virtually impossible) for a new cardiac surgery program to generate excess revenues over total expenses when isolating just on the revenues and expenses directly attributable to the cardiac surgery services.

. . .

If it has been possible to know this about the new HSCRC payment model in the 2013 to 2014 period during which the Cardiac Surgery Chapter was developed, the Commission would not have adopted a standard that required

Recommended Decision, p. 94. As explained above, there is no room for this sort of inquiry in the context of an unambiguous regulation.

Perhaps more importantly, if the Commission shared the Reviewer's view, it could have amended the financial feasibility standards set forth in Standard .05A(7) after it became apparent that the new HSCRC payment policy "would make it extremely difficult (and virtually impossible) for a new cardiac surgery program to generate excess revenues over total expenses" on a stand-alone basis. See Recommended Decision, p. 94. Indeed, the current version of the State Health Plan's cardiac surgery chapter was adopted on October 15, 2015 and became effective on November 9, 2015 after the HSCRC finalized its market shift policy.

Recommended Decision, p. 94.²⁴ If the Commission deemed it necessary to modify the financial

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The Reviewer states: "[b]y July 1, 2015, the manner in which market shifts were recognized in updating hospital budgets can be viewed as established by HSCRC, given that policy was used in the update of hospital GBRs at that time."

Also, the Commission adopted the version of the cardiac surgery chapter applicable in this review with knowledge of the new GBR system, effective August 18, 2014. The Issues and Policies of the chapter provide, in part:

In October 2013, the Maryland Department of Health and Mental Hygiene submitted an application for modernization of Maryland's all-payer model to the Centers for Medicare and Medicaid Services. CMS accepted the application for a new waiver model, and in January 2014, HSCRC began moving the hospital rate setting system away from a focus on the per case costs of inpatient discharges to a focus on per capita Medicare hospital costs. Ultimately, HSCRC will develop a payment model based on controlling the overall health care expenditures of Marylanders. Under the new payment model, growth in inpatient and outpatient expenditures will

feasibility standards for proposed cardiac surgery programs in light of the new HSCRC payment model, it would have done so during the recent revisions to the cardiac surgery chapter. Other State Health Plan chapters expressly define financial feasibility in the manner the Reviewer applies here. For example, an applicant to establish acute inpatient rehabilitation services must meet the following financial feasibility standard:

The hospital will generate excess revenues over total expense (including debt service expenses and plant and equipment depreciation), if the applicant's utilization forecast is achieved for the specific services affected by the project within five years or less of initiating operations with the exception that a hospital proposing an acute inpatient rehabilitation unit that does not generate excess revenues over total expenses, even if utilization forecasts are achieved for the services affected by the project, may demonstrate that the hospital's overall financial performance will be positive.

COMAR § 10.24.09.04(B)(iv)(6). This standard expressly states that if the applicant does not generate excess revenue over total expense for the specific service, the applicant may instead demonstrate that its overall performance of the hospital will be positive. This can be contrasted with other State Health Plan chapters that include a financial feasibility standard that expressly allow a broader approach to feasibility. See COMAR § 10.24.09.04.(b)(13) (Acute Care Hospital Services); COMAR § 10.24.11.05(B)(8)(General Surgical Services); COMAR

be limited by growth in the State's long-term gross state product. All hospitals falling within the scope of HSCRC rate regulation will have a population based budget agreement, a total patient revenue agreement, or a modified charge per episode agreement with HSCRC under the new rate regulation model by the end of FY 2015.

COMAR § 10.24.17, p. 8. This same chapter includes Standard .05A(7) that AAMC and the Reviewer now suggest cannot be met under the GBR system. Thus, the Commission recognized the change to hospital revenue calculations and still adopted Standard .05A(7).

§ 10.24.12.04(14) (Acute Hospital Inpatient Obstetric Services). Had the Commission intended such an exception to be included in the Cardiac Surgery SHP, it would have included similar language. But because no such language was included, the Commission "is presumed to have meant what it said and said what it meant." The Arundel Corp., 383 Md. at 502.

Although characterized as an "interpretation" of the Commission's financial feasibility regulation, the Reviewer has done nothing short of a complete redrafting of that standard. If the Commission adopts the Reviewer's recommended decision, it will change the plain language of the financial feasibility standards for proposed cardiac surgery programs. The Commission will have, in essence, conducted rulemaking without undergoing the proper procedures under the Administrate Procedure Act or the Commission's enabling act. Section 19-118 of the Health General Article requires the Commission, "at least every 5 years," to adopt a State health plan that shall include "[t]he methodologies, standards, and criteria for certificate of need review." MD. CODE ANN., HEALTH-GEN § 19-118(a). The Commission is also charged with "develop[ing] standards and policies consistent with the State health plan that relate to the certificate of need program." <u>Id.</u> § 19-118(d)(1). "The Commission shall adopt rules and regulations that ensure broad public input, public hearings, and consideration of local health plans in development of the State health plan." Id. § 19-118(c). By changing the applicable financial feasibility standards for proposed cardiac surgery programs in the context of this CON review, the Commission will have circumvented the requirement that it set forth the "methodologies, standards, and criteria for certificate of need review" as part of the State Health Plan and it will have failed to obtain public input and provide for public hearings. Moreover, it will have engaged in rulemaking while

deciding a contested case in a quasi-judicial role, in effect changing the rules while applying them to the parties in a case.

UM BWMC's CON application projects revenue for its cardiac surgery service line across the UM Division of Cardiac Surgery, of which UM BWMC would become a third location to the program. That Division "will generate excess revenues over total expenses for cardiac surgery." COMAR § 10.24.17.05A(7). AAMC, however, proposes that any program in its hospital can subsidize the creation of a cardiac surgery program that will generate loss of a minimum of \$3 million in each year projected. This directly contradicts the reference to revenue and expenses for cardiac surgery in Standard .05A(7).

C. Standard .05A(7) requires an applicant to demonstrate feasibility based on retained revenue, not billable charges.

AAMC suggested for the first time in its November 7, 2016 modification that it may satisfy the Standard .05A(7) by projecting revenue for cardiac surgery as billable charges, rather than actual retained revenue. While not relying upon this approach as the primary method for finding financial feasibility, the Recommended Decision seems to give AAMC's novel theory some credence, stating:

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

Recommended Decision, p. 95.

This approach to financial feasibility should be rejected. Following this logic, the HSCRC would apportion an amount of revenue from AAMC's GBR consistent with each

applicant's charge per case and market shift, and would then apply a reduction across the GBR rates equal to 50% of the cardiac surgery revenue. However, Standard .05A(7) measures not what the hospital's financials would look like after the 50% variable cost factor is applied across the hospital's financials, but rather the actual and real financial impact of the proposed new program on the hospital. Indeed, Standard .05A(7) directs applicants to project revenue consistent with adjustments, including current charge levels and rates of reimbursement.

COMAR § 10.24.17.05A(2)(b)(ii). Thus, the Recommended Decision's suggestion that financial feasibility might be established based on revenue projections that are not adjusted to reflect the amount of revenue that may be retained conflicts with Standard .05A(2).²⁵

At bottom, it is inaccurate and a violation of the State Health Plan for the Recommended Decision to rely on financial projections that ignore the 50% reduction in cardiac surgery revenue imposed by the HSCRC's market shift policy or pretend that the 50% reduction is somehow not tied to the cardiac surgery program. This approach is also contradicted by AAMC's prior filings. AAMC's February 20, 2015 and October 17, 2016 projections of revenue for its proposed cardiac surgery service line both calculated revenue to include the real impact of

(DI #69GF, p. 4. (emphasis added).)

