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 REVISED 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 Revised Recommended Decision.

INTRODUCTION

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. 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 respectfully requests that the Commission reject the Revised 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

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.

Arundel Medical Center ("AAMC") and deny UM BWMC's proposal. The Revised Recommended Decision includes the following serious errors:

- The Revised 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.
- The Revised Recommended Decision is inconsistent with the applicable State Health Plan's mandate to protect 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 Revised Recommended Decision finds that 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 Revised Recommended Decision finds that UM BWMC is not cost effective based on an apparent misunderstanding of UM BWMC's proposal to add a third location to the existing UM Division of Cardiac Surgery and allow UMMS patients residing in UM BWMC's proposed cardiac surgery services area to receive cardiac surgery services at lower cost, and in a more accessible and convenient location for patients and their support networks.

The Revised 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 a radical departure from the Commission's prior decisions and is so fundamentally flawed it constitutes an arbitrary method of assessing minimum volume. On the sole basis of this defective model, the Revised

Recommended Decision determines that UM BWMC's Certificate of Need ("CON") application does not comply with three standards and review criteria.

The Revised Recommended Decision repeatedly 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 comparative 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 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 Revised 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 and the Reviewer largely ignored the impact that 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.

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 and 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 "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 Revised Recommended Decision, however, finds AAMC to be in compliance by misconstruing and

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

The Revised 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, financial feasibility, and cost effectiveness 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 INCONSISTENT WITH THE STANDARDS GOVERNING THIS REVIEW AND WITH FINDINGS IN THE REVISED RECOMMENDED DECISION. (COMAR § 10.24.17.05A(1)).

The Revised Recommended Decision eliminates UM BWMC's application from comparative review analysis based primarily on the finding that UM BWMC supposedly did not meet the 200-case threshold minimum volume requirement. The Revised Recommended Decision then uses this finding as the sole basis for concluding that UM BWMC did not meet three other review standards and criteria.

The Revised Recommended Decision does not address or analyze 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 logically flawed, and is based on data that is not properly part of

the record in this review. 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.

Viewed in the context of the introduction and summary to the Revised Recommended Decision, the Alternative Model is even more perplexing. As discussed more fully under Exception No. 11, the Reviewer's remarks comparing the AAMC and UM BWMC applications in the introduction and concluding summary, and throughout the recommendation, demonstrate that the Reviewer "closely and seriously consider[ed] the ability for both of these proposed projects to go forward at this time" but found AAMC to be the be the "stronger" program. Revised Recommended Decision, p. 122. The close and serious consideration of both programs contradicts the finding that UM BWMC does not meet the minimum volume standard. That standard is a threshold barrier to entry – there is no authority to approve UM BWMC's application if the standard is not met.

In light of the numerous comments demonstrating the Reviewer's careful, serious consideration of approving *both* programs, combined with the serious flaws of the minimum volume analysis, the finding that UM BWMC does not meet the threshold minimum volume standard appears to be a result-driven finding to justify the conclusion that is stated throughout the decision but exceeds the scope of the Reviewer's authority – that AAMC presented a "stronger" application based on factors other than the comparative review standard. 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 constitutes impermissible rulemaking.

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 "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");

Here and throughout these Exceptions, UM BWMC cites the version of the State Health Plan chapter effective as of August 18, 2014, the version applicable to this review. The chapter has since been revised.

- 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;

Regardless of the strength of its strategy, system affiliations, internal PCI volume, referral relationships, or any other circumstances, a hospital applicant can only achieve minimum volume under the Alternative Model if there will be at least 660 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	660
Adjust for 20% Market share in 85% MSGA SA	132
Assume 66% of Cardiac Surgery Discharges come from within hospital's 85% MSGA SA	200

The reduction of the 660 cases by even one discharge would place a hospital under the minimum volume threshold of 200 cases. Thus, the Alternative Model could be restated as a new standard as follows: an applicant shall document that there will be 660 cardiac surgery discharges in its existing 85% MSGA service area by its third³ full year of operation.⁴ This model oversimplifies

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The actual minimum volume standard refers to the second full year of operation. The Alternative Model, however, projects volume for CY 2020 – the third full year for either applicant based on their project implementation schedules. (DI #8BW, p. 29; DI #3AA, p. 22.)

Had the Commission intended this as a threshold standard, it should have promulgated it as a rule at the outset, not only for due process reasons, but to avoid waste of significant

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.

That AAMC meets this arbitrary cutoff by just eight cases – the Reviewer projects 668 cardiac surgery discharges in AAMC's 85% MSGA service area in CY 2020 – is at best a convenient accident. If the Commission accepts this model, it must be prepared to implicitly confirm that had there been 9 fewer discharges in AAMC's 85% MSGA SA in CY 2020, resulting in only 199 cases for AAMC, it would have rejected both applicants, despite any other merit to their applications as demonstrated over the course of this two year review.

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.

Although administrative agencies have discretion in choosing whether to develop policy by rulemaking or adjudication, agencies must engage in rulemaking when: (1) changing a policy or rule of general application, and (2) applying the new rule retroactively to the detriment of a party that relied on the agency's past pronouncements. CBS Inc. v. Comptroller of the Treasury, 319 Md. 687, 698 (1990). In CBS Inc., the Court of Appeals vacated an agency's adjudicative ruling which applied an "audience-share" test to determine CBS's taxes rather than the previously established rule determining tax liability based on the location of income-producing

resources by applicants. UM BWMC has incurred considerable expenses over the course of this more than two year review.

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activity. <u>Id.</u> at 690, 699. The Court vacated the agency's adjudicative order because the agency changed existing law and formulated rules of widespread application that were applied retroactively to CBS. Id. at 698.

Likewise, here the Reviewer proposes to change a longstanding policy of general application to the detriment of UM BWMC. There is no support in the State Health Plan or the Revised Recommended Decision to reject the applicable minimum volume standard in favor of a different, arbitrary cut off.⁵ Further, as explained below, this approach departs from consistent Commission precedent for determining an applicant's compliance with the minimum volume standard. The Alternative Model threshold should be rejected in favor of the actual requirement in the State Health Plan chapter – the applicant's documentation of the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation.

B. The Revised Recommended Decision's approach to minimum volume is inconsistent with prior decisions of this Commission.

Not only would the application of a new threshold for entry of the cardiac surgery market based on MSGA service area size constitute impermissible rulemaking, it would be inconsistent with this Commission's prior application of the minimum volume standard. In every decision on a certificate of need for open heart surgery that UM BWMC has located, the Commission has determined an applicant's demonstration of minimum or start up volume on the basis of referral relationships or agreements, and/or the internal volume that the applicant or applicant's member

The Reviewer suggests that the Alternative Model is justified because it "provides a more balanced perspective, allowing for comparison of the applications on the basis of consistent assumptions, grounded in actual experience." Revised Recommended Decision, p. 29. However, there is no need, or authority, to compare the applicants' proposed projects under this standard. It is a threshold barrier to entry requirement that considers whether an applicant has documented an ability to reach 200 cases in the second full year of operation.

system generates.⁶ To now apply the minimum volume standard in a manner that is inconsistent with this Commission's prior decisions would be arbitrary and capricious. See Harvey v.

Marshall, 389 Md. 243, 302 (2005)("[A]n agency action . . . may be "arbitrary or capricious" if it is irrationally inconsistent with previous agency decisions.")

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 (July 21, 2005), p. 53, attached as **Exhibit 1A** by CD.

In the 1993 comparative CON review for open heart surgery in Central Maryland, the Commission found that "A hospital's historical cardiology service volumes, especially cardiac cauterization volumes, serve as an indication of a pool of patients from which the initial volumes of an OHS service may be drawn." In re Central Maryland Open Heart Surgery Comparative Review, Docket Nos. 91-24-1624, 91-24-1625, 91-24-1626, Final Decision, (June 8, 1993), p. 25, attached as **Exhibit 1B** by CD. The Commission further stated its "belie[f] that a strong

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Four cardiac surgery programs existed in Maryland in 1980. UM BWMC has located decisions for five new programs. UM BWMC has not been able to locate any decision for the establishment of cardiac surgery services at St. Joseph Medical Center or Peninsula Regional Medical Center, which each established services between 1978 and 2000. See An Analysis and Evaluation of the CON Program, Ch. 3 - Cardiac Surgery, Maryland Health Care Commission (2001), available at http://msa.maryland.gov/, the Maryland State Archives, via a title word search.

This Decision and two of the four additional decisions discussed below are Recommended Decisions. Although not indicated in the documents, UM BWMC believes these decisions were adopted by the Commission as final.

and stable cardiology program with demonstrated physician support in place is essential and any program that can demonstrate a strong and committed referral network among cardiologists and strong internal volumes offers a more effective alternative." <u>Id.</u> In determining that each of the three applicants had demonstrated the ability to achieve a start-up volume of 200 cases, the Decision considers a combination of the hospital applicants' cardiology discharges, internal volume referred for OHC/PTCA, letters of support from other providers, and referral letters. <u>Id.</u>, pp. 25-29.

In the 1992 cardiac surgery CON review of Sacred Heart Hospital, a member of Western Maryland Health System, the applicant demonstrated compliance with the minimum volume standard by documenting need in the applicable cardiac surgery health planning region and applying a flat 46.3% market share projection. The Recommended Decision found that the applicant supported its market share assumption by documenting its potential for internally generated volume – cardiac cath lab referrals from the system's two hospitals to existing programs for open heart surgery and percutaneous transluminal coronary angioplasty. In Re Western Maryland Open Heart Surgery Review, Sacred Heart Hospital, Docket No. 97-01-2012, Recommended Decision (Aug. 31, 1999), pp. 19-20, attached as **Exhibit 1C** by CD. The applicant further supported its assumptions by "provid[ing] documentation to indicate that [contacted] cardiologists would have referred approximately 230 patients to Sacred Heart of OHS services had been available" in the prior year. <u>Id.</u>, p. 19. That Recommended Decision further found that "[a] hospital's ability to maintain the minimum caseload is dependent upon its internally generated volumes and the hospital's ability to form and maintain referral patterns." Id., 29.

In the 1990 comparative CON review for open heart surgery in Central Maryland, in which Sinai Hospital was granted a CON, the Commission determined that Sinai Hospital, Franklin Square Hospital, and St. Agnes Hospital (but not Maryland General Hospital) each met the minimum volume standard by demonstrating internal cardiac catheterization volume and physician referrals. In re St. Agnes Hospital, Sinai Hospital, Franklin Square Hospital, and Maryland General Hospital, Docket Nos. 86-24-1373, 86-24-1371, 86-03-1372, 86-24-1373), Final Decision, (January 23, 1990), pp. 41-52, attached as **Exhibit 1E** by CD

In the 1989 CON review to establish open heart surgery at PGHC and Doctor's Hospital, the Recommended Decision concludes that both applicants sufficiently demonstrated that their respective proposed programs would "perform cardiac surgical procedures on a minimum of 200 adults per year within three years of initiation and each year after" on the basis of referral sources alone. In Re PGHC, AMI Doctors' Hospital, Docket Nos. 82-16-1051, 82-16-1057 Recommended Decision (Oct. 20, 1989), pp. 24, 30, attached as **Exhibit 1E** by CD. ("The Commission finds that neither the existing nor proposed cardiac catheterization laboratories at the Applicant facilities are, at this time, a significant factor in generating the projected volumes of OHS patients. However, the Commission further finds that both Applicants have identified sufficient referral sources to provide the minimum volume required by this standard.").

A review of the Commission's cardiac surgery CON precedent that could be located, going back almost 30 years, reveals that the Commission has concluded only once before that an applicant (including those that were rejected) failed to meet the minimum volume standard. Given that UM BWMC demonstrated that it would have at least 150 cardiac surgery cases available to be transferred within the UMMS system in addition to other volume, it is a most likely applicant to be only one of two applicants to be rejected on the basis of minimum volume.

Despite these decisions by the Commission, the Reviewer did not analyze UM BWMC's documentation of its ability to meet the minimum volume standard on the basis of the internal volume of UM BWMC or UMMC, their established referral patterns, or the cardiology referral letters submitted in this review. Instead, the Revised Recommended Decision disregards the precedent above and the filings of the parties over a two-year review in favor of a newly disclosed model that establishes a threshold based on MSGA service area and is not authorized by the regulations governing this review.

C. The Reviewer's conclusion that UM BWMC cannot document minimum volume is inconsistent with the Reviewer's findings under the impact standard.

The Revised Recommended Decision finds that UM BWMC does not meet the minimum volume standard based principally on its MSGA service area size and the market share experience of three hospitals that are supposedly comparable to the applicants' proposed projects. Under the impact standard, however, the Reviewer considers whether the approval of AAMC's project would cause PGHC's cardiac surgery volume to drop below an annual volume of 100 cases cardiac surgery cases by relying instead only on need in the surrounding region. The Revised Recommended Decision's analysis under the impact standard states, in part:

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

halfway to the 200-case level and only marginal further penetration of the Prince George's County market and that of surrounding areas will be required to reach a volume of 200 cases. (DI #62GF).

Revised Recommended Decision, p. 45. The Reviewer provides no explanation or justification as to why he may properly conclude that Dimensions and AAMC will both be able to achieve 200 cases based solely on the total volume of 3,470 adult cardiac cases in 11 surrounding counties, yet does not find that significant case volume sufficient to support minimum volume for a program at UM BWMC. The Commission should reject a decision that inconsistently applies data and methodologies to different parties in order to achieve a desired result. See, e.g., Harvey v. Marshall, 389 at 304-05 (2005) ("Just as actions that are inconsistent with prior administrative precedents may be deemed 'arbitrary or capricious,' an agency action also may be deemed 'arbitrary or capricious' if similarly situated individuals are treated differently without a rational basis for such a deviation.")

- II. <u>EXCEPTION NO. 2</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)).
 - A. The Alternative Model 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 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						
				Total MSGA			
		BWMC MSGA	Running	Discharges in Zip	BWMC MSGA	MSGA Population	
<u>#</u>	ZIP	Discharges	Total %	(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 2014

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		
		AAMC MSGA	Running	Discharges in Zip (All	AAMC MSGA	MSGA Population
<u>#</u>	ZIP	Discharges	Total %	Hosp)	Market Share	(Age 15+)
1 2	21401 21403	2,549	13.37% 22.23%	3,259	78.21% 77.98%	32,469
3	21403	1,689 1,005	22.23% 27.50%	2,166 1,301	77.98% 77.25%	25,618 17,247
3 4	21012	828	31.84%	1,301	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
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 27	20733	187	75.65%	253	73.91%	2,616
27 28	21108	183 180	76.61%	1,112 2,040	16.46% 8.82%	14,310 26,465
28 29	21144 21638	149	77.56% 78.34%	388	38.40%	4,137
30	21038	149	78.34% 79.07%	188	74.47%	2,826
31	21140	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
37	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 more than 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 nine 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 service area will have more cardiac surgery discharges in that service area, and thus will be more likely to reach the required 660 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 25%. 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 (<25%), 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			
<i>37</i>	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

The Alternative Model purports to apply three market share assumptions, 17%, 20%, and 22%. The Alternative Model identifies 18-20% as a "normative market share." Revised Recommended Decision, p. 32.

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 has a market share below 25%, representing a combined, average weighted MSGA market share of 7.82%. While the utilization projection will differ slightly based on the 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 – more than double AAMC's MSGA average market share in those Zip Codes.

In contrast, the population in the Zip Codes in UM BWMC's 85% MSGA service area in which it has less than a 25% market share comprises only 26% of its total 85% MSGA service area population (86,383 / 330,743).

Table 5
BWMC MSGA Market Share by Zip Code
Selected Zip Codes (<25%), CY 2014

		Baltimore Washington Medical Center							
		BWMC MSGA	Total MSGA Discharges in	BWMC's MSGA	MSGA Population				
<u>#</u>	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 attributed to it within the service area in order to meet the Alternative Model.

The most striking 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. In contrast, it has only ten cardiac surgery 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.

- B. The Alternative Model makes several assumptions that are inconsistent with the actual experience of Maryland hospitals, including UM BWMC.
 - (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 areas, based on the experience of Washington Adventist Hospital ("WAH"), UM St. Joseph's Medical Center, and Suburban Hospital, with little analysis.

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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.

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

Hospital Name	Population	Cardiac Surgery Discharges			Open He	art Surgery	Discharges	
			<u>Outside</u>	% Outside		<u>Outside</u>	% Outside	
	MSGA (Ages 15+)	<u>85% SA</u>	<u>SA</u>	<u>SA</u>	85% SA	<u>SA</u>	<u>SA</u>	
Maryland hospitals with	Maryland hospitals with cardiac surgery programs							
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	1	3.4%	
PRMC	160,459	341	90	20.9%	332	88	21.0%	
Sinai	1,338,031	245	137	35.9%	243	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	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 Revised Recommended Decision suggests WAH's experience is analogous because it is in a suburban area (Revised Recommended Decision, p. 32, n.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.)¹⁰

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

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.

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 Revised 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

Source: Revised Recommended Decision, Table 5B.

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 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 an MSGA 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. The model also disregards the applicants' more relevant cardiology market share. UMMS has a 51% market share for cardiology throughout the proposed UM BWMC cardiac surgery service area including a 47.8% market share in Anne Arundel County and a 77.5% market share in the Mid Shore counties. By contrast, AAMC's cardiology market share in the UM BWMC cardiac surgery area is only 22.9%. (DI #48GF p. 17 and Exh. 52.) Despite these significant differences in actual market share experience, the Alternative Model assigns each party a flat 18-20%.

Second, the assumption is driven, in part, by the experience of WAH. Revised Recommended Decision, p. 29, n.32. 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.)¹¹ 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 Shady Grove. In addition, WAH, Suburban, and St. Joseph's Medical Center all have competing cardiac programs in close proximity.

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.

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 hospital, if approved, would have 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 significantly different than the experience of the applicants. Despite the substantial evidence entered into the record by both applicants that would have allowed the Reviewer to develop a model that considered these factors, the Alternative Model and Revised Recommended Decision give them no weight at all.

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

	MSGA Discharges	Total MSGA Discharges	MSGA Market
Hospital	in 85% MSGA SA	in 85% MSGA SA	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 *greater* than their MSGA market share in the same Zip Codes. This makes sense because there are fewer cardiac surgery hospitals than acute care hospitals. One should logically conclude that a hospital would achieve a greater market share in a service for which it has far fewer competitors. 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. EXCEPTION NO. 3: THE REVISED 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. The Reviewer failed to consider the primary driver of volume for UM BWMC's project, and thus rejects, without any justification, the entire premise of UM BWMC's program.

UM BWMC proposed a unique project that would expand the existing University of Maryland Cardiac Surgery Services Program to an additional location at UM BWMC. (BWMC DI #8BW, 4). The proposed program at UM BWMC would be part of the existing University of Maryland Cardiac Surgery Program currently located at the UMMC and University of Maryland St. Joseph Medical Center ("UM SJMC") and operated as one program by the UM Division of Cardiac Surgery. Id., 5. With approval of the proposed project, UM BWMC would join the program, making one program at three locations. 12

The primary driver of cardiac case volume under UM BWMC's proposal is the deliberate shifting of cases from UMMC to UM BWMC. 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. As described in UM BWMC's application, the project would allow UMMS cardiac surgery patients to seek treatment "at lower cost, and in a more

Also, the UM Division of Cardiac Surgery operates the cardiac surgery program at PGHC, although that program presently is part of the Dimensions Healthcare System.

accessible and convenient location for patients and their families and friend support networks." Id., 5.

UM BWMC reasonably assumes that a significant number of UMMS patients who live closer to UM BWMC will 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, 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, Exh. 44, attached as **Exhibit 2**.) 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.

The Revised Recommended Decision notes the advantages of UM BWMC's affiliation with UMMS throughout the decision, including the fact that such affiliation may drive volume as UMMS shifts cases from the costlier UMMC academic medical center to UM BWMC. For example, the Revised Recommended Decision contains the following findings:

- "Both applicant hospitals have bases of support that could, theoretically, allow either hospital or both hospitals to achieve the minimum surgery case volume threshold included in the Cardiac Surgery Chapter of 200 cases by the second year of operation." (Revised Recommended Decision, p. 34.")
- "BWMC's system affiliation with UMMC is clearly a factor that could potentially provide the means for overcoming this organic service area weakness if, in collaboration with clinicians, it could shift large amounts of clinicians' caseload from UMMC to the new BWMC program, producing a very high market share for BWMC." (Id., p. 79.)

- "Each applicant is working with a system affiliate or partner hospital that is an academic medical center. Together, the two collaborating hospitals are the largest providers of cardiac surgery in Maryland and each applicant hospital is a relatively large community hospital with substantial experience in providing major surgery procedures and helping patients recover from major surgery." (Id., p. 96.)
- "Each proposed project is appealing in that it would engage the Maryland academic medical centers in support of a community hospital, in a partnership or as a system component. The basis of the appeal is the promise this brings for development of high-quality programs, sharing clinical resources, while also reducing charges for cardiac surgery cases that shift from the higher charge academic medical centers and other higher charge urban hospitals to the lower cost settings of AAMC and BWMC." (Id., p. 121.)

Despite this recognition, the Revised Recommended Decision minimum volume analysis fails to give <u>any</u> consideration to UM BWMC's proposed full integration with the UM Division of Cardiac Surgery, Maryland's largest cardiac surgery program. ¹³ Revised Recommended Decision, p. 34 ("My baseline analysis did not account for the impact of collaborative initiatives to shift case volume to BWMC, from UMMC, and to AAMC from JHH.") Indeed, none of the so-called comparison hospitals relied on by the Reviewer to form the assumptions that underlie the Alternative Model developed a cardiac surgery program as a part of an existing, fully-integrated system. ^{14,15}

The UM Division of Cardiac Surgery had 1440 cardiac surgery discharges in CY 2014 alone. See Table 6.

UM SJMC is now a part of the UM Department of Cardiac Surgery. However, its cardiac surgery program was developed long before that affiliation, and the program had many years of full volume prior to the affiliation. Thus, its referral patterns were strongly established, and it does not rely on a significant referral relationship with UMMC as UM BWMC would.

To a lesser degree, the same criticism applies to the application of the Alternative Model to AAMC, because the model fails to give any weighted consideration to AAMC's license agreement with JHH. However, this affiliation would result in far fewer cases than UM BWMC's full integration with UMMS.

Thus, the Revised Recommended Decision supplants the applicants' evidence and assertions regarding minimum volume in favor of the invented, overly simplified Alternative Model, which is based on established MSGA inpatient service areas. Revised Recommended Decision, p. 37. The Revised 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." Revised Recommended Decision, p. 34. 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 Revised Recommended Decision demonstrates that the Reviewer failed to sufficiently analyze and understand the parties' submissions. The Reviewer acknowledges that "[b]oth applicant hospitals have bases of support that could, theoretically, allow either hospital or both hospitals to achieve the minimum volume surgery case volume threshold included in the Cardiac Surgery Chapter of 200 cases by the second year of operation." Revised Recommended Decision, p. 34. Yet he concludes, with no support, that "AAMC would likely require less proactive support in shifting cases from JHH," and suggests that JHH "may be able to facilitate a greater shift of Anne Arundel residents to a program at AAMC" than AAMC has assumed. Revised Recommended Decision, p. 34. Thus, the Reviewer simultaneously, and inconsistently, suggests that AAMC would require less support from JHH than UM BWMC would require from UMMC, and that AAMC might receive even more support from JHH than even AAMC has projected.

The Revised 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, Exh. 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. The Reviewer's attempt to categorize UM BWMC's reliance on proactive support from UMMS, with which its cardiac surgery program will be fully integrated, as a weakness should be rejected – UM BWMC's proposed, fully integrated program with the state's largest cardiac surgery program is its greatest strength.

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 10 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 11	
21144	26,465	13		
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	330,743	191	176	

Table 11 JHH Cardiac Discharges in Applicant MSGA Service Areas 85% MSGA Service Area for AAMC, CY 2014

AAMC MSGA	Service Area	The Johns Hopkins Hospital Cardiac Open Heart	
	CY14 MSGA	Surgery	Surgery
Zip Codes	Population	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

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

B. UM BWMC documented that it would achieve minimum volume consistent with the minimum volume standard.

In response to the minimum volume standard, UM BWMC documented that its program would "attain a minimum annual volume of 200 cardiac surgery cases by the end of the second 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). The Reviewer did not substantively address UM BWMC's documentation, other than to recognize that "BWMC's approach to evaluating the demand it would likely experience as a cardiac surgery hospital was also practical and sufficiently documented." ¹⁶

UM BWMC summarized its minimum volume and need analysis in a document identified in the review as Exhibit 44 (DI #8BW, Exh. 44, attached as **Exh. 2**), which describes how many cases UM BWMC expects would shift from UMMC, other Maryland hospitals, and D.C. hospitals. UM BWMC also documented minimum volume through referral letters, which UM BWMC estimated would result in 259 cases of appropriate severity being performed at UM BWMC. (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.

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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. This language was removed from the Revised Recommended Decision. The Reviewer confirmed, however, that changes made in the Revised Recommended Decision "did not materially alter my findings or conclusions. . . ." March 3, 2017 Memorandum to the Revised Recommended Decision, p. 2.)

As recognized by the Reviewer, UM BWMC's approach to demonstrating minimum volume was "practical and sufficiently documented." (DI #98GF, p. 96). The Revised Recommended Decision further acknowledges that "[b]oth applicants forecast the ability to reach a level of cardiac surgery that would result in compliance with the standard." Revised Recommended Decision, p. 30. Yet, the Reviewer 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 Revised Recommended Decision states that the Alternative Model is not intended "as a rejection of the applicants' response to this standard." Id., p. 29. Yet, the Revised 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 Revised 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 does not meet 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 their likely cardiac surgery service areas and the market share levels they forecast, especially with respect to market share outside the collaborative framework that is proposed by both applicants to 'steer' case volume to their new

programs from affiliated hospitals, cannot be characterized as conservative." <u>Id.</u>, p. 29. 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 cardiovascular market share.¹⁷

The third factor that resulted in the finding that UM BWMC did not meet the minimum volume standard results from the Revised 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 Revised 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." Revised Recommended Decision, p. 34.

As the Reviewer has acknowledged, 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 Revised 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.

UMMS has a 51% market share for cardiology throughout the proposed UM BWMC cardiac surgery service area, including a 47.8% market share in Anne Arundel County and a 77.5% market share in the Mid Shore counties. (DI #48GF p. 17 and Exh. 52.)

C. UM BWMC's market shift assumptions for non-UMMC cases 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, Exh. 44, attached as **Exh. 2**.) 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 12
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, Exh. 44

The Revised Recommended Decision provides no justification for its conclusion that this 20% market share assumption is not conservative. Other data submitted in the Revised Recommended Decision and in the review shows it is not. For example, the Revised 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 *greater* 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 13
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.

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

IV. <u>EXCEPTION NO. 4</u>: THE REVISED 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 Revised 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.) Indeed, only 30.7% of UM BWMC's projected volume would shift from hospitals other than UMMS affiliated hospitals. (DI #42GF, 2.) Therefore, the Reviewer correctly concludes that UM BWMC complies with Standard .05A(2) as well as the impact review criterion. Revised Recommended Decision, pp. 43, 45.

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 Revised Recommended Decision overlook this harm. Indeed, they even fail to assess the extent of the impact on PGHC. Initially, AAMC dismissed its obligation to quantify the estimated shift in volume from PGHC, claiming that PGHC was not entitled to be protected from adverse impact because it lacked sufficient volume in CY 2013 and AAMC had not transferred any patients to PGHC for cardiac surgery. (DI #45GF, p. 27.)

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. AAMC assumed no impact on PGHC's cardiac surgery program as a result of a new program at AAMC, based primarily on its use of CY 2013 data, when PGHC had just 3 cardiac surgery discharges in AAMC's proposed cardiac surgery service area. (DI #3AA, p9. 92, 138.) Even after PGHC supplemented the record with data demonstrating substantially increased volume (more than 100 cardiac surgery discharges 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. Instead, it claimed that it was proper to account only for impact on hospitals to which AAMC physicians have transferred or referred patients for cardiac surgery. (DI #66GF, p.4.) There is no valid

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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.

basis for excluding a hospital that will be impacted merely because AAMC has never referred a patient to the hospital.

Unlike AAMC, the Reviewer recognizes that a new cardiac surgery program at AAMC would draw volume from PGHC. Revised Recommended Decision, p. 45. But he finds, without any quantitative analysis, that there is a sufficiently large market of cardiac surgery cases to support both AAMC and PGHC. <u>Id</u>. This conclusion is not based on any meaningful impact analysis, such as a zip code level analysis of likely market share shift by provider after the establishment of a new program AAMC. Rather, the Revised Recommended Decision merely lists the volume of adult cardiac surgery cases in 11 Maryland counties in FY 2014, totaling 3,470 cases, and concludes that the market for cardiac surgery cases is large enough to support both PGHC and AAMC. Revised Recommended Decision, p. 45.

This simple and superficial conclusion fails to take into account a number of important factors and considerations. First, at least a dozen other cardiac surgery programs in Maryland and elsewhere compete for cardiac surgery cases involving patients who live in the 11 Maryland counties, and the Reviewer does not assess how much volume should be attributed to each competing provider. Second, PGHC's cardiac surgery service area does not extend into 11 counties throughout the State, so it does not compete for many of the cases included in the large count of available volume. Also, reliance on the total number of cardiac surgery cases in 11 Maryland counties as conclusive support for a finding that the market is sufficiently large to support cardiac surgery programs at both PGHC and AAMC conflicts with the Reviewer's Alternative Model for determining that UM BWMC would not likely achieve 200 cardiac surgery cases in its second year of operation. If PGHC can be expected to achieve more than 200 cardiac surgery cases based merely on the large volume of cases available throughout much

of the State, how could the Revised Recommended Decision conclude that UM BWMC cannot achieve the same results drawing from the same "more than enough" volume?