#579797 011598-0019

Moreover, in his October 5, 2016 letter to the applicants, the Reviewer correctly instructed AAMC to project revenue consistent with the HSCRC's GBR adjustment policies, not based on a "conventional accounting perspective." He stated:

Given HSCRC staff's comment regarding this issue, I request that AAMC provide revised versions of all the financial schedules previously submitted that fully conform with standard HSCRC policy with respect to retention of revenue generated from projected shifts in cardiac surgery case volume from hospitals with existing cardiac surgery programs to AAMC.

the variable cost factor. (DI #3AA, pp. 62, 160-164; DI #94GF, Exhibit 4.) AAMC's approach also contradicts its approach to cost effectiveness in the same modification. In analyzing the impact and cost savings of its program, AAMC portrays the revenue saved based on a 50% variable cost factor applied to cardiac surgery revenue. (DI #22AA, Exhibit 39.) AAMC should not be permitted to show that the cardiac surgery program will be feasible because it will generate revenue based on charges, while at the same time it suggests that the program will generate only half as much revenue when analyzing cost effectiveness.

UM BWMC is not aware of any pending or recent CON applications for rate-regulated services that calculate revenue based on billable charges rather than actual revenue retained under GBR. If accepted, the so-called "conventional accounting" approach would render meaningless any State Health Plan financial feasibility standard that differentiates between the feasibility of the program and the feasibility of the hospital – the financial viability of the hospital would always render the subject program feasible (unless billable charges were implausibly and unrealistically low). Indeed, in the Commission's consideration of recent hospital CON reviews, following the State's implementation of the Global Budget Revenue ("GBR") model of hospital payment, the Commission and the HSCRC have evaluated financial feasibility based on the applicant hospital's GBR, *i.e.*, the revenue it will actually retain, not the total of billed charges. In the Matter of Adventist Healthcare, Inc. d/b/a Washington Adventist Hospital, Docket No. 13-15-2349, Decision (December 17, 2015), pp. 54-71; In the Matter of Dimensions Health Corporation d/b/a Prince George's Hospital Center and Mt. Washington Pediatric Hospital, Inc. Docket No. 13-16-2351, Decision (October 20, 2016), pp. 43-54.

AAMC's inability to meet Standard .05A(7) if the variable cost factor is applied to its cardiac surgery revenue does not mean the standard should be reinterpreted as the Reviewer and AAMC attempt to do. It also does not mean that only an applicant with an existing program with which to share revenue, such as UM BWMC, can meet the standard. AAMC correctly notes that the HSCRC has the ability to grant rate increases in GBR revenue if GBR methodology does not provide sufficient revenue. Similarly, HSCRC has the authority to permit variable cost adjustments greater than 50%. Indeed, AAMC previously relied on an assumption that such an adjustment would be made for its program. (DI #3AA, p. 82) (assuming an 85% variable cost factor based on HSCRC's ability to make revenue adjustments). That the HSCRC has not agreed to make such an accommodation for AAMC does not render Standard .05A(7) impossible to meet. However, since the Reviewer requested that the applicants not seek such adjustments, and AAMC admits that it cannot be financially feasible without them, the Commission should reject the Reviewer's finding of financial feasibility and AAMC's application should be denied.

Additional Review Standards and Criteria

- VII. EXCEPTION NO. 7: THE RECOMMENDED DECISION'S DETERMINATION THAT UM BWMC'S APPLICATION FAILS TO MEET THE COST EFFECTIVENESS STANDARD (COMAR § 10.24.17.05A(4)) SHOULD BE REJECTED.
 - A. The Cost Effectiveness Standard is not predicated on Minimum Volume.

The Recommended Decision incorrectly concludes that UM BWMC does not meet the cost effectiveness standard based on the finding that UM BWMC does not meet the minimum

volume standard and that its volume is overstated.²⁶ However, the cost effectiveness standard makes no reference to minimum volume and is independent of the minimum volume standard. An applicant can, and UM BWMC does, meet the cost effectiveness standard even if its volume would not hit the threshold minimum volume.

COMAR § 10.24.17.05A(4) ("Standard .05A(4)") provides

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

...

- (b) An applicant shall provide an analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care system will change as a result of the proposed cardiac surgery program, quantifying these changes to the extent possible.
- (c) An applicant shall provide an analysis of how the establishment of its proposed cardiac surgery program will alter the effectiveness of cardiac surgery services for cardiac

I have not found that BWMC has demonstrated that it can establish a cardiac surgery program large enough to meet the Minimum Case Volume requirements of the State Health Plan, especially if AAMC's proposed project, which is likely to meet the Minimum Volume Standard, is approved. Coupled with the more modest BWMC projection of system savings, predicated on reaching higher volumes than I have found to be likely, I am compelled to find that BWMC has not proposed a project that complies with this standard. It has not demonstrated that the benefits of its proposed cardiac surgery program to the health care system, as a whole, are likely to exceed the cost to the health care system.

Recommended Decision, 62.

For ease of reference, the Recommended Decision's conclusion as to this standard is copied below.

surgery patients in its proposed service area, quantifying the change in effectiveness to the extent possible. The analysis of service effectiveness shall include, but need not be limited to, the quality of care, care outcomes, and access to and availability of cardiac surgery services.

Id. 27

UM BWMC met subparts (b) and (c) of Standard .05A(4) by providing the requested analyses. UM BWMC Appl. pp. 54-57. Thus, UM BWMC meets the cost effectiveness standard as long as it demonstrated that "the benefits of its proposed cardiac surgery program to the health care system as a whole exceed the cost to the health care system." COMAR § 10.24.01.08G(3)(b).

B. UM BWMC is Cost Effective Even at the Lower Volumes Projected by the Recommended Decision.

The Recommended Decision concludes that UM BWMC did not demonstrate that the cost of its proposed program outweighed the benefits based on the finding that its volumes are overstated. However, the Recommended Decision does not analyze UM BWMC's cost effectiveness at lower volumes. Had the Reviewer done so, he would have found that UM BWMC is cost effective even at the projected lower volumes.

-

Subpart (a) is not quoted because it is not applicable to UM BWMC's application.