The only quantitative analysis of AAMC's likely impact on PGHC was submitted by PGHC, which 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.) In particular, PGHC analyzed the cardiac surgery volume in the Zip Codes in PGHC's service area that overlap with AAMC's proposed cardiac surgery service area, and showed that 40% of its volume derives from the area of overlap. (DI #62GF, pp. 8-10.)

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 Revised 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 requires 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 Revised 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." Revised Recommended Decision, p. 44. There is no valid basis for this finding. Other statements in the Revised 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 and additional programs in Maryland, in terms of access, cost reduction, and quality of care, against the negative impact on these existing programs." Revised Recommended Decision, p. 45. Moreover, in summarizing the Revised Recommended Decision, the Reviewer again repeats that there likely would be sufficient volume for both PGHC and AAMC to achieve 200 cases, but states: "[o]bviously, neither program is guaranteed to succeed nor is it the objective of this review to provide such guarantees." Revised Recommended Decision, p. 123.¹⁹

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

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In the original Recommended Decision, issued on December 30, 2016, the following sentence followed this language: "I do not believe that Maryland stakeholders should forego the positive gains offered in the AAMC project to shelter existing competition from healthy competition." (DI #98GH, p. 118.) This sentence was deleted, but the sentiment continues.

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 March 3, 2017, 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 March 3, 2017 Memorandum, p. 3. Yet, the Revised Recommended Decision shows no such regard for saving PGHC's cardiac surgery program from the same possible fate of closure.

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, Exh. 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). <u>Id.</u>, 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.; Revised Recommended Decision, p. 44. 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.²⁰

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

In fact, the cardiac surgery program at PGHC was already experiencing significant

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.

likely impact on the reviving PGHC program. The Reviewer instead closed the record on the impact issue. (DI #92GF.)

C. If the same assumptions used in the Revised 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 Revised 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 Revised 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 Revised 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 a 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 Revised 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 a meaningful 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 REVISED 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 Revised 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 Revised 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, Exh. 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, 2014²¹ 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 Revised Recommended Decision as Appendix 3, p. 1.))

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

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.

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. (DI #94GF, Exh. 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. Id. 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. (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, Exh. 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 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%

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 Table J, the revenue and expenses (uninflated) for the cardiac surgery service – Table J-1 and Table J-2. Id.

AAMC's Table J-1 portrayed revenue as equal to billable charges, and thus violated 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

variable cost factor, while the October 17, 2016 projections calculated revenue based on a 50% variable cost factor, as demonstrated in Table 1.

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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).

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 Revised 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 Revised Recommended Decision 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. CBS, Inc., 319 Md. at 698 (agencies must engage in rulemaking when: (1) changing a policy or rule of general application, and (2) applying the new rule retroactively to the detriment of a company that relied on the agency's past pronouncements). It is improper to change the standard in the context of a contested case under these circumstances.

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, as a stand-alone service line, 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.²⁴

The interpretation of a regulation is governed by the same principles that govern the interpretation of a statute. <u>Maryland Comm'n on Human Relations v. Bethlehem Steel Corp.</u>, 295 Md. 586, 592–93 (1983) (collecting cases). The starting point of statutory interpretation "is

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:

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

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." Kushell, 385 Md. at 577; see also The Arundel Corp. v. Marie, 383 Md. 489, 502 (2004). 25

Here, citing the "simple initial statement of the standard," 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." Revised Recommended Decision, p. 99 (emphasis added). The "initial 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

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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)

standard is inconsistent with the regulation, and the Commission should reject the Reviewer's proposed finding.

As a threshold matter, the Revised 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. 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). 27

It is not enough to simply cite the general "initial 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." <u>Bd. of Cnty.</u>

<u>Comm'rs of Garrett Cnty. v. Bell Atlantic-Maryland, Inc.</u>, 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." <u>J.P. DelpheyLtd. P'Ship v. Mayor and City of Federick</u>, 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.

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[&]quot;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."

[&]quot;It is our duty to give effect, where possible, to every clause and word of a statute."

Even when separately considering only the initial statement in Standard .05A(7), the Reviewer's findings should be rejected. The initial 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 Revised 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." Revised Recommended Decision, p. 97 (emphasis added). This should have been the end of the analysis. See Crofton Convalescent Ctr., Inc., 413 Md. at 215.²⁸

Nevertheless, the Revised 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 had been possible to know in the 2013 to 2014 period during which the Cardiac Surgery Chapter was developed, how HSCRC would elaborate its payment model to account for shifts in market share for specific services from one hospital to another in adjusting GBR, the Commission would not have adopted a financial feasibility standard that required a new service line, on a stand-alone basis, to generate revenue over expenses.

Revised Recommended Decision, p. 98. 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 supposedly "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. <u>See</u> Revised Recommended Decision, p. 98. Indeed, the current version of the State Health Plan's cardiac surgery chapter was adopted on October 15,

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[&]quot;[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."

2015 and became effective on November 9, 2015 after the HSCRC finalized its market shift policy. Revised Recommended Decision, p. 98.²⁹ If the Commission deemed it necessary to modify the financial 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

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 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).

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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."

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 § 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 Revised Recommended Decision, it will change the plain language of the financial feasibility standards for proposed cardiac surgery programs. The Commission will have, in effect, 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." Mdd. 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." Id. § 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 the Revised Recommended Decision neither elaborates on

this approach nor relies upon it as the primary method for finding financial feasibility, the Reviewer 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.

Revised Recommended Decision, p. 99.³⁰

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 Revised Recommended Decision's suggestion that

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In that portion of the Revised Recommended Decision entitled "Reviewer's Recommendation," which summarizes the bases of the recommendations, there is no mention of the "conventional accounting perspective" as a basis for finding financial feasibility. Instead, the Reviewer states: "[i]n terms of the financial feasibility standard, I find that when the entirety of that standard and the context of its adoption are considered, the Commission's regulatory intent was to permit flexibility in its assessment of financial feasibility at the hospital level and that AAMC meets the financial feasibility standard at the hospital level."

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).³¹

At bottom, it is inaccurate and a violation of the State Health Plan for the Revised 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 financial impact of the variable cost factor. (DI #3AA, pp. 62, 160-164; DI #94GF, Exh. 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, Exh. 39.) AAMC wants the benefit of both contradictory methods. It should not be permitted to show that the proposed cardiac surgery program will be feasible because it will generate revenue based on 100% of the charges, while at the same time it suggests that the program will generate only 50% as much revenue when analyzing cost effectiveness.

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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.

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

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:

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 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. The HSCRC has the ability to grant rate increases in GBR revenue if GBR methodology does not provide sufficient revenue. Similarly, the HSCRC has the authority to permit variable cost adjustments greater than 50%. In fact, 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) "virtually 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.

Cost-Effectiveness, COMAR § 10.24.17.05A(4)), COMAR § 10.21.01.08G(3)(c))

- VII. EXCEPTION NO. 7: THE REVISED 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 Reviewer expressly finds that UM BWMC meets the requirements of the cost effectiveness standard elsewhere in the Revised Recommended Decision.

The Reviewer fails to perform an analysis of UM BWMC's cost effectiveness under the relevant standard, instead making the general, inaccurate assumption that UM BWMC would not be cost effective at the lower volumes projected by the Alternative Model. Yet, the Reviewer expressly acknowledges the cost effectiveness of UM BWMC in other sections of the Revised Recommended Decision. The following statement appears in the discussion of COMAR \$10.24.01.08G(3), Viability:

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

Revised Recommended Decision, p. 121. This finding is directly consistent with the requirements of the cost effectiveness standard, COMAR § 10.24.17.05A(4) ("Standard .05A(4)"). More importantly, this finding directly contradicts the Reviewer's conclusion under Standard .05A(4) that UM BWMC "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." Revised Recommended Decision, p. 65.

The refusal to acknowledge that UM BWMC meets Standard .05A(4) is not supported by any analysis of UM BWMC at the lower volumes projected by the Alternative Model. Indeed, as described more fully below, such an analysis would demonstrate the UM BWMC's program would be cost effective even at that volume. The Reviewer's conclusion to the contrary is thus not supported or supportable, and suggests that the finding is simply a result-driven rather than based on the actual facts of UM BWMC's proposal that the Reviewer recognizes elsewhere. This inconsistent finding must be rejected.

B. The cost effectiveness standard is not predicated on reaching minimum volume.

The Revised 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.³² However, the cost effectiveness standard makes no reference to minimum volume and is independent of the minimum volume

I found that BWMC has not demonstrated that it can establish a cardiac surgery program large enough to meet the minimum volume standard in the Cardiac Surgery Chapter, especially if AAMC's proposed program, which is likely to meet the minimum volume Standard, is approved. Coupled with BWMC's more modest projection of system savings, predicated on reaching higher volumes than I have found 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.

Revised Recommended Decision, p. 65.

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

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 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.

<u>Id</u>. 33

UM BWMC met subparts (b) and (c) of Standard .05A(4) by providing the requested analyses. DI #8BW, 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." Standard .05A(4).

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

C. UM BWMC is cost effective even at the lower volumes projected by the Recommended Decision.

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

Table 14
Healthcare System & Medicare Savings Analysis
CY 2020

		 вимс
Rate Center Methodology Charge per Case (1)		\$ 51,952
CY 2020 Cardiac Surgery Cases (1)	(A)	100
CY2020 Incremental Charges to Payors	(B)	\$ 5,195,200
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
CY 2020 Cardiac Surgery Cases (1)		 100
CY2020 Incremental Gross Charges		\$ 4,049,007
Variability Factor		50.0%
Approved GBR Adjustment CY 2020	(C)	\$ 2,024,503
Projected Healthcare System Charge Savings	(D) = (B) - (C)	\$ 3,170,697
CY 2020 Hospital-Wide Medicare Payor Mix (3)		40.0%
CY 2020 Medicare Charge Savings		\$ 1,268,279
Medicare Differential, including 2% sequestration (2)		92.0%
CY 2020 Medicare Payment Savings (4)		\$ 1,166,816
Average Healthcare System Charge Savings per Case	(E) = (D) / (A)	\$ 31,707

Note 1: Revised Recommended Decision, Table 10. CY 2020 volume at 20% market share (100 cases)

Note 2: DI #8AA, p.168

Note 3: DI #8BW, Exh. 1.

Note 4: Excludes impact of existing providers on Medicare payments

As demonstrated in the above table, even at the lower volume projected by the Revised Recommended Decision's Alternative Model, UM BWMC's program would achieve almost \$3 million in savings to the healthcare system in CY 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 Revised 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 supposedly overstated, together with the failure of the Revised Recommended Decision to take the next logical step and analyze the cost savings at the volumes projected by the Revised Recommended Decision, demonstrates the overarching problems with the Revised 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 REVISED RECOMMENDED DECISION'S DETERMINATION THAT UM BWMC'S APPLICATION FAILS TO MEET THE COST EFFECTIVENESS CRITERION (COMAR § 10.21.01.08G(3)(c)) SHOULD BE REJECTED.

The Reviewer's finding that UM BWMC is not the most cost effective option for the service UM BWMC proposed to provide either misconstrues the cost-effectiveness criterion, fails to understand UM BWMC's proposal, or both. The criterion provides:

Availability of More Cost-Effective Alternatives. The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

COMAR § 10.21.01.08G(3)(c). This criterion does not require UM BWMC to demonstrate that it would be the most cost-effective provider of cardiac surgery services. That interpretation of the criterion – which applies to all certficate of need reviews, for any service – would prevent any new provider from developing or relocating a service unless its cost per case would be lower than that of any existing programs for the same service, irrespective of whether it projected drawing any volume from existing, lower cost providers. Instead, an applicant must compare the cost-effectivness of its proposal for the service the applicant proposes to provide – that is, for the discharges that would shift to an applicant if its program were approved, would the applicant be cost effective as compared to the hospitals where those patients would otherwise obtain that care? Here, the answer is indisputably yes.

The central component of UM BWMC's project is the proposal to provide a lower cost, more convenient location for the existing UM Division of Cardiac Surgery program for patients who would otherwise seek cardiac surgery at UMMC. (DI # 8BW, p. 5.) UM BWMC would be fully integrated with, and staffed by, the UM Division of Cardiac Surgery. As demonstrated in its application and in numerous letters of support from UMMC and cardiologists who would otherwise refer patients to UMMC, UM BWMC can reasonably expect these patients to be referred instead to UM BWMC and to select it as their provider.

UM BWMC projected that 151 cardaic surgery discharges would shift to it from UMMC in its second full year of operation. (DI #8BW, Exh. 44, attached as **Exh. 2**.) There is no

dispute that the shift of these discharges from UMMC, an academic medical center with significantly higher charges than UM BWMC, will result in cost savings.³⁴

The Reviewer's finding that UM BWMC does not meet this standard because the Reviewer finds that AAMC projects higher savings than UM BWMC misses the mark. AAMC does not project providing the service UM BWMC will provide. That is, AAMC does not project shifting significant volume from UMMC. Its project is principally based on shifting cases from D.C. hospitals, and it projects shifting only 29 cases from UMMC in its second full year of operation. (DI #3AA, p. 92.) Those 29 cases would very likely be from the same Zip Codes where UM BWMC projects drawing volume, and thus are appropriately considered in analyzing the cost effectiveness AAMC as an alternative to the service UM BWMC proposes to provide.

If AAMC's application is approved, and if it succeeds in shifting 29 cases from UMMC, it will still not be a more cost-effective provider of the service that UM BWMC proposes. Of the patients that UM BWMC proposes serving, 122 would instead continue to seek care at UMMC. The cost savings AAMC would achieve by performing 29 of these cases does not offset the higher cost of performing the remaining cases at UMMC rather than UM BWMC.

UM BWMC is also better positioned than AAMC to ensure that the cost effectiveness of its proposed services will not be offset by the incremental cost increases associated with the loss of these 151 cases by UMMC. As stated in UMMS' Global Budget Revenue ("GBR")

The finding that UM BWMC's cost savings are predicated on higher volume than the Reviewer finds to be likely is incorrect. UM BWMC will be cost effective even at the unreasonably low volume projected by the Reviewer. <u>See</u> the discussion under Exception 7, <u>supra</u>.

agreement with the HSCRC, GBR is a system designed to "manage [hospitals'] resources efficiently and effectively in order to slow the rate of increase in health care costs and improve health care delivery processes and outcomes." Unlike AAMC, UM BWMC is part of a fully integrated health system. According to the UMMS GBR Agreement, "the HSCRC will allow revenue to be redistributed among UMMS Hospital for movement of services to achieve the desired goals of the new All-Payer model." Id. Further, "this structure will allow UMMS to potentially move services within the System to achieve the desired goals of the new waiver."

Id. Thus, the HSCRC enacted GBR arrangements with hospitals in part to encourage strategic redistributions of services within health systems. Through its CON application, UM BWMC and UMMS seek to do exactly what the GBR system promotes. By transferring lower acuity cardiac surgery cases from UMMC to UM BWMC, patients will move from a tertiary academic medical center with higher rates to a community hospital with a lower rate structure for the same services. By adding a third location to its cardiac surgery program, UMMS is able to effectively reduce the cost of care for cardiac patients.

As a stand-alone hospital, AAMC is not part of a large system with a thriving cardiac surgery program with which to coordinate in order to directly and effectively reduce costs for patients.

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Agreement Between the Health Services Cost Review Commission and the University of Maryland Medical System Regarding Global Budget Revenue and Non-Global Budget Revenue (the "UMMS GBR Agreement"), p. 3 (http://www.hscrc.state.md.us/documents/global-budgets/Global-Budget-Revenue-Agreement-UMMS-08-06-14.pdf).

These features are unique to GBR agreements for multi-hospital health systems, such as UMMS, and are not part of AAMC's GBR agreement.

Access, COMAR § 10.24.17.05A(5)

IX. <u>EXCEPTION NO. 9</u>: THE REVISED 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 Revised Recommended Decision states that "the primary access barrier identified by AAMC is travel distance and consequent travel time." Revised Recommended Decision, p. 72. 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 Revised 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." Revised Recommended Decision, p. 73. 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 Revised Recommended Decision finds that AAMC failed to demonstrate an access barrier, inexplicably the Revised Recommended Decision finds that AAMC meets

Standard .05A(5) based on AAMC's "potential for reducing travel time and distance for the service" as a "secondary justification." Revised Recommended Decision, p. 73. 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.

The Reviewer's erroneous conclusion on this point appears to have improperly influenced the ultimate recommendation. Various statements throughout the Revised Recommended Decision show 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 supposed better geographic position as one of several reasons he recommends approval of AAMC's

proposal. (DI #121GF, Commr. Tanio's Memorandum dated March 3, 2017, 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.

Revised Recommended Decision, p. 122.

Accordingly, UM BWMC requests that the Commission reject the Revised 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.

Need, COMAR § 10.24.17.05A(6)

X. <u>EXCEPTION NO. 10</u>: THE REVISED 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.

The Revised Recommended Decision finds that UM BWMC did not meet subpart (a) of the State Health Plan need standard based solely 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. The finding that UM BWMC did not meet the need review criterion, COMAR § 10.24.01.08G(3)(b), was based solely the finding that UM BWMC did not meet the State Health Plan need standard. As addressed more fully in Exceptions No. 1-3, related to minimum volume, UM BWMC complied with the State Health Plan need criteria and demonstrated an ability to generate at least 200 open heart surgery cases per year form its

proposed service area. Thus, for reasons stated above, the findings that UM BWMC did not meet the need State Health Plan standard and review criterion should be rejected.

Additional Procedural and Due Process Issues

XI. EXCEPTION NO. 11: THE COMMISSION SHOULD REJECT THE REVISED RECOMMENDED DECISION BECAUSE IT COMPARES THE TWO PROGRAMS FOR REASONS THAT EXCEED THE SCOPE OF THE COMMISSION'S AUTHORITY AND VIOLATE UM BWMC'S RIGHT TO DUE PROCESS.

The memorandum summarizing the Revised Recommended Decision and the "Reviewer's Recommendation" that closes the decision suggest that the Revised 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 State Health Plan chapter governing this review sets forth eight review standards for cardiac surgery programs. COMAR § 10.24.17.05A. The Certificate of Need regulations that govern all Certificate of Need reviews set forth another five review criteria. Of these 13 review standards and criteria, eleven are applicable to applicants on an individual basis. That is, based on the text of the standards and criteria, the Commission must determine whether an applicant has satisfied the standards and criteria on the merits of that applicant's proposed project, irrespective of whether the application is subject to a comparative review proceeding. The only standards that authorize the Commission to compare two projects in a comparative review are the comparative review standard, COMAR § 10.24.17.05A(8), and, to a lesser extent, the cost effectiveness review criterion, COMAR § 10.24.01.08G(3)(c).

The Reviewer did not apply the comparative review standard, finding instead that it was not applicable "because [the Reviewer] did not find that both applicants have met all policies and

standards." Revised Recommended Decision, p. 100. Thus, any comparative statements made in the 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 consideration of factors outside of the 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.

Accordingly, the Revised Recommended Decision should not contain language purporting to compare the two programs as unauthorized and an impermissible abuse of authority. Further, because those statements appear throughout each section of analysis and appear to strongly influence the Reviewer's findings, the Commission should entirely reject the Revised Recommended Decision in its current form.

Specifically, the following statements and/or findings violate UM BWMC's due process rights:

- 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. (Revised Recommended Decision, p. 3.)
- I have determined that public policy favors the establishment of the single new cardiac surgery program proposed at AAMC, which is likely to result in greater savings to the health care system through lower charges and better access for the

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The cost-effectiveness review criterion requires a narrow scope of comparison as well. That standard is discussed under Exception No. 8.

- relatively large population of Anne Arundel County and the population of the Eastern Shore. (Revised Recommended Decision, p. 45.)
- The potential for maximizing the reduction of charges for cardiac surgery led me to closely and seriously consider the ability for both of these proposed projects to go forward at this time. . . . In the end, I concluded that the most prudent approach is to recommend approval of the stronger AAMC application and to recommend denial of BWMC's weaker proposal. (Revised Recommended Decision, p. 122.)

XII. <u>EXCEPTION NO.12</u>: THE REVISED RECOMMENDED DECISION RELIES ON DATA THAT WAS NOT PROPERLY ENTERED INTO THE RECORD.

A. The reliance on data entered into the record before or without providing an opportunity to meaningfully comment violates the parties' rights to due process.

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. <u>Id.</u> 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. <u>Id.</u> at 5. ³⁸ The Court's reasoning was as follows:

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. 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.

AAMC's attempt to distinguish In re Clarksburg Community Hospital is misplaced. First, AAMC's argument is inconsistent with the plain text of the APA, which states: "Before taking official notice of a fact, the presiding officer . . . shall give each party an opportunity to contest the fact." MD. CODE, STATE GOVERNMENT, § 10-214(h)(2). Second, the case AAMC cites in support, Mehrling v. Nationwide Ins. Co., is distinguishable: it considers whether parties to a review may enter new evidence when filing exceptions. Mehrling v. Nationwide Ins. Co., 371 Md. 40, 58-60 (2002). It makes no finding regarding the entry of facts into the record by an agency or person acting in the capacity of an Administrative Law Judge. The distinction is important because an Administrative Law Judge's decisions regarding evidence admitted into the record are restricted by the parties' rights to due process. Third, AAMC provides no support for its conclusion that the decision in In re Clarksburg Community Hospital, which considered a factually analogous case before the Maryland Health Care Commission, is incorrect. To the contrary, that decision is directly on point and expressly finds that the Reviewer may not do what occurred in this review. In re Clarksburg Community Hospital (Balt. City Cir. Crt., Feb 21, 2012) No. 24-C-11-001046 (Pierson, J.), p. 5 ("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.").

Id. at 5.

As demonstrated by the following table, the were not given the opportunity to contest data before its entry into the record. The data, and the Alternative Model based upon it, should be rejected for this reason alone.

Table 15
Data entered into record, opportunity to comment

Data / Facts	(1) Disclosure of reliance on data / disclosure of purpose for which data would be used (if different)	(2) Opportunity to comment ¹	(3) Entry of Data into the Record	(4) Reliance on Data / Facts by Reviewer
Virginia Health Information data set	Jan. 23, 2017	Before entry: none After entry: Feb. 3, 2017 ³	Jan. 23, 2017 ³	Dec. 30, 2016, Mar. 3, 2017
CY 2015 and 2020 population projections	Dec. 30, 2016	Before entry: none After entry: Feb. 3, 2017 ⁴	Dec. 30, 2016 / Jan. 23, 2017 ⁴	Dec. 30, 2016, Mar. 3, 2017
CY 2020 use rates	Dec. 30, 2016	None	Dec. 30, 2016 ⁵	Dec. 30, 2016, Mar. 3, 2017
HSCRC discharge database	Oct. 5, 2016 / Dec. 30, 2016 ⁶	None	Dec. 30, 2016 ⁶	Dec. 30, 2016, Mar. 3, 2017
DC discharge database	5, 2016 / Jan. 23, 2017	None	Oct. 5, 2016 ⁶	Dec. 30, 2016, Mar. 3, 2017

Note 1: Exceptions filing not included as opportunity to comment. See In re Clarksburg Community Hospital.

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Note 2: Opportunity insufficient to comply with APA because not provided before entry of data into the record.

Note 3: Information sufficient to analyze relevance of data still missing, as discussed below.

Note 4: The January 23, 2017 Ruling acknowledges that the data was first provided (Dec. 30, 2017) without any key identifying what the years the data represented. That key was provided on January 23, 2017. (DI #105GF)

Note 5: Disclosure of assumptions sufficient to replicate analysis not provided until March 3, 2017.

Note 6: Reviewer gave notice of reliance on October 5, 2016. However, the data was not entered into the record in this review until January 25, 2017. (DI #108GF). Moreover, the Reviewer did not give notice that the data would be used for the purposes of assessing minimum volume until December 30, 2016, for the HSCRC database, and until January 23, 2017 for D.C. database.³⁹

As discussed more fully in UM BWMC's February 3, 2017 comments, parties cannot sufficiently oppose the admissibility of data without notice as to the purposes for which the data will be used. Under the Administrative Procedure Act ("APA"), the Reviewer may exclude evidence that is irrelevant. Md. Code Ann., State Gov't § 10-213(d)(2). The Maryland Rules define "relevant evidence" to mean "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Maryland Rule 5-401. In other words, relevant evidence

Moreover, the parties were not given a meaningful opportunity to contest the data even after its entry. The January 23, 2017 Order allowed the parties to comment only narrowly on the VHI dataset and CY2020 population projections. This opportunity was not meaningful because in providing the opportunity, the Reviewer expressly stated that the Recommended Decision would not be withdrawn, making it plain that the Reviewer had no intention of allowing the parties' comments to alter his findings regarding the admissibility of the data. The Reviewer also did not issue any ruling on UM BWMC's comments regarding the data, either in the Revised Recommended Decision or as a separate ruling.

As set forth more fully in UM BWMC's comments on that data, and under Exception 2, supra, the data was not admissible for at least two reasons. First, the data was not relevant. The Alternative Model relies upon an unsupportable premise that there is a correlation between the population size of a hospital's MSGA service area, and the hospital's case volume from all geographic locations. See Exception No. 2. Second, the VHI data set lacks sufficient information to be reliable. The State Health Plan chapter applicable to this review contains a definition of "Cardiac Surgery" that is based on International Classification of Disease (9th Revision) procedure codes ("ICD-9 codes"). COMAR § 10.24.17.09 (Aug. 18, 2014). The data provided from Virginia hospitals does not indicate how cardiac surgery is defined or contain

tends to either establish or disprove issues in a case. <u>Parker v. State</u>, 156 Md. App. 252, 268, <u>cert. denied</u>, 383 Md. 347 (2004). Evidence that is not relevant is not admissible. Maryland Rule 5-402. It is not possible to determine the relevance and admissibility of evidence without assessing the purpose for which it is offered, because one could not determine that the evidence

tends to prove or disprove an issue in the case. See DI #112GF.

For this same reason, AAMC's response that the HSCRC and D.C. discharge data had been used in the parties' applications does not demonstrate that the data were admissible for the purpose of creating an alternative forecast model. The parties should have been given the opportunity to comment on the use of the data to create that model.

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ICD-9 codes. Thus, there is no way, from the available record, to determine whether the cases reported as cardiac surgeries would meet the definition of cardiac surgery that applies to this review. ⁴⁰

B. The entry of new data and Alternative Model projections demonstrate a genuine issue of 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.

An evidentiary hearing is the proper forum for allowing the parties – and the Reviewer – to better contest or support the Alternative Model. Such a hearing would require the Reviewer place into evidence all assumptions used for the model, and would allow the parties to question the sources and assumptions used in forming the Alternative Model and argue that the underlying

As this Commission's regulatory history demonstrates, ICD-9 codes that are considered cardiac surgery can change over time. Cardiac surgery, as defined in the version of the applicable State Health Plan chapter that became effective on August 18, 2014, and governs this review, contains 48 ICD-9 codes that are not included in the definition of cardiac surgery included in the version that went into effect just 14 months later, on November 9, 2015. Also, the November 9, 2015 version contains 25 ICD-9 codes that are not included in the earlier version. *Compare* COMAR § 10.24.17.09 (Aug. 18, 2014) with COMAR § 10.24.17.11(8) (Nov. 9, 2015). Although the Revised Recommended Decision, n.45, p. 28, states "VHI-filtered dataset using the Cardiac Surgery Chapter definition of cardiac surgery effective August 17, 2014," UM BWMC is unable to determine whether the Revised Recommended Decision relies on an updated data set that was not provided to the parties, or whether the decision relies on some other record not provided to the parties that would allow them to determine how the data was filtered or how cardiac surgery was defined.

data is 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.") An evidentiary hearing would also allow the parties to demonstrate to the Reviewer how the Alternative Model discounts the entire premise of UM BWMC's program – shifting cases from its service area that are currently performed by its affiliate to its more cost efficient and geographically convenience location.

While an evidentiary hearing is a time-consuming endeavor, it is for good reason. It allows the parties and Reviewers to disclose and discuss all data and assumptions via a formal, in person exchange, leading to far less opportunity for data and assumptions to be inadvertently omitted, not sufficiently disclosed, or misconstrued. As the record in this review demonstrates, use of data and methodologies through the written comment process can cause substantially more delay.

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

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

CONCLUSION

For the reasons set forth above, UM BWMC respectfully asks that the Commission reject the Revised 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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March 10, 2017

Table of Exhibits

	Description				
1.	Prior cardiac surgery CON decisions				
	A <u>In re Metropolitan Washington Open Heart Surgery Review</u> , Docket				
	Nos. 04-15-2133, 04-15-2134, and 04-15-2135, Recommended				
	Decision (July 21, 2005)				
	B In Re Central Maryland Open Heart Surgery Comparative Review,				
	Docket Nos. 91-24-1624, 91-24-1625, 91-24-1626, Final Decision,				
	(June 8, 1993)				
	C In Re Western Maryland Open Heart Surgery Review, Sacred Heart				
	Hospital, Docket No. 97-01-2012, Recommended Decision (Aug. 31,				
	1999)				
	D In re St. Agnes Hospital, Sinai Hospital, Franklin Square Hospital,				
	and Maryland General Hospital, Docket Nos. 86 24 1373, 86 24 1371,				
	86 03 1372, 86 24 1373), Final Decision, (January 23, 1990)				
	E <u>In Re PGHC, AMI Doctors' Hospital</u> , Docket No. 82-16-1051,				
	Docket No. 82-16-1057 Recommended Decision (Oct. 20, 1989)				
2.	UM BWMC Cardiac Surgery Projected Cases (DI #8BW, Exhibit 44)				
3.	Decision - In re Clarksburg Community Hospital (Balt. City Cir. Crt,				
	Feb. 21, 2012) No. 24-C-11-001046				

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of March 2017, the University of Maryland Baltimore Washington Medical Center's Exceptions to Revised Recommended Decision was sent via email and first-class mail to:

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I hereby declare and affirm under the penalties of perjury that the facts stated in UM BWMC's Exceptions to the Reviewer's Revised Recommended Decision and its attachments are true and correct to the best of my knowledge, information, and belief.