Table 17
Healthcare System & Medicare Savings Analysis
FY 2020

		BWMC
Rate Center Methodology Charge per Case (1)		\$ 51,952
FY 2020 Cases (1)	(A)	94
FY 2018 Incremental Charges to Payors	(B)	\$ 4,883,488
Charge per Case Methodology CPC @ CMI of 1.0 (1)		\$ 11,911
Projected CMI of Cardiac Surgery Cases (1)		3.40
Cardiac Surgery CPC		\$ 40,490
FY 2020 Cases (1)		94
FY 2018 Incremental Gross Charges		\$ 3,806,066
Variability Factor		50.0%
Approved GBR Adjustment FY 2020	(C)	\$ 1,903,033
Projected Healthcare System Charge Savings	(D) = (B) - (C)	\$ 2,980,455
FY 2020 Hospital-Wide Medicare Payor Mix (3)		40.0%
FY 2020 Medicare Charge Savings		\$ 1,192,182
Medicare Differential, including 2% sequestration (2)		92.0%
FY 2020 Medicare Payment Savings (4)		\$ 1,096,807
Average Healthcare System Charge Savings per Case	(E) = (D) / (A)	\$ 31,707

Note (1): Recommended Decision Alternative Minimum Volume Model, FY 2020 Volume at 20% Market Share (100 cases) x 94% adjustment factor for open heart surgery cases

Note (2): AAMC CON Application, _

Note (3): BWMC CON Application, Table H - Entire Facility

Note (4): Excludes impact of existing providers on Medicare payments

As demonstrated in the above table, even at the lower volume projected by the Recommended Decision's Alternative Model, UM BWMC's program would achieve almost \$3 million in savings to the healthcare system in FY 2020 alone. UM BWMC's program is projected to cost only \$1.26 million to implement – less than half the savings that would be generated in the first year. Thus, even at volumes as low as that projected in the Recommended Decision's alternative minimum volume analysis, the benefits of UM BWMC's proposed cardiac

surgery program to the health care system as a whole very clearly exceed the cost to the health care system. In fact, UM BWMC would generate just over \$1.26 million in savings after performing only 40 cases: \$1.26 million total project costs ÷ \$31,707 average savings per case = 39.74)

The finding that UM BWMC does not meet Standard .05A(4) based solely on the finding that its volume is overstated, together with the failure of the Recommended Decision to take the next logical step and analyze the cost savings at the volumes projected by the Recommended Decision, demonstrates the overarching problems with the Recommended Decision – it is a seriously flawed conclusion that fails to conduct a meaningful review of UM BWMC's application, it is internally inconsistent, and it does not apply supportable analyses and assumptions.

VIII. EXCEPTION NO. 8: THE RECOMMENDED DECISION'S FINDING THAT AAMC PRESENTED A STRONGER PROGRAM ARE IS NOT BASED ON THE PREFERENCE FOR COMPARATIVE REVIEWS STANDARD (COMAR § 10.24.17.05A(8)) AND SHOULD BE REJECTED.

The State Health Plan chapter sets forth a Preference in comparative review standard that defines what factors this Commission deems relevant and appropriate to consider in a comparative review. COMAR § 10.24.17.05A(8). The Recommended Decision finds this standard is not applicable on the basis that UM BWMC has not met all policies and standards (based solely on minimum volume). Recommended Decision, p. 96. Yet, the Recommended Decision contains several statements concluding that AAMC presented a stronger application than UM BWMC, and that the approval of AAMC's application over UM BWMC's was based on such conclusions. For example, the decision states:

- While lower charges for cardiac surgery could be obtained through implementation of this program and UMMS and BWMC have made a strong case that they could develop a quality program, my consideration of all the applicable standards and criteria leads me to recommend approval of only the stronger application in this review. Recommended Decision, p. 3.
- I have determined that public policy favors the establishment of the proposed program at AAMC, which will result in savings to the health care system through lower charges and better access for the relatively large population of Anne Arundel County and the population of the Eastern Shore. Recommended Decision, p. 42.
- The potential for maximizing the reduction of charges for cardiac surgery led me to closely consider the ability for both of these proposed projects to go forward at this time. However, in the end, I have concluded that the most prudent approach is to recommend approval of the strongest application and to deny the weaker proposal. Recommended Decision, p. 117.

The consideration of factors outside of Preference in comparative review standard violates the State Health Plan Chapter, and the application of factors not relevant in this review is arbitrary and capricious, and violates UM BWMC's right to due process. Because the recommendation of AAMC's application is based on factors not properly a part of this review, the Recommended Decision is inconsistent with the State Health Plan chapter and must be rejected.

IX. <u>EXCEPTION NO. 9</u>: THE RECOMMENDED DECISION'S DETERMINATION THAT DISTANCE AND TRAVEL TIME CAN SERVE AS A "SECONDARY JUSTIFICATION" FOR AAMC'S PROPOSED PROGRAM UNDER THE ACCESS STANDARD (COMAR § 10.24.17.05A(5)) SHOULD BE REJECTED.

The access standard, COMAR §10.24.17.05A(5) ("Standard .05A(5)"), provides:

- (5) Access.
 - (a) An applicant that seeks to justify establishment of cardiac surgery services, in whole or in part, based on inadequate access to cardiac surgery services in a health planning region shall:
 - (i) Demonstrate that access barriers exist; and

- (ii) Present a detailed plan for addressing such barriers.
- (b) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement cardiac surgery program.
- A. To justify the establishment of a cardiac surgery program on the basis of inadequate access, an applicant must demonstrate that access barriers exist, and AAMC failed to make any such showing.

Citing the supposed geographic advantages of its location near Annapolis, AAMC argued that its proposed cardiac surgery program can be justified under Standard .05A(5). The Recommended Decision states that "the primary access barrier identified by AAMC is travel distance and consequent travel time." Recommended Decision, p. 68. However, the Commission has determined that there are no geographic barriers to cardiac surgery in Maryland. The State Health Plan is quite clear on this point:

Unlike emergency PCI services, quick access to cardiac surgery and elective PCI services is not essential. One additional cardiac surgery program has been established in Maryland in the past decade and nine additional elective PCI programs have been established, while the volume of both cardiac surgery and PCI have steadily declined, for over ten years in the case of cardiac surgery, and for seven years in the case of PCI. Geographic access to cardiac surgery services and elective PCI is not a problem in Maryland, with respect to patient travel time or survival.

COMAR 10.24.17.03 (Issues and Policies: Access to Care). The Recommended Decision confirms this conclusion as applied here, stating: "I find that AAMC has not demonstrated that travel distance and travel time or delays in patient transfers are an access barrier that can serve, in whole, as a primary justification for the project." Recommended Decision, p. 69. This finding should have ended the Reviewer's inquiry because an applicant is not permitted to justify its project under Standard .05A(5) based on access if it cannot demonstrate that an access barrier exists.

B. There exists no basis under the State Health Plan to find distance and travel time to be a "secondary justification" for a proposed cardiac surgery program where no barriers to access exist.

Although the Recommended Decision finds that AAMC failed to demonstrate any access barrier, the Recommended Decision appears to give some additional support to the project under Standard .05A(5) based on AAMC's "potential for reducing travel time and distance for the service" as a "secondary justification." Recommended Decision, p. 69. It is not clear what benefit AAMC derived from the Reviewer's conclusion that it was entitled to a "secondary justification." However, there is no regulatory basis for awarding a "secondary justification" preference to an applicant, especially one that has failed to demonstrate that an access barrier exists.

UM BWMC is concerned that the Reviewer's conclusion on this point may have improperly influenced the ultimate recommendation. Various statements throughout the Recommended Decision suggest that geographic access was a factor in the Reviewer's consideration of the CON applications. For example, in the Reviewer's transmittal memorandum to the Commissioners and the parties, the Reviewer identifies AAMC's relatively better geographic position as one of several reasons he recommends approval of AAMC's proposal. (DI #98GF, Commr. Tanio's Memorandum dated December 30, 2016, p. 2.) Also, in the summary of the recommendation at the conclusion of the Recommended Decision, the Reviewer again cites to AAMC's geographic position as a reason to approve its project:

Geographically, [AAMC] is better positioned than BWMC to draw from the two urban areas where existing programs are concentrated and also better positioned to have the most positive impact on reducing travel time for cardiac surgery services, especially for the population of the Eastern Shore and some areas of Southern Maryland. Recommended Decision, p. 117.

Accordingly, UM BWMC requests that the Commission reject the Recommended Decision due to the Reviewer's apparent reliance on the improper consideration of a secondary justification of the AAMC project based on geographic access.

- X. <u>EXCEPTION NO. 10</u>: THE RECOMMENDED DECISION'S DETERMINATION THAT UM BWMC'S APPLICATION FAILS TO MEET THE NEED STANDARD (COMAR § 10.24.17.05A(6)) AND THE NEED REVIEW CRITERION (COMAR § 10.24.01.08G(3)(b)) SHOULD BE REJECTED.
 - A. UM BWMC demonstrated that its proposed program can generate at least 200 open heart surgery cases per year from its proposed service area.

The Recommended Decision finds that UM BWMC did not meet subpart (a) of the State Health Plan need standard based on the conclusion that UM BWMC did not demonstrate that its proposed program can generate at least 200 open heart surgery cases per year from its proposed service area. As addressed more fully in Exception Nos. 1 and 2, related to minimum volume, this conclusion is not supportable. UM BWMC has demonstrated an ability to generate at least 200 open heart surgery cases per year form its proposed service area.

B. Contrary to the Recommended Decision's finding, UM BWMC indicated how many patients referred for cardiac surgery following a diagnostic cardiac catheterization at UM BWMC it expected to treat if its program were approved.

The Recommended Decision is ambiguous as to its finding of whether UM BWMC meets subpart (c) of standard, stating, "BWMC assigned corroborative value to the information it provided on cardiac surgery cases identified through its diagnostic cardiac catheterization program (subparagraph (c) of the standard) but did not indicate what assumption it would make with respect to how many of these cases would obtain surgery at BWMC, if that service were

available." Recommended Decision, 76. This is incorrect, as UM BWMC expressly detailed its assumption as to how many of these cases would obtain surgery at UM BWMC if the service were available.

The Commission's March 10, 2015 completeness question number 19, and UM BWMC's response, were as follows.

19. Regarding the response to subpart (c), how many of the patients referred to cardiac surgery would have been good candidates to have their surgery performed at UM BWMC and how many would have still been referred to UMMC.

Applicant Response

In FY14, 979 diagnostic catheterization procedures were performed at UM BWMC, and 144²⁸ of these patients were referred for coronary artery bypass surgery (CABG). Of the 144 patients who were referred for cardiac surgery following a diagnostic catherization in UM BWMC's catherization lab, 107 (74%) were transferred/admitted to UMMC. Of these, 89 underwent cardiac surgery and 72 of those procedures could have been performed at UM BWMC if cardiac surgery services were available. Thus, 67% of the patients referred to UMMC, and 81% of those who underwent surgery, could have been treated at UM BWMC.

UM BWMC does not have detailed data for 37 of the 144 patients who were referred for cardiac surgery because they were not admitted to UMMC. However, if the percentage that applies to the patients referred to UMMC also applies to patients referred elsewhere (67%), then another 25 cases could have been performed at UM BWMC. Thus, UM BWMC estimates that a total of 97 of 144 patients could have received cardiac surgery services at UM BWMC.

(DI #6BW, p. 18) The finding that UM BWMC did not provide its assumption as to how many of these referrals it expects would have been treated at UM BWMC if the service existed is plainly incorrect. This incorrect finding is indicative of the level of attention paid to UM BWMC's actual filings and its demonstrated ability to meet the SHP standards.

-

The application incorrectly identified 145 patients referred for CABG procedures.

C. UM BWMC meets the Need review criterion.

The finding that UM BWMC did not meet the need review criterion, COMAR § 10.24.01.08G(3)(b), was based on the finding that UM BWMC did not meet the SHP need standard. As discussed above, UM BWMC did meet that standard. Thus, the finding that UM BWMC did not meet the need review criterion should be rejected.

CONCLUSION

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

Respectfully submitted,

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January 11, 2017

Table of Exhibits

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1.	Regression Analysis
2.	DI #8BW, Exhibit 44
3.	Decision - In re Clarksburg Community Hospital (Balt. City Cir. Crt,
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CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of January 2017, a copy of the foregoing Exceptions to Recommended Decision 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 Exceptions to the Reviewer's Recommended Decision and its attachments are true and correct to the best of my knowledge, information, and belief.

January 11, 2017
Date

Alfred Pietsch

Senior Vice President and CFO

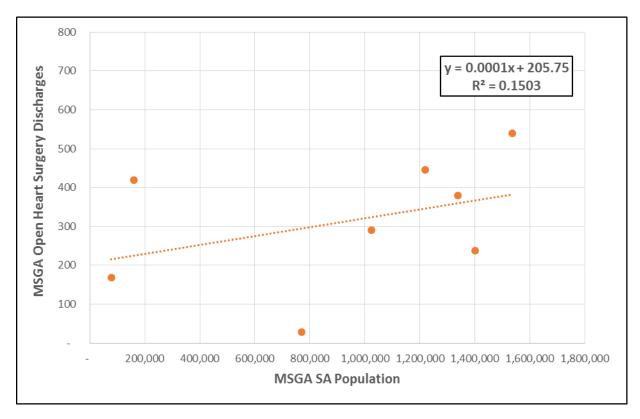
UM BWMC

EXHIBIT 1

In order to determine whether there is truly a relationship between the population size of a hospital's 85% MSGA service area and its total count of open heart surgeries, UM BWMC performed a linear regression analysis. For the purposes of this analysis, UM BWMC examined eight Maryland hospitals with cardiac surgery programs, excluding UMMC and JHH due to their cardiac program size and the population size within their 85% MSGA, both of which are more than 200% greater than the experience of any other Maryland program. UM BWMC Exceptions to Recommended Decision, Table 6. UM BWMC analyzed the total population of each hospital's 85% MSGA service area and each hospital's CY 2014 total open heart surgery volume.

The analysis demonstrates that there is no significant statistical correlation between the population in a hospital's service area and its number of open heart surgery cases. Primarily, this conclusion is drawn from both the intercept and population coefficient having P-values well above the statistically significant benchmark of 0.05 (0.14 and 0.34, respectively). Furthermore, the residuals squared value of 0.150 suggests that the data points are not closely associated with their trend line. Residuals squared values fall between 0 and 1, with more closely fitting data points equaling a result closer to 1. The graphical and summary output of this analysis follows.

The graphical output of these data points on a scatterplot confirms that the variables used — 85% MSGA population size and open heart surgery volume - are not highly correlated and not closely fitting to the trend line. Additionally, the flat horizontal nature of the trend line does not suggest that the correlation would be significantly positive or negative, even if it was statistically significant. Lastly, the standard errors of the intercept and population coefficient are relatively large, resulting in widely spread upper and lower 95th percentile ranges, adding further uncertainty to the correlation. Although this spread is likely due in large part to the small sample size, the analysis still suggests that a correlation is not statistically significant, and there is no evidence in the record to the contrary.