March 10, 2017

Date

Alfred Pietsch

Senior Vice President and CFO

UM BWMC

EXHIBIT 1A SEE CD FOR FULL DECISION

IN THE MATTER OF	*	
	*	
METROPOLITAN WASHINGTON	*	BEFORE THE
	*	
OPEN HEART SURGERY REVIEW	*	MARYLAND HEALTH
	*	
Holy Cross Hospital	*	CARE COMMISSION
Docket No. 04-15-2133	*	
	*	
Southern Maryland Hospital Center	*	
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	*	
Suburban Hospital	*	
Docket No. 04-15-2134	*	
	*	

Reviewer's Recommended Decision

July 21, 2005

The Reviewer considered information related to existing cardiovascular quality improvement activities and systems used for public reporting of performance measures. Publicly reported quality measures for AMI, pneumonia, and heart failure are provided in Appendix C, Table C-14. The Reviewer also considered the historical deficiencies of each applicant hospital, such as the hospital's compliance with Maryland or federal legal requirements for the provision of health care services, payment for health care services, and quality of health care services. These measures are factors in determining a hospital's willingness and ability to implement the quality review activities associated with the proposed OHS/PCI program. The three applicant hospitals in this CON review are currently licensed, certified, and accredited by JCAHO. Appendix C, Table C-13 provides information about previous deficiencies cited and JCAHO accreditation.

The Reviewer finds that the three applicants meet the standard regarding a quality review program for the proposed PCI program.

- (4) <u>Minimum Cardiac Surgery Volume.</u> Each applicant shall document that the proposed cardiac surgery program will maintain the following minimum operating volumes.
 - (i) For an adult cardiac surgery program, a minimum caseload of 200 open heart surgery cases per hospital per year;
 - (ii) For a pediatric cardiac surgery program, a minimum caseload of 130 cardiac surgery cases per hospital per year; and
 - (iii) For programs performing both adult and pediatric cardiac heart surgery, a minimum caseload of 50 pediatric cardiac surgery cases per year, and 200 adult open heart surgery cases per hospital per year.

Applicant Responses

Holy Cross Hospital

HCH states that it will maintain a minimum of at least 200 open heart surgery cases per year. HCH points to its current overall and cardio-specific case volumes which suggest HCH can easily reach and surpass the minimum. HCH states it will maintain at least the minimum volume because it has the strong support of its physicians and the community (as demonstrated by letters of support), the commitment from Kaiser Permanente to send its subscribers to HCH for open heart surgery, and its historical service to cardiovascular patients. These indicators, along with the following factors, lead HCH to the conclusion that it will exceed minimum OHS volume requirements:

- Using the use rates published in the Maryland Register associated with its CON review, and estimates of 2008 population, HCH estimated that there will be 2,163 OHS cases in Montgomery and Prince George's Counties in year three of its proposed OHS/PCI program. Two hundred cases is less than 10% of these estimated cases, and HCH already has 10% of all cardiology (with Medical MDC5 diagnoses) discharges from this area. HCH argues that the hospital will achieve greater than 10% of the cases given the limited availability of OHS services.
- HCH has a 13% share of all patients from Montgomery and Prince George's Counties who go to Maryland or Washington, D.C. hospitals for care.

- In fiscal year 2003, there were 298 cardiovascular patients needing OHS or PCI who were transferred from HCH to other hospitals for care.
- Kaiser Permanente had 183 OHS cases in 2003 that could go to HCH in the future.
- HCH had 2,601 cardiac patients (with MDC5 diagnoses) in fiscal year 2003. (HCH, D.I. # 3, pgs. 62-63)

Southern Maryland Hospital Center

SMHC expects to retain and maintain substantially more than the minimum start-up volume of 200 cases per year and it is projecting that it will achieve 424 OHS cases per year by the third year of its proposed program. SMHC bases this projection upon the following factors:

- In February-March 2004, SMHC sent a survey questionnaire to all cardiologists on its staff. One of the questions on the questionnaire was: "If SMHC receives approval to provide open heart surgery, how many patients per year do you estimate you would refer to it after the program has been fully operational for at least a year?" SMHC reported that the responses to that question added up to between 424 and 432 OHS cases (some respondents answered with a range instead of a single number).
- SMHC determined that 760 adult residents of the Southern Maryland Peninsula who underwent open heart surgery in either a Maryland or District of Columbia hospital in 2002. To achieve 200 OHS cases, SMHC determined it would only have to attract 26.3% of these 760 patients residing in the Southern Maryland peninsula. In order to reach its projected volume of 424 OHS patients, SMHC notes that it would have to attract slightly more than 56% of these patients. SMHC views this task as a realistic and attainable goal that it believes it can easily reach. (SMHC, D.I. # 17, p. 187)
- SMHC points out that it is highly significant that the vast majority of patients from the Southern Maryland peninsula go to the Washington Hospital Center for open heart surgery. In 2002, 511 individuals from the area or 67% of the total 760 patients went to the WHC. SMHC states that this is one of the many reasons why SMHC is partnering with the WHC and its cardiac surgeons in the proposed SMHC cardiac surgery program. (SMHC, D.I. # 17, pgs. 187-188)
- SMHC has a large cardiology program, a factor that the hospital contends, other factors being equal, would strongly indicate that an OHS program will attract minimum volumes of OHS cases. SMHC notes that a hospital with a larger number of cardiology cases is likely to generate a larger volume of OHS cases. SMHC argues that it is very important to have the "critical mass" of cardiology patients necessary to generate a sufficient number of OHS cases in order to ensure quality and viability. SMHC reports that it has the largest number of medical (non-surgical) cardiology patients of any Maryland hospital in the Metropolitan Washington area. (SMHC, D.I. # 17, p. 188)

Suburban Hospital

Suburban conducted a survey of the cardiologists who actively practice at its hospital and asked them how many patients they would refer to an OHS program at Suburban. Based on the

results of that survey, the cardiologists at Suburban Hospital identified 471 patients in fiscal year 2003 who would have been referred to Suburban if a cardiac surgery program were operational there. These cardiologists have noted the advantages of referring their future patients to an OHS program at Suburban. Suburban asserts that this documents that Suburban will achieve and maintain a "minimum caseload of 200 open heart surgery cases" per year. (SH, D.I. # 4, pgs. 75, 149; Exhibits 61, 62)

Reviewer's Analysis and Findings

The three applicants have developed agreements with cardiac surgeons. In the case of SMHC Dr. Paul Corso, of the cardiac surgery group Washington Regional Cardiac Surgery, P.C., will serve as SMHC's medial director for cardiac surgery. At Suburban Hospital, Dr. Keith Horvath is the chief of cardiac surgery working with Johns Hopkins Hospital's Department of Cardiac Surgery. Holy Cross Hospital will be in partnership with the University of Maryland Medical System and the University of Maryland School of Medicine ("UMSOM"). Bartley P. Griffith, M.D., Chief of Cardiac Surgery at the UMSOM will serve as the initial medical director of the HCH cardiac surgery program until a lead surgeon joins the program.

SMHC and Suburban conducted physician surveys that indicated support for the hospital's proposed OHS programs. The Commission notes that physician surveys are one tool to judge a hospital's ability to maintain a minimum volume of 200 OHS procedures per year. However, surveys are not an absolute predictor of future volumes because they do not reflect a firm commitment on the part of the physicians to send patients to the proposed program.

Table 9: Physician Referral Survey Results

	OHS Referrals	PTCA Referrals
SMHC	424	992- 1,064 ¹⁴
Suburban	471	1,659

Source: SMHC, D.I. # 17, pgs. 144 – 145; CON application pages 144 & 190, referrals by Southern Maryland Hospital Center-based cardiologists. Suburban - Exhibit 61, Referrals by Suburban Hospital -based cardiologists.

Holy Cross Hospital obtained letters of support from local cardiologists; however, HCH did not request a survey of historical or projected referrals.

The Reviewer finds that all three applicants have demonstrated an ability to achieve 200 OHS cases annually and, therefore, all the applicants meet this standard. Based on data reflecting the distribution of Metropolitan Washington area residents using Washington, D.C. hospitals for open heart surgery services (Refer to Map 29), Holy Cross and Suburban may be more successful in maintaining volumes higher than the stated 200 cases per year given the number of cases within their service areas.

¹⁴ Southern Maryland Hospital Center reports that some cardiologists, in responding to its survey, answered with a range instead of a single number. (SMHC, D.I. # 17, p. 189)

EXHIBIT 1B SEE CD FOR FULL DECISION

IN THE MATTER OF:

** BEFORE THE MARYLAND

** HEALTH RESOURCES PLANNING

DOCKET NO. 91-24-1624

** COMMISSION

ST. AGNES HOSPITAL

DOCKET NO. 91-24-1625

** THE UNION MEMORIAL HOSPITAL

DOCKET NO. 91-24-1626

**

DECISION

INTRODUCTION

In 1988-89, the Maryland Health Resources Planning Commission convened a Technical Advisory Group (TAG) on Cardiac Surgery & Therapeutic Catheterization Issues to assist it in the development of a State Health Plan (SHP) chapter on Open Heart Surgery (OHS) and Percutaneous Transluminal Coronary Angiography (PTCA). The recommendations and guidance of this group resulted in the adoption of COMAR 10.24.17, Cardiac Surgery and Therapeutic Catheterization Services (the Chapter), effective October 15, 1990. This guide serves as the overview, rationale, and decision-making blueprint for the approval of an OHS/PTCA program.

In January 1991, letters of intent to establish an additional OHS/PTCA program in Central Maryland were submitted by the applicants in this review. The proposals submitted are summarized below.

As will be discussed in this Decision, the Commission has found that all of the applicants are consistent with the Policies and Standards set forth in the SHP. All of the applicants are also consistent with the Criteria for Review set out in the Code of Maryland Regulations (COMAR), found at 10.24.01.07.H.2(b) - (h). After reviewing the applications and considering evidence put forth by each applicant, the Commission finds that all applicants have demonstrated the ability to put forward an OHS/PTCA program that will serve the residents of Central Maryland. However, based on the need methodology found in the Plan, the Commission has found that only one additional OHS/PTCA program is needed. This Decision, therefore, will allow only one of the potential providers to go forward with development of its proposal.

In that regard, the Commission looked to the guidance offered by the TAG, as set forth in the SHP, to aid it in its charge to comparatively analyze the applications submitted. The Chapter states, program." (SHP, p. 7) Of critical importance is the size of the cardiac catheterization program and cardiology service at the applicant hospital. A review of the volume of cardiology cases of each of the applicants is found below:

Volume of Cardiology Cases: 1989 - 1991

Hospital		1989		1990	1991	Total
MGH		1294		1009	917	3220
SAH		2412		2738	2831	7981
UMH		2514		2103	2130	6747
Source:	SAH	Closing mer	mo, p.	17	*	

The above figures reveal that SAH had the largest number of cardiology discharges and that both SAH and UMH had at least double the number of cardiology discharges as MGH. The Commission notes that SAH verified 209 OHS cases from its internal volumes, and UMH verified 205 cases. MGH submitted no evidence of internal volumes of OHS patients. UMH also notes that it has over 300 vascular cases annually, and thus has an OR staff that is well versed in vascular procedure. The Commission finds that UMH and SAH have demonstrated strong established cardiology programs.

F. PROJECTED PROGRAM VOLUMES

Because of the correlation between patient outcomes (quality) and numbers of procedures performed, the Commission has a responsibility to choose a proposal that will be successful in terms of volumes of patients. As noted in the Chapter,

Since the need for cardiac surgery is finite, it follows that cardiac surgery programs should only be located where a minimum start-up volume of 200 cases can be generated, so that patient outcomes may be optimized. An inadequate caseload of cardiac surgery patients in any one hospital raises serious questions regarding the efficiency, safety, and economic soundness of a cardiac surgery program. (SHP, p. 7)

In addition, certain SHP standards relate to volumes of cardiac surgery patients for both the start-up phase and Year 3 (the point at which the program is considered established). See Approval Policy 4, and CSS 4 - Minimum Volume. Thus, the Commission has reviewed the applications and evidence presented to analyze the applicants' ability to generate start-up volumes of OHS patients, volume of patients and volume of cardiology patients.

^{3.} FY 1992 annualized plus capture of 60% of Garcia Mispireta patients residing in Baltimore City or County.

A hospital's historical cardiology service volumes, especially cardiac catheterization volumes, serve as an indication of a pool of patients from which the initial volumes of an OHS service may be drawn. This internal pool is especially important in the start-up phase of a project. In subsequent years, referral patterns are established and strengthened and there is less reliance on internal volumes. The Commission believes that applicants with high cath lab volumes, especially those that refer in excess of 200 cases for OHS procedures annually, would have an advantage with regard to capturing start-up volumes quickly. Providers with lower volumes would have a greater initial dependence on establishing referral patterns.

The Commission notes that the program approved in this review will be the fifth OHS program in the Central Maryland region. The Commission believes that establishing strong referral patterns to ensure minimum start-up volumes will be a greater task for the fifth program in a region than it was for the first, second, third, or fourth program.

In this regard, the analysis that follows concerns the ability of any new OHS provider to establish a program that will quickly stabilize and expand to meet patient needs. The Commission believes that a strong and stable cardiology program with demonstrated physician support in place is essential and any program that can demonstrate a strong and committed referral network among cardiologists and strong internal volumes offers a more effective alternative.

Start-up Volumes {Approval Policy 4}

Maryland General Hospital

MGH projects 200 OHS cases in 1993, 275 in 1994 and 350 cases in 1995 (MGH 9, p. 26, Table 2 - OHS). MGH states that its cardiac surgery program will attract at least 200 cases in year 1 through a combination of the following sources: current referrals of Maryland cases to Virginia Heart Surgery Associates (VHSA) at Fairfax Hospital, referrals of cardiac surgery cases from catheterizations at MGH and other local hospitals, patients not currently in the system that are "found" by MGH's targeted outreach efforts, and cases referred from the MGH Electrophysiology program (AP., p. 25). MGH quantifies each of these variables (AP., pp. 26-28) and concludes that it will meet the minimum volume requirement in year 1 of the project. MGH provided letters from cardiologists documenting potential referrals of cardiac surgery cases from area catheterization laboratories (AP. Appendix 1 and Miller pre-filed testimony (pft)). MGH's catheterization laboratory experienced 333 procedures in 1988, 421 in 1989 and 326 in 1990 (MGH 19, At. 7). MGH substantiates its OHS caseload projections as follows:

EXHIBIT 1C SEE CD FOR FULL DECISION

IN THE MATTER OF

BEFORE THE

SACRED HEART HOSPITAL

MARYLAND HEALTH RESOURCES

DOCKET NO. 97-01-2012

PLANNING COMMISSION

REVIEWER'S RECOMMENDED DECISION

I. INTRODUCTION

This is a Certificate of Need ("CON") review for the establishment of a new cardiac surgery and therapeutic catheterization service ("cardiac surgery," "open heart surgery," or "OHS") service in the Western Maryland Region, which for this service consists of Garrett, Allegany, Washington, and Frederick Counties. The sole applicant review in this review is Sacred Heart Hospital of the Sisters of Charity, Inc. ("SHH") of Cumberland, Allegany County, Maryland. SHH's proposed OHS project is summarized below.