Source: Nielsen Population Projections (DI #97GF), HSCRC Maryland Discharge Database CY 2014, DC Hospital Discharge Database CY 2014

SUMMARY OUTPUT

Regression Stati	stics
Multiple R	0.387726702
R Square	0.150331996
Adjusted R Square	0.008720661
Standard Error	165.1009484
Observations	8

ANOVA

	df		SS	MS	F	Significance F
Regression		1	28936.93603	28936.93603	1.061581663	0.342586153
Residual	(6	163549.939	27258.32316		
Total		7	192486.875			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	205.7519506	120.0821404	1.713426742	0.137467074	-88.0784618	499.5823631	-88.0784618	499.5823631
Population Coefficient	0.000114939	0.000111555	1.030330851	0.342586153	-0.000158027	0.000387905	-0.000158027	0.000387905

EXHIBIT 2 (DI #8BW, EXHIBIT 44)



Volume Projections - 6 Years with Market Impact

					FY2016			FY2017			FY2018			FY2019			FY2020			FY2021	
		UMMC V	OLUME SHIFT %	30%			70%			75%			80%			80%			80%		
	ОТІ	HER HOSPITAL V	OLUME SHIFT %	5%			15%			20%			25%			30%			34%		
		DC V	OLUME SHIFT %	5%			15%			20%			25%			30%			33%		
ASSUMPTIONS:	CARDIAC SURG	GERY VOLUME IN	I SERVICE AREA	616			599			584			569			556			545		
<u> </u>		MARYLAND HOS	SPITAL VOLUME	458			446			434			423			414			405		
	WASHING	GTON, DC HOSPI	TAL VOLUME (2)	157			153			149			145			142			139		
			(1)	5 400/			2.552/			2 522/			2.550/			2.250/			2.000/		
		MHCC PROJECTI	ED DECREASE (1)	-5.12%			-2.66%			-2.63%			-2.55%			-2.25%			-2.00%		
		ACTUAL										PROJ	ECTED								
		FY2014 MARKET			FY2016			FY2017			FY2018			FY2019			FY2020			FY2021	
	(EXCL	UDING EXTREME SEV	/ERITY)	UM	LINANAC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER
	TOTAL	UMMC	OTHER	BWMC	UMMC SHIFT	SHIFT	BWMC	SHIFT	SHIFT	BWMC	SHIFT	SHIFT	BWMC	SHIFT	SHIFT	BWMC	SHIFT	SHIFT	BWMC	SHIFT	SHIFT
BWMC PRIMARY SERVICE AREA	167	96	71	30	27	3	72	62	10	78	65	13	83	67	16	84	66	18	84	64	20
BWMC SECONDARY SERVICE AREA	104	46	58	16	13	3	38	30	8	41	31	10	45	32	13	47	32	15	48	31	17
SHORE SERVICE AREA	95	58	37	19	17	2	42	37	5	46	39	7	49	41	8	50	40	10	50	39	11
OTHER SERVICE AREA	117	24	93	11	7	4	29	16	13	33	16	17	37	17	20	40	16	24	42	16	26
SUBTOTAL	483	224	259	76	64	12	181	145	36	198	151	47	214	157	57	221	154	67	224	150	74
DC HOSPITALS FROM SERVICE AREA ⁽²⁾	166		166	8		8	23		23	30		30	36		36	43		43	46		46
GRAND TOTAL	649	224	425	84	64	20	204	145	59	228	151	77	250	157	93	264	154	110	270	150	120
LENGTH OF STAY	4,258	2,118	2,140	739			1,796			2,009			2,205			2,325			2,383		
AVG LENGTH OF STAY	8.82	9.46	8.26	8.82			8.82			8.82			8.82			8.82			8.82		
AVG DAILY CENSUS	11.7	5.8	5.9	2.0			4.9			5.5			6.0			6.4			6.5		
MARKET SHIFT BREAKDOWN HOPKINS			259 119	246 113	Γ0/	12	239	1	36	233	200/	47	227	250/	57	222	200/	67	218	2.40/	74
UNION MEMORIAL					5% 5%	6 3	110 56	15% 15%	17 8	107 55	20%	21 11	104 54	25% 25%	26 14	102 52	30% 20%	31 16	100 51	34% 24%	34 17
SINAI			61 g	58 a	5% 5%	0	56 8	15% 15%	0	55 g	20% 20%	11 2	<i>54</i> 8	25% 25%	14 2	52 8	30% 30%	16 2	51 8	34% 34%	17 3
PENINSULA REGIONAL			19	18	5%	1	18	15%	3	17	20%	1	17	25%	1	16	30%	5	16	34%	6
WASHINGTON ADVENTIST			11	10	5%	1	10	15%	2	10	20%	2	10	25%	3	9	30%	3	9	34%	3
UM SJMC			40	38	5%	1	37	15%	5	36	20%	7	35	25%	8	34	30%	10	34	34%	11
o o			.0		5/1			20/0				,								0 1,70	
PROCEDURE MIX	TOTAL	UMMC	OTHER ⁽³⁾	UM BWMC			UM BWMC			UM BWMC			UM BWMC			UM BWMC			UM BWMC		
VALVE ONLY (25.7%)	167	68	99	22			52			59			64			68			70		
CABG ONLY (59.3%)		121	264	50			121			135			148			156			160		
VALVE & CABG COMBINED (12.0%)	78	31	47	10			24			27			30			32			32		
OTHER (2.9%)	19	4	15	2			6			7			7			8			8		
GRAND TOTAL	649	224	425	84			204			228			250			264			270		
			(2)	UM			UM			UM			UM			UM			UM		
PAYOR MIX	TOTAL	UMMC	OTHER ⁽³⁾	BWMC			BWMC			BWMC			BWMC			BWMC			вимс		
BLUE CROSS (16.2%)	105	38	67	14			33			37			40			43			44		
COMMERCIAL (12.6%)	82	34	48	11			26			29			32			33			34		
HMO (11.9%)	77	20	57	10			24			27			30			31			32		
MEDICAID (6.8%)	44	19	25	6			14			15			17			18			18		
MEDICARE (50.1%)	325	108	217	42			102			114			125			132			135		
OTHER (1.2%)	8	2	6	1			3			3			3			3			3		
SELF-PAY (1.2%)	8	3	5	1			3			3			3			3			3		
GRAND TOTAL	649	224	425	84			204			228			250			264			270		
_																					

Source: HSCRC Non-Confidential State Database (Excludes Ages 0 - 14)

(1) Projection based on MHCC Projected Adult Cardiac Surgery by Baltimore Upper Shore Region

Procedures based on MHCC cardiac surgery definition

Shore includes Kent, Queen Anne's, Talbot and Caroline Counties

Other Service Areas contain selected zip codes in the Anne Arundel and Howard

⁽²⁾ DC Data based on CY2011 data

⁽³⁾ OTHER Total includes DC Data

BWMC PROJECTIONS

		ACTUAL					PROJECTED			
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
POPULATION: BWMC SERVICE AREA	639,286	650,025	661,398	668,253	675,108	681,963	688,818	695,673	702,528	709,383
USE RATE	0.85	0.85	0.88	0.88	0.88	0.88	0.88	0.88	0.88	0.88
CARDIAC SURGERY DISCHARGES	541	553	580	586	592	598	604	610	616	622
PERCENT CHANGE		2.2%	4.9%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%

Source: HSCRC Non-Confidential State Database; Nielsen 2014 Population Estimate and 2019 Projection

BWMC Service Area based on previously defined zip codes

Excludes ages 0 - 14





UM BWMC CARDIAC SURGERY IMPACT BY HOSPITAL

ſ	ACTUAL									PROJ	ECTED								
	2014		2016			2017			2018			2019			2020			2021	
	Total Cardiac Surgery Market Discharges	Total Cardiac Surgery Market Discharges	BWMC	Discharges Shifting to	Total Market Cardiac Discharges	Shift to UM BWMC	% of Discharges Shifting to UM BWMC	Cardiac	Shift to UM BWMC	Discharges Shifting to	Cardiac	Shift to UM BWMC	Shifting to	Cardiac	Shift to UM BWMC	% of Discharges Shifting to UM BWMC	Total Market Cardiac Discharges	Shift to UM BWMC	% of Discharges Shifting to UM BWMC
иммс	828	786	64	8.1%	765	145	19.0%	745	151	20.3%	726	157	21.6%	710	154	21.7%	696	150	21.6%
JOHNS HOPKINS	1,054	1,000	6	0.6%	973	17	1.7%	947	21	2.2%	923	26	2.8%	902	31	3.4%	884	34	3.8%
UNION MEMORIAL	544	516	3	0.6%	502	8	1.6%	489	11	2.2%	477	14	2.9%	466	16	3.4%	457	17	3.7%
SINAI	360	342	0	0.0%	333	1	0.3%	324	2	0.6%	316	2	0.6%	309	2	0.6%	303	3	1.0%
PENINSULA REGIONAL	409	388	1	0.3%	378	3	0.8%	368	4	1.1%	359	4	1.1%	351	5	1.4%	344	6	1.7%
WASHINGTON ADVENTIST	316	300	1	0.3%	292	2	0.7%	284	2	0.7%	277	3	1.1%	271	3	1.1%	266	3	1.1%
UM SJMC	417	396	1	0.3%	385	5	1.3%	375	7	1.9%	365	8	2.2%	357	10	2.8%	350	11	3.1%
SUBURBAN	243	231	0	0.0%	225	0	0.0%	219	0	0.0%	213	0	0.0%	208	0	0.0%	204	0	0.0%
WESTERN MARYLAND	170	161	0	0.0%	157	0	0.0%	153	0	0.0%	149	0	0.0%	146	0	0.0%	143	0	0.0%
PRINCE GEORGES	6	6	0	0.0%	6	0	0.0%	6	0	0.0%	6	0	0.0%	6	0	0.0%	6	0	0.0%
DC HOSPITALS	1		8		1	23			30			36		1	43		1	46	
MARKET TOTAL	4,347	4,126	84	2.0%	4,016	204	5.1%	3,910	228	5.8%	3,811	250	6.6%	3,726	264	7.1%	3,653	270	7.4%

Source: HSCRC Non-Confidential State Database Procedures based on MHCC cardiac surgery definition

Excludes ages 0 - 14



 MHCC PROJECTED DECREASE
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						CARDIAC	SUKGEKT	IVIAKKET P	KOJECTED	VOLUME	213	113	58	9	18	10	38	157	616
					CARDIAC S	URGERY M	ARKET VO	LUME						FY16	SHIFT TO B	WMC			
Zip Code	Service Area	ПММС	圭	UNION MEM	SINAI	PRMC	WASH ADV	UM SJMC	DC HOSP	TOTAL	ПММС	HH	UNION MEM	SINAI	PRMC	WASH ADV	им ѕлмс	DC HOSP	BWMC SHIFT
	Primary Service Area	22	5	4	-	-	-	2	-	33	6	-	-	-	-	-	-	-	6
	Primary Service Area	31	3		-	-	-	2	2	43	8	-	-	-	-	-	-	-	8
	Primary Service Area	30 9	6		1	-	-	3	7	58 20	9	-	1	-	-	-	-	1	11
	Primary Service Area Primary Service Area	4	1	14	1	-		3	1	23	1	1	1		-	_			2
	ice Area Sub Total	96	21		2	-	-	11	10	177	27	1	2	-	-	-	-	1	31
	Secondary Service Area	4	2		-	-	-	1	2	9	1	-	-	-	-	-	-	-	1
	Secondary Service Area	3	2		-	-	-	-	1	7	1	-	-	-	-	-	-	-	1
	Secondary Service Area	8	2		-	-	-	1	1	13	2	-	-	-	-	-	-	-	2
	Secondary Service Area Secondary Service Area	9	4	2	1	1	_	3	4	19 15	3		-		-	_	-	-	3
	Secondary Service Area	11	4		1	-	_	-	7	23	3	1	_		-	_	-	1	5
	Secondary Service Area	1	1	3	-	-	-	-	-	5	-	-	-	-	-	-	-	-	-
	Secondary Service Area	6	5		1	-	-	11	-	32	2	-	1	-	-	-	1	-	4
	ervice Area Sub Total	46	21		3	1	-	17	19	123	13	1	1	-	-	-	1	1	17
	Upper Shore Areas Upper Shore Areas	10	3	1	-	6	-	-	1	21	4	1	-	-	1	-	-	-	6
	Upper Shore Areas	1		_		_		-	1	2	-		-		-		-		-
	Upper Shore Areas	1	-	-	-	1	-	-	-	2	-	-	-	-	-	-	-	-	-
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	Upper Shore Areas Upper Shore Areas	4	2	-	-	-	-	-	2	12 6	1 2	-	-	-	- -	_	-	1	2
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21623	Upper Shore Areas	-		-	-	1		-	-	1		-	-		-	-	-	-	-
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Grand Total		224	119	61	9	19	11	40	166	649	64	6	3	-	1	1	1	8	84