Sacred Heart Hospital of the Sisters of Charity, Inc., a 240-bed non-profit acute care hospital located in Cumberland, proposes to develop cardiology services, including OHS and percutaneous transluminal coronary angioplasty (PTCA or angioplasty) as part of the plan by its corporate parent, the Western Maryland Health System to reorganize and reconfigure acute care services between its two hospitals. The cardiology services currently provided at Memorial Hospital and Medical Center, Inc. ("Memorial"), except for emergency care, will be discontinued. Existing components of both hospitals' programs will become part of a Western Maryland Health System Cardiac Care Center, including:

- Prevention and Education
- Provider Education and Outreach
- Medical/surgical capabilities, including
 - Non-invasive cardiac services
 - Invasive cardiology
 - Cardiac catheterization laboratories
 - Chest pain emergency department
 - Cardiovascular critical care unit

Western Maryland Health System. Inc. ("WMHS") was formed on April 10, 1996 by the affiliation of Memorial Hospital and Medical Center of Cumberland, Inc. ("Memorial") and Sacred Heart Hospital of the Sisters of Charity, Inc. SHH has stated in its application that an objective of the affiliation was to eliminate unnecessary duplication in the development of new health care resources to serve the citizens of Allegany County and surrounding areas. Since the Fall of 1996, the WMHS Board, the Planning Committee, and other groups have explored various ways to reconfigure the existing hospital resources in a way that will provide a continuing role for both institutions. Sacred Heart filed its Letter of Intent to establish this program in June 1997. This service is part of the overall plan of WMHS to reconfigure services at the two hospitals.

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10.24.17.04C(3): APPROVAL POLICIES

The first three approval policies concern projection of need for OHS services. Since these policies are interrelated, they will be discussed concurrently in the section below.

(a) <u>Identification of Need for Cardiac Surgery Programs.</u> Maximum need for cardiac surgery programs is identified using the need projection methodology in Regulation .07 of this Chapter and is found in the Appendix to this Chapter or in subsequent updates published in the <u>Maryland Register</u>.

SHH is responding in this review to the December 1997 Cardiac Surgery Services Section of the State Health Plan, which identifies need for an OHS program in Western Maryland. (SHH # 3, p. 51)

(b) Minimum Net Need Identified. Net need for cardiac surgery projected in a Regional Service Area is no less than 200 open heart surgery cases for an adult program, or 130 cardiac surgery cases for a pediatric program.

The State Health Plan projects a need for service capacity to accommodate 345 cases in Western Maryland in 1999. (SHH # 3, P. 52)

(c) <u>Number of New Programs Allowed</u>. The Commission will certify only one new adult and pediatric cardiac surgery program at a time in each Regional Services Area.

SHH is the sole applicant in this review, which began with a Letter of Intent submission deadline of June 6, 1997; it is the only approveable applicant. (SHH # 3, p. 53)

Summary

The SHP projects enough need to support one new OHS program in the Western Maryland Health Service Area. This Reviewer finds that the Sacred Heart Hospital application is consistent with Approval Policies (a) - (c).

(d) <u>Minimum Volume Standards</u>. The Commission will approve a cardiac surgery program only if an applicant demonstrates that the proposed program can retain enough patients to meet the minimum start-up volume of 200 cases annually.

Minimum volumes are further discussed under Cardiac Standard D(2)(d), below. This Approval Policy concerns start-up volumes of 200 cases in Year 1 of operation, while Standard (d) requires an established cardiac surgery program to reach and maintain a minimum operating volume per year. Commission Staff notes that need is projected for OHS cases in Western Maryland. The SHP documents need in the region for 345 OHS cases for 1999. The issue of

need in the Western Maryland region was originally confirmed on March 12, 1991 when the Commission adopted Commissioner Frank A. Pommett's Proposed Decision supporting a finding of need for a Cumberland-based OHS program, following an evidentiary hearing held on that question. Therefore, discussion under this policy will focus on the applicant's ability to attract cases in the first year of operation.

Sacred Heart used MHRPC data to illustrate the number of OHS cases from Western Maryland in 1996, which were the latest data available prior to the filing of its application.

Table 3
Open Heart Surgery Cases
by Location of Hospitalization and Jurisdiction of Patient Residence
1996

		Region of	<u>Care</u>		
County of Residence	D.C.	Suburban D.C.	Metro.Balto.	Eastern Sho	re Total
Allegany	103	12	92	0	207
Frederick	135	75	27	0	237
Garrett	5	1	70	0	76
Washington	45	24	128	0	197
Western Maryland	288	112	317	0	717

The Western Maryland counties generated 717 OHS cases, 480 from the three western-most counties. (As noted above under the general travel time standard, Sacred Heart does not anticipate that it will attract many patients from Frederick County, and assumes that it will attract an equal share, or one-fourth, of Washington County patients.

Sacred Heart does not equivocate about the fact that – in terms of drive time, distance, travel by family members, and the impact of adverse and unpredictable weather conditions – the residents of Allegany and Garrett Counties will be the most immediate beneficiaries of an OHS program in Cumberland. Even though SHH acknowledges that it will not capture 100% of the volume generated by these two counties, it believes that current volumes from the two counties can be used as a proxy for the program's expected volume, since cases from Garrett and Allegany Counties which do not come to SHH are likely to be compensated for by cases from the nearby portions of West Virginia and Pennsylvania.

Sacred Heart projects that it will achieve 46.3% of the total Western Maryland OHS volumes, nearly the exact percentage assumed by the HRPC in the OHS section of the SHP, as likely to be retained by an OHS program in Western Maryland. That capture rate, applied to the Commission's 1999 projection of 766 total OHS cases from Western Maryland, translates into approximately 350 OHS cases for the proposed new program at Sacred Heart. This projection is supported by internal data from memorial and Sacred Heart, which show that during CY 1996, the System's cardiac catheterization lab reports showed that Memorial and SHH referred 222 patients to existing programs for OHS, and 233 patients for PTCA. Given the additional patients

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expected from the other jurisdictions, SHH believes that the 350-case volume projection is reasonable. (SHH # 3, pgs. 54-56)

WMHS FY 1997 data show that patients from Pennsylvania and West Virginia comprise 24 percent of all inpatients at Sacred Heart and Cumberland Memorial Hospitals (See Table 4 below). Patients from these two states comprise 22 percent of all cardiology admissions and 20 percent of all cardiac catheterizations; since they are not accounted for in the Commission's projections of need for OHS in Western Maryland, they essentially represent additional volume for a Western Maryland program. Sacred Heart is confident that it will attract these patients to its proposed cardiac surgery program, just as it already attracts them for related services, including cardiology and cardiac catheterization.

Table 4
Patients from Pennsylvania and West Virginia
Served at Sacred Heart and Cumberland Memorial Hospitals
FY 1997

	Total		PA			WVA	
	Any State		<u>#</u>	<u>%</u>		<u>#</u>	<u>%</u>
All Inpatient Cases	18,369	1,106	6.02%		3,369	18.349	70
Inpatient Cardiology	3,280		230	7.01%		504	15.37%
Cardiac Caths.	1,093		62	5.67%		153	14.00%

The reviewer concurs that Sacred Heart's assumptions about the extent to which it will meet this State Health Plan standard is reasonable, and is confirmed by the HRPC's own projections. (SHH # 29, p.7)

The Washington County Hospital Association argues that SHH must document that existing referral patterns will change if SHH develops its proposed cardiac surgery program. (SHH # 58, p. 3) Addressing that challenge, Sacred Heart contacted the cardiologists who practice at Sacred Heart Hospital and Memorial regarding their referral plans if the proposed project is approved, and has provided documentation to indicate that these cardiologists would have referred approximately 230 patients to Sacred Heart if OHS services had been available in 1998. Resolutions of support from the WMHS Board and from the Medical Executive Committees of the Medical Staffs of both Memorial and Sacred Heart Hospitals demonstrate a complete reversal of the anxiety and divisiveness evidenced by physicians in January 1998.

Additionally, SHH has determined that some patients needing OHS are not referred to cardiologists practicing in Allegany County, but instead are referred directly to cardiologists at hospitals where OHS is available. The apparent reason for these referrals is that some patients prefer having a cardiac catheterization done at the facility where angioplasty and open heart surgery are available. Log books maintained by Memorial's cardiac care coordinator reflect that

53 patients potentially needing OHS were sent to other hospitals for cardiac catheterization. SHH anticipates that many of these patients will be retained in Western Maryland, once the proposed OHS program is established at Sacred Heart.

Based on the above information and analysis, the Reviewer finds that Sacred Heart Hospital has documented that it can retain enough patients to meet the minimum start-up volume of 200 cases annually, as required by this approval policy, and is thus consistent with the policy.

(e) <u>Size of Hospital</u>. The applicant has at least 200 acute general hospital beds, and an average daily census... of at least 100 patients in each of the two most recent calendar years of data available from the Commission's Hospital Discharge Abstract Data Base.

With a current total of 240 licensed beds and ADCs of 157 and 149, respectively, in FY 1996 and 1997, Sacred Heart Hospital is consistent with this policy. (SHH # 3, p. 57)

(f) <u>Intensive Care Unit.</u> The applicant has a fully staffed intensive care unit of at least eight beds.

SHH currently operates a fully-staffed, 19-bed ICU, (SHH # 3, p. 58) consisting of ten ICU/CCU beds and ten step-down beds, one of which is not operational at the present time, and is therefore consistent with this policy.

(g) Cost Effectiveness.

- (i) In the case of a comparative review of applications in which all policies and standards have been met by all applicants, the Commission will give preference to the applicant which offers the best balance between program effectiveness and costs to the health care system as a whole.
- (ii) Hospitals applying to establish a new cardiac surgery program will be required to agree to an initial GIR base that is low compared with other providers in the hospital's market and will be required to rebase in the open heart surgery DRG each time the entire GIR is rebased. The new base for each DRG will be either the original base, trended forward for inflation, or the statewide minimum, adjusted for labor market, markup, and case mix, if necessary, whichever is lower:
- (iii) Hospitals applying to establish a new cardiac surgery program will be required to agree to a minimum giveback, as defined by the Health services Cost Review Commission, based on their projected volumes and costs for the new service established in their Certificate of Need application.

Although this is not a comparative review, and so some sections of this policy do not apply, Sacred Heart has addressed the intent of the standard, by entering into a minimum

EXHIBIT 1DSEE CD FOR FULL DECISION

IN THE MATTER OF

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BEFORE THE MARYLAND

ST. AGNES HOSPITAL DOCKET NO. 86-24-1369

HEALTH RESOURCES PLANNING

SINAI HOSPITAL

COMMISSION

DOCKET NO. 86-24-1371

*

FRANKLIN SQUARE HOSPITAL DOCKET NO. 86-03-1372

*

MARYLAND GENERAL HOSPITAL DOCKET NO. 86-24-1373

*

I. INTRODUCTION

This Phase II proceeding for a Certificate of Need (CON) involves the evaluation of four applicants seeking authority to establish an open heart surgery (OHS) service in Central Maryland, which consists of Baltimore City, Baltimore, Anne Arundel, Howard, Harford, and Carroll Counties. On January 21, 1987, the Applicants requested that the hearings be bifurcated into two phases with Phase I to be concerned with the determination of need and Phase II to consider all other issues should need be established. This request was granted by Staff (GF.51,56). At the conclusion of Phase I of this proceeding, Hearing Officer Pamela Brewington, found need for an additional OHS program in this service area.(GF.94). At the request of the Applicants, the full Commission ratified this finding. In Phase II, evidentiary hearings were held to assess whether any of these applicants is capable of meeting the need in Central Maryland.

Franklin Square Hospital (FSH) is a 405 bed private non-profit general acute care hospital located at 9,000 Franklin Square Drive in Eastern Baltimore County. It is a part of the

The findings under Standards CS/CC 4, CS/CC 10 and Criteria 10.24.01.07h(2)(c), (d), (e), and (f) are incorporated by reference herein. The Commission findings under the Standards and criteria cited above indicate that all Applicants other than Sinai have failed to satisfy all other Standards and criteria and thus, the lowest net revenue per case comparison is inapplicable.

Based on the above, the Commission cannot base its decision as to which Applicant in this review should be granted a CON for an OHS program on the basis of net revenue alone.

D. 10.24.07 CS/CC 9a

Each adult cardiac surgical program must perform cardiac surgical procedures on a minimum of 200 adults per year within three years of initiation and each year thereafter.

PROJECTED UTILIZATION

FSH proposes to serve 200 adult OHS patients in year one; 250 in year two; and 300 in year three. It also proposes to serve 125 adult PTCA patients in year one; 185 in year two; and 250 in year three. (Appl.,p.12; Update, 11-28-88, Att. E, Rev.).

MGH proposes to serve 200 adult OHS patients in year one and 275 in year two. It also proposes to serve 150 adult PTCA patients in year one and 225 in year two. No projections were provided for year three. (Appl.,p. V-4; Higdon, Pre-filed, Ex.6).

SAH proposes to serve 200 adult OHS patients in year one; 275 in year two; and 350 in year three. It also proposes to serve 200 adult PTCA patients in year one; 275 in year two; and 350 in year three. (Update, 11-28-88, p.7; Atkinson, Pre-filed Rebuttal, Ex. 17).)

Sinai proposes to serve 250 adult OHS patients in year one and 340 in years two and three. It also proposes to serve 150 adult PTCA patients in year one and 350 in years two and three. (Appl., p.24; Barrick, Pre-filed, pp.10-11 & Ex.1).

PATIENT ORIGIN

Catheterization Laboratory

FSH

FSH opened its first cardiac catheterization laboratory in 1971. The laboratory performed catheterizations on 682 adult patients in 1988. In addition, Union Memorial, FSH's sister facility in the Helix Health System, performed catheterizations on 380 adult patients in 1988. Dr. Arnett testified that 209 patients were referred for OHS and 101 for PTCA from the FSH catheterization laboratory during the past year. Dr. Moran testified that 169 patients were referred for OHS and 39 for PTCA from the Union Memorial catheterization laboratory in FY 1988, for a Helix total of 378 and 140 OHS and PTCA combined, respectively. (Appl., pp.31,; Arnett, Pre-filed, p.8; Moran, Pre-filed, p.4; Comm. Ex. 13).