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	Γ			5	FY17	SHIFT TO B	WMC	l		!-			5	FY18	SHIFT TO B				!-
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Zip Code	Service Area	UMMC	_	UNION	₫	PRMC	WASH ,	им ѕлмс	ноѕР	/MC	ОММС	_	NOI	₫	PRMC	WASH /	1 SJMC	DC HOSP	/MC
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	Primary Service Area	6	1	-	-	-	-	-	-	7	6	1	1	-	-	-	-	-	8
	Primary Service Area	3	-	2	-	-	-	1	-	6	3	-	3	-	-	-	1	-	7
	ice Area Sub Total	62	3	6	-	-	-	1	1	<i>73</i>	65	4	8	-	-	-	1	2	80
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	Secondary Service Area	5	1	-	-	-	-	-	-	6	5	-	-	-	-	-	-	-	5
	Secondary Service Area	6	-	-	-	-	-	-	1	7	6	-	-	-	-	-	1	1	8
	Secondary Service Area	3	1	-	-	-	-	-	1	5	3	1	-	-	-	-	-	1	5
	Secondary Service Area Secondary Service Area	6	1	-	-	-	-	-	1	8	7	1	1	-	-	-	-	2	10
	Secondary Service Area	4	2	1	-	-		2	-	9	4	1	2		-	-	3	-	10
	ervice Area Sub Total	30	5		-	-	-	2	3	41	31	3	3	-	-	-	4	4	45
	Upper Shore Areas	4	1	-	-	2	-	-	-	7	5	1	-	-	2	-	-	-	8
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21146	Secondary Service Area	7	1	-	-	-	-	-	3	11	8	1	-	-	-	-	-	2	11
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21640	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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21649	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
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21660	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
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21671	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
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21679	Upper Shore Areas	-		-		-		-	-	-	-	-	-	-	-	-	-	-	-
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20724	Other Service Area						1			1	-	1				1			2
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20764	Other Service Area	1	-	-	-	-	-	-	1	2	1	1	-	-	-	-	-	1	3
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21032	Other Service Area	1	-	-	-	-	-	-	-	1	1	1	-	-	-	-	1	-	3
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21114	Other Service Area	1	1	-	_	-	-	-	2	4	1	1	-	-	-	-	-	2	4
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21409	Other Service Area	1	1	-	-	-	-	-	1	3	1	1	-	_	-	-	-	1	3
Other Service	Area Sub Total	17	14	1	1	-	3	1	22	59	16	16	1	2	-	3	2	25	65
Grand Total		157	26	14	2		2	8	36	250	154	31	16	2		2	10	43	264
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21122 Primary Service Area 20 2 3 - - - -	1 3	29	
21144 Primary Service Area 6 2 1		9	
21225 Primary Service Area 3 - 4	1 -	8	
Primary Service Area Sub Total 64 6 10	4 5	89	
21054 Secondary Service Area 3 1	- 1	5	
21076 Secondary Service Area 2 1	1 1	3	
21090 Secondary Service Area 5 1	_	6	
21108 Secondary Service Area 6 - 1	1 1	9	
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21227 Secondary Service Area 4 1 4	3 -	12	
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21606 Upper Shore Areas	-	-	
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21635 Upper Shore Areas		-	
21636 Upper Shore Areas 1		1	
21638 Upper Shore Areas 1	- 1	2	
21639 Upper Shore Areas 1 1 - 1 -		2	
21640 Upper Shore Areas			
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21641 Upper Shore Areas		-	
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IN THE MATTER OF THE * IN THE

PETITION OF * CIRCUIT COURT

CLARKSBURG COMMUNITY * FOR BALTIMORE CITY

HOSPITAL, INC. * Case No.: 24-C-11-001046

* * * * *

ORDER

For the reasons set forth in a Memorandum of even date, it is, this ______ day of February, 2012,

ORDERED that the Final Decision of the Maryland Health Care Commission in Docket Nos. 08-15-2286 and 09-15-2294 is reversed and the case remanded to the Commission with direction to comply with Md. Ann. Code State Government Article § 10-213(h)(2) as set forth in the Memorandum.

W. MICHEL PIERSON, Judge

Judge's signature appears on original document

Judge W. Michel Pierson

IN THE MATTER OF THE IN THE PETITION OF **CIRCUIT COURT CLARKSBURG COMMUNITY** FOR BALTIMORE CITY HOSPITAL, INC. Case No.: 24-C-11-001046

ORDER

The court having read and considered the Motion to Correct Administrative Record (No. 12), along with the opposition and reply, it is, this ______ day of February, 2012,

ORDERED that the motion is GRANTED, and further

ORDERED that the documents attached to the motion shall be included in the record before this court.

> W. MICHEL PIERSON, Judge Judge's signature appears on original document

Judge W. Michel Pierson

IN THE MATTER OF THE * IN THE

PETITION OF * CIRCUIT COURT

CLARKSBURG COMMUNITY * FOR BALTIMORE CITY

HOSPITAL, INC. * Case No.: 24-C-11-001046

* * * * *

MEMORANDUM

Before the court is a petition for judicial review of a decision of the Maryland Health Care Commission relating to proposed new hospitals in Montgomery County. The decision in question is the Commission's Final Decision of January 20, 2011 approving the application of Holy Cross Hospital of Silver Spring for a Certificate of Need to establish a new 93 bed acute care general hospital in Germantown, Maryland and denying the application of Clarksburg Community Hospital, Inc. for a Certificate of Need to establish a new 86 bed acute care general hospital in Clarksburg, Maryland. The petitioners are Clarksburg Community Hospital, Inc. and Adventist Healthcare, Inc. d/b/a Shady Grove Adventist Hospital.¹

Participating in the proceedings before this court were the petitioners, as well as the Maryland Health Care Commission and Holy Cross Hospital. The parties all filed memoranda in accordance with Rule 7-207. In addition, the Commission filed a Motion to Correct Administrative Record, seeking to supplement the administrative record with certain documents that were not included in the record transmitted to this court. This motion was opposed by petitioners.

Petitioners present three questions. First, they argue that the Commission violated the

¹ CCH was an applicant before the Commission; it is a wholly owned affiliate of the other petitioners, who were interested parties.

Administrative Procedure Act and the parties' right to due process by relying on extra-record evidence to support its decision. Second, they assert that the Commission misapplied the law by disregarding the State Health Plan in determining to issue a Certificate of Need to Holy Cross. Finally, they contend that the Commission exceeded its statutory authority by approving the Holy Cross project without required input from the Health Services Cost Review Commission. Each of these arguments will be addressed in turn.

1. Reliance on Extra-Record Evidence

Marilyn Moon, Ph.D., the Chair of the Commission, acted as the Reviewer on the applications. Between October 2009 and August 23, 2010, an extensive administrative record was compiled, and numerous procedural rulings were made. The Reviewer determined that the record would be closed to further submissions on August 27, 2010, and that an evidentiary hearing would be held on certain specified issues. An evidentiary hearing was held from August 30, 2010 through September 16, 2010, culminating in closing arguments.

A Recommended Decision was issued by the Reviewer on December 17, 2010. In the Recommended Decision, the Reviewer relied upon several sources of data that are the subject of petitioners' argument. She cited population data from Spatial Insights, Inc.; historical population data, current population estimates and projected population for 2014 prepared by Applied Geographic Solutions, Inc.; and the "D.C. Discharge databases/Data Set."

The significance of this information relates to the bed need standard. That standard permits an applicant to justify an increase in beds by application of projection methodology, assumptions and targets. Data employed for this purpose include zip code population data sets. Each of the

applicants used zip code level data provided by Claritas in presenting their analysis of a need for their proposed hospitals in estimating the projected market share of the hospital. The Reviewer used zip code area population estimates and projections provided by another vendor. There is no dispute that the population data used by the Reviewer was not part of the administrative record compiled before September 16, 2010.

Petitioners filed exceptions to the Recommended Decision on January 6, 2011, the deadline imposed at the time the Recommended Decision was issued. In their exceptions petitioners protested the use of the data in question. An exceptions hearing was conducted on January 20, 2011, at which time the full Commission voted to adopt the Recommended Decision.

Petitioners rely on the provisions of the Administrative Procedure Act, specifically State Government Article § 10-213(h). That section states:

- (1) The agency . . . may take official notice of a fact that is:
- (i) judicially noticeable; or
- (ii) general, technical, or scientific and within the specialized knowledge of the agency.
- (2) Before taking official notice of a fact, the presiding officer:
- (i) before or during the hearing, by reference in a preliminary report, or otherwise, shall notify each party; and
- (ii) shall give each party an opportunity to contest the fact.