MGH has operated a cardiac catheterization laboratory for 27 years. It recently opened a second laboratory. MGH performed catheterizations on 221 adult patients in 1988. Dr. Dembo, Chief of Cardiology at MGH, testified that 141 patients were referred for OHS by the group of five staff cardiologists at MGH within the 13 1/2 month period prior to his testimony on 2-22-89. This same

MGH's Reply Brief notes that the catheterization laboratory was closed for part of 1988.

physician group also performed 71 PTCAs in 1988, all of them at the University of Maryland, for a total of 216 OHS and PTCA combined. Other physicians using the MGH cardiac catheterization laboratory referred approximately 75 patients for OHS. (Appl., p.II-1; Dembo, Pre-filed, p.4, & Ex.C; Dembo, 2-22-89, Trans.,pp.3,663-5; Comm. Ex.13).

SAH operates a cardiac catheterization laboratory which performed catheterizations on 549 adult patients in 1988. From July 1, 1987 to June 30, 1988, 233 patients were referred from the catheterization laboratory for OHS or PTCA. Approximately 150 of these were OHS patients and 83 were PTCA patients. (Appl.,p.38; Comm. Ex.13; Marlowe, Pre-filed, p.3 & Ex. 1; Marlowe, 1-3-89, Trans. p.159; Atkinson, 5-22-89, Trans. pp. 9,310-1).

Sinai operates a cardiac catheterization laboratory and anticipated opening a second laboratory in July, 1989. It performed catheterizations on 345 adult patients in 1988. Ninety one patients were referred for OHS and 41 for PTCA in 1988. Sinai has presented its application as being "in conjunction with The Johns Hopkins Health System" and, in particular, with Homewood Hospital Center (formerly N. Charles Hospital). Homewood's cardiac catheterization laboratory performed catheterizations on 812 adult patients in 1988. In FY 86, the last year for which complete data were available, 237 patients were referred from Homewood's catheterization laboratory for OHS. Dr. Pollock testified that there are 26 cardiologists with privileges at Homewood and that many of them are committed to referring patients to Sinai for OHS and PTCA. Dr. Reitz testified that the Hopkins

program is near the limits of its physical capacity and that a program at Sinai would allow the Hopkins surgeons to accommodate patients at Sinai. Neither Dr. Pollock or Dr. Reitz quantified the number of referrals that they expected to go to the Sinai program. (Appl., p.1; Reitz, Pre-filed, p.11; Veltri, Pre-filed, p.2; Veltri, 1-23-89, Trans. p.1262; Pollock, Pre-filed, pp.10-11; Comm. Ex.13).

Referrals

FSH

Dr. Arnett testified on behalf of FSH that he expected FSH to retain approximately 80% of the OHS referrals from its catheterization laboratory and 100 % of its PTCA referrals if it were granted a CON. Dr. Arnett also provided numerous letters of support from physicians: however, only one of these letters quantified the expected referrals to FSH. Dr. Wyman K. Wong indicated that he anticipated sending 8-10 patients per year to an OHS program at FSH. Dr. Dean L. Vassar's letter indicates that his physician group refers between 75-100 patients per year for OHS and that they refer patients to Christiana Hospital in Delaware, Johns Hopkins Hospital, St. Joseph's Hospital and University Hospital, and occasionally to Milwaukee, Wisconsin and Richmond, Virginia. He did not specify how many of these patients he would expect to be referred to an OHS program at FSH or from which hospitals these patients would be drawn. The Commission notes that at least some of these letters of support are from physicians currently referring patients to FSH for catheterization and so any referrals that they might make to FSH have already been

accounted for in the number of patients that FSH currently refers for OHS from its catheterization laboratory.

Dr. Moran, Chief of Cardiology at Union Memorial Hospital, testified that approximately one third of their patients are referred to Hopkins, one third to UMMS, one sixth to SJH and one sixth to Washington Hospital Center (WHC). He expected that they would continue referring to SJH, Hopkins, and UMMS but that the patients who are currently referred to WHC would be referred to a Baltimore provider when additional capacity became available. He did not quantify the number of patients that he expected to be referred to FSH. (Arnett, 2-15-89, Trans. p. 2924 & Ex. B; Moran, 2-16-89, Trans. pp.3,247-51).

MGH

Daniel A. Baldwin, Vice President of Planning for MGH, testified that he expected all of the patients referred by Dr. Dembo's physicians' group (approximately 100 per year) to be referred to an OHS program at MGH. He further testified that his discussions with other cardiologists on the MGH staff indicate that they too would refer patients to an OHS program at MGH. He provided no estimate of the number of referrals to be received from these physicians. Mr. Baldwin also testified that MGH is using a screening program, referred to as The Heart Test, which he estimated would produce approximately 15 OHS patients for every 5,000 persons screened, or a total of approximately 45-60 OHS patients in the first year of operation.

Dr. Donald Dembo, Chief of Cardiology at MGH, testified to an affiliation with Good Samaritan Hospital (GSH). Dr. Dembo is

Chief of Cardiology at GSH as well as at MGH. He testified that some, but not all, of the cardiac catheterizations from GSH are done at MGH. He was not able to quantify the number of catheterization patients that MGH receives from GSH, but he did testify that the Cardiology Department at GSH is smaller than that at MGH. (Baldwin, Pre-filed, pp.20-21; Dembo, Pre-filed, p. 1; Dembo, 4-5-89, Trans. pp.7,879 & 7,884)

MGH did not provide any evidence of referrals from physicians not associated with MGH.

SAH

David Marlowe, Vice President of Marketing at SAH, testified that SAH expected to capture 98% of the OHS/PTCA volume currently referred from its catheterization laboratory (150/83 patients in FY 1988) by the second year of operation. In addition he identified a Cardiology group from Carroll County and the Columbia Medical Plan in Howard County as anticipated sources of referral. Dr. Graham Atkinson, Consultant to SAH, indicated in his Pre-filed Rebuttal testimony that the Carroll County group refers approximately 100 patients for OHS/PTCA per year (25-50 OHS and 50-75 PTCA) and that the Columbia Medical Plan currently refers approximately 40 patients per year for OHS. Mr. Marlowe stated that SAH also expected to receive OHS/PTCA referrals of patients currently going to the Washington, D.C. from Baltimore City, and Baltimore, Howard, Carroll, Anne Arundel, and Frederick Counties, although he could not project a specific volume of cases and did not offer documentation from physicians in these Counties that they would refer patients to SAH, except as cited above.

SAH also operates a Chest Pain Emergency Room, which it expects to serve as an entry point into the system. (Marlowe, Pre-filed, p. 6, 9 & Ex. 6; SAH Ex. 2; Atkinson, Pre-filed Reb., pp.24-5).

Sinai

Dr. Enrico P. Veltri, Co-Director of the Coronary Care
Unit(CCU)/Progressive Care Unit(PCU), Director of the
Electrophysiology Laboratory, and Director of the Sudden Death
Prevention Program at Sinai, and Chief of Cardiology at Sinai,
testified that 91 OHS patients and 44 PTCA patients were referred
from Sinai's cardiac catheterization laboratory in FY 1988. He
estimated that an OHS program at Sinai would have retained
approximately 72 of these 91 OHS patients.

Dr. Stephen H. Pollock, proposed Medical Director of the OHS program at Sinai and a practicing Cardiologist at Homewood Hospital Center (HHC or Homewood), testified that his physician group refers approximately 125-150 patients per year for OHS.

Dr. Pollock and 3 other members of his physician group also perform catheterizations at Sinai. He estimated that his group was responsible for approximately 40 to 60 of the catheterizations performed at Sinai which would have yielded approximately 15 OHS referrals. These 15 referrals are included in the 125-150 OHS referrals mentioned above.

This physicians' group also has privileges at Baltimore
County General Hospital, Greater Baltimore Medical Center, St.

Joseph's, Franklin Square, and University of Maryland Hospital.

The 125-150 estimated OHS referrals made by this group result from

its work in all 7 facilities. Dr. Pollock testified that the group does only a small amount of work at FSH and UMMS. He further testified that he personally is most active at Homewood, Sinai, and SJH. He would continue to refer patients to SJH if Sinai were granted a CON for OHS.

Dr. Pollock also provided numerous letters of support from physicians. Many of the letters did not quantify the number of patients to be referred. However, two of the letters identified a total of 125 OHS patients and 30 PTCA patients plus 60 non-differentiated OHS/PTCA patients, with both of these physicians indicating that they would refer their patients to an OHS program at Sinai. The Commission notes that a number of these letters are from physicians who currently perform cardiac catheterizations at Homewood: however none of them are from Dr. Pollock's group and their patients are not included in the 125-150 patients identified by that group. These letters also indicate support from the Chiefs of Cardiology at Liberty Medical Center and Bon Secours Hospitals. (Veltri, 1-23-89, Trans. p. 1276; Pollock, 1-30-89, Trans. pp.1,774-8, 1,807-8, 1,820; Sinai Exs. 2a-2j).

Discussion

All of the Applicant facilities in this case have currently functioning cardiac catheterization laboratories which would provide some initial volume for an OHS program. Table II, below, summarizes the number of adult patients receiving cardiac catheterization at the relevant hospitals for 1988.

TABLE II
Cardiac Catheterization Patients
1988

<u>Hospital</u>		Number	of	Patients
FSH			68	2
MGH			22	1
SAH	4,		54	9
Sinai			34	5
UMH			38	0
Homewood			81	2

Source: Commission Exhibit 13

All of the laboratories at the Applicant's facilities will be operated on an "open" basis: that is, anyone who has fulfilled the criteria for staff privileges would be allowed to perform cardiology procedures in these laboratories. Testimony in this case indicates that the open catheterization laboratory, in conjunction with an OHS program, would serve to attract additional cardiologists to the facility, thus providing additional volume to the OHS program. (Arnett, Pre-filed, p.21; Dembo, Pre-filed, p.11; Warbasse, Pre-filed, p. 11; Pollock, Pre-filed, pp.3,6; Pollock, 1-30-1989, Trans., p. 1,813)

The Commission considers it appropriate to include the cardiac catheterization volume of UMH with that of FSH because they are sister facilities under the Helix Health Care System. It also considers it appropriate to include the cardiac catheterization volume of Homewood with that of Sinai in that the Sinai application was presented "in conjunction with" the Homewood Hospital Center, and Dr. Pollock testified to the support of the Homewood cardiologists for the Sinai program, although neither FSH nor Sinai quantified the referrals to be received from its

affiliated catheterization laboratory. However, the Commission notes the testimony of Dr. Moran, Chief of the Division of Cardiology at UMH, who testified that:

I think Franklin Square will have to earn the referrals that they get from Union Memorial physicians just as Maryland General would have to or St. Agnes or Sinai, and I anticipate that because of arrangements ... in terms of having a Union Memorial presence involved at Franklin Square, that that transfer will be facilitated and I would hope would increase the proportion of patients that would be sent over there. (Moran, 2-16-89, Trans. p.3250).

The Commission further notes the strong support expressed in the letters provided by Dr. Pollock as Sinai Exhibits 2a-j, in support of the Sinai application and Dr. Pollock's involvement as Medical Director of the Sinai program. The Commission believes that it is reasonable to expect Sinai to benefit from this affiliation and the large cardiac catheterization volume at Homewood.

SAH has operated a "closed" cardiac catheterization laboratory, that is, only the geographically based cardiology group was permitted to perform cardiology procedures in this laboratory. It proposes to add a second laboratory and to operate it on an open basis. As noted above, this should increase its already substantial volume of catheterizations.

MGH has recently opened a second cardiac catheterization laboratory and currently operates these laboratories on an open basis. MGH's catheterization volume is relatively small compared to that of the other Applicants and it is not a part of an institutional system operating more than one hospital and has not

identified affiliations with other hospitals or cardiologists or community centers with substantial cardiac catheterization volumes. Dr. Dembo is Chief of Cardiology at both MGH and Good Samaritan Hospital (GSH), however, GSH does not operate a cardiac catheterization laboratory. (Comm. Ex. 13).

The Commission notes the concerns of SJH and UMMS with regard to the FSH and SAH applications. These concerns will be addressed further under COMAR Criterion 10.24.01.07H(2)(f).

The Commission finds that FSH, SAH, and Sinai have projected sufficient OHS volume in year three to be consistent with this Standard. All have functional cardiac catheterization laboratories which are expected to generate a significant proportion of the projected OHS volume. The Commission finds that FSH, SAH, and Sinai are consistent with this Standard.

The Commission is skeptical of MGH's projections. Mr. Baldwin testified that he expected MGH to receive 100% of the referrals from Dr. Dembo's physician group (approximately 100 patients per year). The Commission believes that patient preference may not permit MGH to capture <u>all</u> of these patients. Some patients may elect to go elsewhere for surgery.

MGH did not provide evidence that it would receive referrals from physicians not directly associated with MGH. Further, the

^{4.} In its Exceptions, SAH argues that it should receive a preference over Sinai because of its greater number of cardiology cases and catheterizations. The Commission notes that this standard requires a minimum number of OHS cases and provides no basis for the preference requested. The Commission further notes that SAH projects fewer OHS cases in years 1 and 2 than Sinai, and only 10 more in year 3.

Commission notes that the surgeons proposed by MGH are from Fairfax, Virginia and have no established relationship with the referring physicians in Baltimore. Dr. MacManus testified that it would be necessary for the Fairfax group to establish itself with the referring physicians and build up a referral base. When asked, on cross examination, how many patients he anticipated in year 2 of the program, he responded:

...it's a guess. I don't know how popular the program is going to be and how the referral patterns will change. (MacManus, 6-15-89, Trans. p.10374).

The Commission finds that MGH has failed to demonstrate that it will perform a minimum of 200 cardiac surgical procedures per year within 3 years of initiation of its OHS program. MGH takes exception to this finding, arguing that the testimony that any new program would attract "plenty" of new cases, suffices. Although the Commission believes that a new project will attract some new cases, it is not convinced that any new program — especially one whose surgeons have no track record in central Maryland — will attract enough new cases, absent evidence of past referral patterns, linkages, and demonstrated support, to achieve volumes consistent with this Standard. The Commission finds that MGH has not met its burden of proof under this Standard.

E. 10.24.07 CS/CC 10

Staffing levels for cardiac surgery and cardiac catheterization programs must be consistent with the most recent guidelines established by the Inter-Society Commission for Heart Disease Resources. Applicants for new or expanded services must demonstrate in writing that this standard is met.

EXHIBIT 1E SEE CD FOR FULL DECISION

IN THE MATTER OF

PRINCE GEORGE'S HOSPITAL
CENTER

DOCKET NO. 82-16-1051

DOCKET NO. 82-16-1057

BEFORE THE MARYLAND
HEALTH RESOURCES
PLANNING COMMISSION

*

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. INTRODUCTION

This Phase II proceeding for a Certificate of Need (CON) involves the evaluation of two applicants seeking authority to establish an open heart surgery (OHS) service in Southern Maryland which consists of Prince George's, Calvert, Charles, and St. Mary's Counties . At the second Pre-Hearing Resumption Conference (12/16/85), the Hearing Officer ruled that the hearing would be bifurcated into Phase I, to consider the issues regarding need, and Phase II for all other issues should need be established. At the conclusion of Phase I of this proceeding, the Maryland Health Resources Planning Commission (MHRPC or Commission), on October 11, 1988, found need for an additional OHS program in this service area. (Docket Item G.F 125). In Phase II, evidentiary hearings were held to assess whether either of these applicants is capable of meeting the need in Southern Maryland.