Section 10-214(a) provides that "[f]indings of fact must be based exclusively on the evidence of record in the contested case proceeding and on matters officially noticed in that proceeding." Petitioners contend that the Commission's action contravened the express terms of the statute.

Respondents make several arguments in response. They suggest that the Commission complied with the terms of the statute because it afforded an opportunity to contest the facts. To

Administrative Law (2011) at 89: "Official notice may even be taken for the first time in the proposed decision as long as the opportunity for objection is provided." They claim that petitioners were not surprised by the use of the data in the Recommended Decision and dispute the argument that petitioners had no meaningful opportunity to challenge the data. They also state that petitioners have failed to establish that any prejudice occurred as a result of the supposed violation.

In support of their position, respondents state that petitioners could have addressed any disparities in the data in their exceptions to the Recommended Decision or in a later filed request for reconsideration. They note that on December 21, 2010 counsel for petitioners informed counsel for the Commission that he would be requesting data used in the decision that was not in the record.² However, petitioners' counsel waited until January 26, 2011, after the exceptions hearing had taken place, to request the data. Commission staff sent the requested data in a serious of e-mails, ten of which were sent on January 28 and the eleventh on January 31, 2011.

Respondents point to COMAR § 10.24.01.19, which permits the filing of a motion for reconsideration of a Commission decision. They state that petitioners could have sought reconsideration based on an allegation that the data presented significant and relevant information which was not previously presented to the Commission or that the data demonstrated that there had been significant change in factors or circumstances relied upon by the Commission in reaching its

² This information is contained in the Motion to Correct Administrative Record. While the court is not convinced that this material properly forms a part of the administrative record as such, it deems it expeditious to grant the motion in order to consider the impact of this information on the contention that petitioners had an opportunity to contest the use of these facts.

decision.

As to prejudice, the Commission states that while CCH used zip code area population data sets "that could be expected to differ to some degree from that used by the Reviewer, given that the data were supplied by different vendors[,] ... [i]t is common sense that all zip code area population data sets will contain very similar estimates and projections because the universe of inputs and techniques used to develop these data sets is limited." The Commission argues that petitioners fail to allege any harm or substantive error in the use of the data by the Reviewer.

The court concludes that petitioners' position has merit. The explicit terms of the statute mandate that before an agency takes official notice of a fact it shall give each party an opportunity to contest that fact. Contrary to respondents' arguments, the court's review of the record convinces it that petitioners were not presented with a meaningful opportunity to contest the data relied upon by the reviewer. The issues presented in this case are of great complexity, and the record, as the Commission notes, is measured in feet rather than inches.³ The Reviewer's analysis of the data required a 180 page decision. Following the service of the Recommended Decision, petitioners had twenty days to file exceptions, and were allotted twenty minutes at the exceptions hearing to present all of their objections to the Recommended Decision. It is unrealistic to state that petitioners had a meaningful opportunity to contest the use of this information. And given the circumstances, the failure of petitioners' counsel to secure the data prior to the exceptions hearing does not militate against this conclusion. Finally, in the court's view, the right to file a request for reconsideration of a final decision is not an opportunity to contest a fact that the agency proposes to notice within

³ It probably could more readily be measured in yards.

the contemplation of section 10-213.

Respondents also argue that the case should not be remanded because petitioners have failed to establish that any prejudice occurred as a result of the violation. The court believes that this argument is misplaced. Whether petitioners were prejudiced by use of the information is ineluctably linked to an analysis of what part that information plays in the findings that were the foundation of the decision. To determine whether the data used by the Commission was equivalent to the data otherwise in the record and what part that information played in the Decision would require the court to undertake the weighing of the data. In seeking to place upon petitioners the burden to demonstrate to this court how the use of this data prejudiced them, respondents would have this court take on the functions of the administrative agency, whose role is to determine the weight to be accorded to evidence.

For this reason, the Decision must be reversed to permit petitioners the opportunity to contest the facts noticed by the Commission after the closing of the record. The Commission must comply with the provisions of section 10-213 by giving the parties a meaningful opportunity to contest the facts of which it took official notice.

2. Misapplication of the law

Petitioners' second argument asserts that the Commission disregarded the bed need standard embodied in the 2009 Acute Care Hospital State Health Plan, COMAR § 10.24.10.04B(2), by the manner in which it determined that Holy Cross had established a bed need at its new proposed location. Petitioners contend that the Commission allowed Holy Cross to relocate 39 beds currently licensed for use at its existing hospital to the new location. Petitioners argue that this contravenes

the provisions of the Plan because the Plan does not permit the shifting of licensed beds in order to make a showing of need.

This argument is founded entirely upon comments made on page 36 of the Decision. After careful consideration of those statements in the context of the entire passage relating to the analysis of the showing of bed need under section (c)(i)(iv), the court does not believe that petitioners' characterization is accurate. The Decision finds that there was an adequate demonstration of bed need based on a service area analysis. The comments on page 36 are not necessary to this analysis. Notably, petitioners seize upon a single statement and do not consider its relation to the entire text of the lengthy and closely-reasoned discussion of the bed need showing. Furthermore, if there were a showing of need, Holy Cross's decision not to use licensed beds at its existing location would not amount to a "shifting" of beds (although it might look like it). The court is convinced that this is an illusory issue.

3. Disregard of Health Services Cost Review Commission

The third argument is based on the provisions of Health-General Article §19-103(d), which provides that the Commission shall coordinate the exercise of its functions with the Health Services Cost Review Commission to ensure an integrated, effective health care policy for the State. Petitioners argue that in awarding a Certificate of Need to Holy Cross, the Commission disregarded the requirements of this section. They rely upon a memorandum from HRCRC provided in response to a request for that agency's input. That memorandum expressed the opinion of HRCRC staff that "neither [applicant] can prudently and successfully undertake the financing, construction and successful operation of a new facility at this time."

In its Decision, the Commission undertook a detailed discussion of the viability of each

proposal, which review included the availability of resources necessary to sustain the project. (Final

Decision at 148 - 163). Within that discussion, the Decision acknowledges the conclusions of the

Health Services Cost Review Commission. After that acknowledgement, the Decision integrates that

input with its findings on viability. In the court's view, the Commission's treatment of the HSCRC

input complies with the requirements of section 19-103(d).

The statute requires coordination of the Commission's functions with HRCRC. The

language does not vest HRCRC with veto power over the Commission decisions. Given the

deference that the court must extend to the agency, the weight to be given to HRCRC input should

be measured by the Commission, as long as it is cognizant of its statutory obligation to coordinate

its function. The Decision of the Commission adequately documents its compliance with this

standard.

4. Conclusion

Because the court has concluded that the only defect in the proceedings below was the use

of extra-record information in the Decision, that defect may be rectified by a remand for the purpose

of enabling petitioner to respond to the information in question. Accordingly, the decision will be

reversed and remanded for the purpose of permitting petitioner to comment on the information

employed in the Decision.

Dated: Lebruary 21, 2012

W. MICHEL PIERSON, Judge

Judge's signature appears on original document

Judge W. Michel Pierson