Prince George's Hospital Center (PGHC), (formerly Prince

findings under the Standards and criteria cited above indicate that AMI has failed to satisfy all other Standards and criteria or to make adequate provisions for quality of care and thus, the lowest net revenue per case comparison is inapplicable.

Based on the above, the Commission cannot base its decision as to which Applicant in this review should be granted a CON for an OHS program on the basis of net revenue alone.

D. 10.24.07 CS/CC 9a
Each adult cardiac surgical program must perform cardiac surgical procedures on a minimum of 200 adults per year within three years of initiation and each year thereafter.

PROJECTED UTILIZATION

PGHC

PGHC proposes to serve 150 adult OHS patients in year one; 225 in year two; and 300 in year three. It also proposes to serve 260 adult PTCA patients in year one; 390 in year two; and 525 in year three. (Appl., Part II, Project Budget, pp. unnumbered)

AMI

AMI proposes to serve 150 adult OHS patients in year one; 200 in year two; and 250 in year three. It also proposes to serve 125 adult PTCA patients in year one; 175 in year two; and 225 in year three. (Appl., III-3).

PATIENT ORIGIN

Catheterization Laboratory

PGHC

PGHC opened its cardiac catheterization laboratory in October, 1988. No additional equipment or construction/renovation costs are proposed as a part of the OHS program. The laboratory had performed 25 catheterizations at the time the pre-filed testimony was submitted (11-14-88) and 38-40 catheterizations by the time of Dr. Shawl's cross examination (12-9-88). The Catheterization laboratory was only open two days per week at that time and the equipment was still undergoing standardization. (Shawl, Pre-filed, p. 3; Shawl, 12-9-88, Trans. p 11; Punja, 11-21-88, Trans. p. 33).

IMA

AMI plans to open a cardiac catheterization laboratory. Witnesses for AMI testified that equipment for this laboratory had been purchased from a hospital in California and was currently in a warehouse in Washington. This equipment was manufactured by the Phillips Corporation and is approximately 5 years old. The space within the hospital which will house the catheterization laboratory requires renovation. Dr. Seides testified that these renovations were "out for bid" at the time of his rebuttal testimony in this case (3-3-89) and that the actual renovations would take approximately 120 days. He further testified that no personnel had been trained at that time but that he expected to "bring in one or more individuals who were already highly skilled from a technical standpoint" and that they "could get up and running with experienced people rather quickly" once

the equipment was in place. (Seides, 11-30-88, Trans. p 21 and 3-3-89, Trans. pp 18-24; Hantman, 11-30-88, Trans. pp 131-2).

Referrals

PGHC

Drs. Neimat, Shawl, Punja, and Goldman testified as to the referral sources from which they expected to obtain OHS and PTCA patients. Drs. Punja and Shawl testified that approximately 300-400 catheterizations would be referred to PGHC by their group. This would result in approximately 80 OHS patients in year 1 of the program. Dr. Goldman testified that he and his partner refer approximately 10-12 patients per year for OHS and that these patients would be referred to Dr. Neimat at PGHC if an OHS program were available there. Dr. Neimat testified that he had personally spoken to 4 physician groups including Drs. Satin, Schwartz, Mathew, Dorian, Goldman, and Nashanani. He indicated that these physicians had told him that they would support a program at PGHC and would refer patients to him at that facility, although he was unable to estimate a specific number of patients. (Appl. p. unnumbered; Goldman, Trans. pp.84-86; Punja, 11-21-88, pp.27-28,43; Shawl, 12-9-88, Trans. p.4; Neimat, 12-9-88, Trans. pp.56-57)

In addition to referrals from private physicians, PGHC has both a medical clinic and a cardiology clinic from which they expect to receive patients for OHS. (Punja, 11-21-88, Trans. pp 85-86).

AMI

Drs. Seides and Hantman testified as to the referral sources from which they expected to obtain OHS and PTCA patients. Dr. Seides testified that approximately one half of his group's patients were geographically located such that they could be served at AMI. This would be approximately 400-500 catheterizations and 125-150 OHS patients per year. These patients are currently treated primarily at WHC. He indicated that his group would continue to practice at WHC and that some of these patients and/or their physicians might want to continue to use WHC. He testified that he had no specific commitment from physicians referring patients to his group to refer to AMI.

Dr. Hantman testified that he had spoken to the following physicians who had indicated to him that they would refer patients to AMI and provided the following estimated numbers of referrals: Dr. Ramakrishna, 30-50 OHS patients; Dr. Shah 50-75 OHS patients; Dr. Meshel, 15-20 patients; Dr. Mathew 10-15 OHS patients; Drs. Rao and Ko, 30-40 OHS patients. Drs. Ramakrishna and Shah currently refer patients to Fairfax Hospital. Drs. Meshel and Mathew currently refer to WHC. Drs. Rao and Ko currently refer to WHC. In addition, he estimated that the other cardiologists on the AMI staff would refer a total of approximately 30-40 patients per year to the program, although he had not personally spoken to these physicians. (Appl. p. III-3; Seides, Pre-filed Dir., p.6; Seides, 11-30-88, Trans. pp.24-30;

Hantman Pre-filed Dir. pp.5-9; Hantman, 11-30-88, Trans. pp 136,141-2,172-3).

AMI does not operate any clinics from which they could receive OHS patients at this time. (Hantman, 11-30-88, Trans. p.159)

Discussion

The Cardiologists who would be performing catheterizations and PTCA for each of the Applicants would also continue to practice at other facilities as well; Dr. Seides at WHC and Dr. Shawl at WAH. Patients or the referring physician often express a preference about the particular facility at which a patient is to receive services. Witnesses for both Applicants testified that OHS is generally performed in the same facility as the catheterization, if an OHS program is available. Therefore, it seems unlikely to the Commission that all of the 400-500 catheterization patients and 125-150 OHS patients that Dr. Seides testified were seen by his group and who were "geographically located" such that they could be treated at AMI, or their referring physicians, would express a preference for AMI or that they would all consent to treatment at that facility. The Commission also notes that Dr. Hantman testified that he expected 50-100 OHS patients from the Seides group to receive surgery at AMI.

There is some overlap in the referral sources cited by witnesses for the two Applicants. For example, Dr. Neimat testified that he had personally spoken with Dr. Mathew who

had indicated that he would refer patients to PGHC. Dr. Hantman testified that Dr. Mathew would refer approximately 10-15 patients per year to AMI. Dr. Hantman also testified that Drs. Rao and Ko are currently members of the AMI cardiology department. They currently perform all of their catheterizations at WAH and refer all of their OHS patients to Dr. Neimat at WAH. Dr. Hantman anticipated that these two physicians would refer approximately 30-40 OHS patients per year to AMI. However, these two physicians have applied for staff privileges at PGHC since the catheterization laboratory opened and, as noted above, they currently refer all of their OHS patients to Dr. Neimat, who would be performing OHS at PGHC. (Hantman, 11-30-88, Trans., pp.134,142; Hantman Pre-filed, pp.8-9)

The Commission does not find that the testimony of these witnesses is necessarily in conflict. Instead, the Commission believes that these physicians, as well as others, might refer patients to an OHS program in either of the applicant facilities, if the quality of the program were acceptable to them.

The Commission notes, however, that Dr. Hantman himself was somewhat tentative in committing referrals from his own physician group to the AMI program. During cross examination, he stated that he does not currently admit patients to AMI and does not see patients there on a consulting basis, but that "...if a quality cardiac catheterization laboratory and surgical program were

developed closer to home, which Doctors' Hospital certainly is, we may very well find it much more efficient and appropriate to send our 100 cardiac catheterizations, 20 angioplasties, 30 surgical cases to Doctor's Hospital".

(Hantman, Pre-filed Dir. pp. 8-9; Hantman, 11-30-88, Trans. p 127,142,176; Neimat, 12-9-88, Trans. pp 56-57).

Testimony from Dr. Seides indicated that there is a ratio of approximately 1 OHS and 1 PTCA for every 4 catheterizations. (Seides, 11-30-88, Trans., pp.31-2).

The Commission finds that both Applicants have projected sufficient OHS volume in year three to be consistent with this Standard.

Although PGHC has a functional cardiac catheterization laboratory, it has been in operation for only a short time and has not yet generated a significant volume of patients.

AMI has proposed, but not yet opened, a cardiac catheterization laboratory.

The Commission finds that neither the existing nor proposed cardiac catheterization laboratories at the Applicant facilities are, at this time, a significant factor in generating the projected volumes of OHS patients.

However, the Commission further finds that both Applicants have identified sufficient referral sources to provide the minimum volume required by this Standard.

E. 10.24.07 CS/CC 10
Staffing levels for cardiac surgery and cardiac catheterization programs must be consistent with the most recent guidelines established by the Inter-Society Commission for Heart Disease Resources.

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	N SERVICE AREA	616			599			584			569			556			545		
ASSOVII HONS:		MARYLAND HOS		458			446			434			423			414			405		
	WASHING	GTON, DC HOSPI	TAL VOLUME (2)	157			153			149			145			142			139		
				5 420/			2.550/			2 522/			2.550/			2.250/			2 222/		
		MHCC PROJECTI	ED DECREASE 1-7	-5.12%			-2.66%			-2.63%			-2.55%			-2.25%			-2.00%		
		ACTUAL										PROJ	ECTED			<u> </u>					
		FY2014 MARKET UDING EXTREME SEV			FY2016			FY2017			FY2018			FY2019			FY2020			FY2021	
	(EXCL	ODING EXTREME SEV	/ENITY	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER	UM	UMMC	OTHER
	TOTAL	UMMC	OTHER	BWMC	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		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		
			272	246		- 12	222			222		4-				222			240		
MARKET SHIFT BREAKDOWN HOPKINS			259 119	246 113	5%	12	239 110	15%	36	233 107	20%	47 21	227 104	25%	57 26	222 102	30%	67 31	218 100	34%	74 34
UNION MEMORIAL			61	58	5%	3	56	15% 15%	8	55	20%	11	54	25% 25%	20 14	52	30%	16	51	34% 34%	17
SINAI			9	a 38	5%	0	8	15%	1	Q	20%	2	8	25%	2	8	30%	2	8	34%	3
PENINSULA REGIONAL			19	18	5%	1	18	15%	3	17	20%	4	17	25%	4	16	30%	5	16	34%	6
WASHINGTON ADVENTIST			11	10	<i>5%</i>	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
c.n. ssinte			.0		370			1370			2070	,		2370	- J		3070	10		3 170	
PROCEDURE MIX	TOTAL	ИММС	OTHER ⁽³⁾	UM BWMC			UM BWMC			UM BWMC			UM BWMC			UM BWMC			UM BWMC		
VALVE ONLY (25.7%)		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		
			(0)	UM			UM			UM			UM			UM			UM		
PAYOR MIX	TOTAL	UMMC	OTHER ⁽³⁾	BWMC			BWMC			BWMC			BWMC			BWMC			BWMC		
BLUE CROSS (16.2%)	105	38	67	14			33			37			40			43			44		
COMMERCIAL (12.6%)		34	48	11			26			29			32			33			34		
HMO (11.9%)	<i>77</i>	20	57	10			24			27			30			31			32		
MEDICAID (6.8%)		19	25	6			14			15			17			18			18		
MEDICARE (50.1%)		108	217	42			102			114			125			132			135		
OTHER (1.2%)		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							PROJECTED											
	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	Discharges Shifting to
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



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21037 Other Service Area 5 2 1 - - 1 - 1 - <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>-</td> <td>1</td> <td>_</td> <td></td> <td></td> <td>-</td> <td>-</td> <td>-</td> <td><u>-</u></td> <td></td> <td>-</td> <td>-</td> <td>-</td> <td>-</td>							-	1	_			-	-	-	<u>-</u>		-	-	-	-
21056 Other Service Area - <td></td> <td></td> <td>5</td> <td></td> <td></td> <td></td> <td></td> <td>1</td> <td></td> <td></td> <td></td> <td>1</td> <td></td> <td>-</td> <td></td> <td></td> <td></td> <td>-</td> <td>1</td> <td>2</td>			5					1				1		-				-	1	2
21114 Other Service Area 1 3 - - - 1 1 9 15 - <td></td> <td></td> <td>-</td>			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21140 Other Service Area - 1 - <td></td> <td></td> <td></td> <td>-</td> <td></td> <td>-</td> <td>-</td> <td></td> <td>2</td> <td>-</td> <td></td> <td>1</td> <td>1</td> <td>-</td> <td></td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>2</td>				-		-	-		2	-		1	1	-		-	-	-	-	2
21401 Other Service Area 3 7 1 - - - 1 19 31 1 1 - - - - 1 3 21403 Other Service Area 2 6 - - - - 1 14 23 1 - - - - - 1 2 21409 Other Service Area 2 6 - - - - - 5 13 1 - - - - - 1 Other Service Area Sub Total 24 65 6 4 - 11 7 102 219 7 3 - - - - - 3 14			1			-	-	1				-	-	-	<u>-</u>		-	-	-	-
21409 Other Service Area 2 6 - - - - 5 13 1 - - - - - 1 Other Service Area Sub Total 24 65 6 4 - 11 7 102 219 7 3 - - - 1 - 3 14				7	1	-	-	-	1	19	31	1	1	-	-	-	-	-	1	
Other Service Area Sub Total 24 65 6 4 - 11 7 102 219 7 3 1 1 - 3 14						-	-	-	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	Januar Service		27	0.5	ı U	7	_	11	,	102	LLJ	,	3		-	_	1	-	3	17
	Grand Total		224	119	61	9	19	11	40	166	649	64	6	3	-	1	1	1	8	84



584

-2.7% -2.7% -2.7% -2.7% -2.7% -2.7% -2.7% -2.7% -2.6% -2.6% -2.6% -2.6% -2.6% -2.6% -2.6% -2.6% 20.0% 20.0% 20.0% 70.0% 15.0% 15.0% 15.0% 15.0% 15.0% 15.0% 15.0% *75.0%* 20.0% 20.0% 20.0% 20.0% 8 149 207 110 56 8 18 10 37 153 599 201 107 55 18 10 36

		207	110	56	8	18	10	37	153	599	201	107	55	8	18	10	36	149	584
	Γ			5	FY17	SHIFT TO B	WMC	l		!-			5	FY18	SHIFT TO B				!-
.				MEM			ADV	JC JC	д.	BWMC SHIFT			UNION MEM			ADV	ΛC	۵	BWMC SHIFT
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 Primary Service Area	14 20	1	1	-	-	-	-	-	16 21	15 21	1	1	-	-	-	-	-	17 23
	Primary Service Area	19	1	2	-	-	-	-	1	23	20	1	2		-	-	-	2	25
	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
	Secondary Service Area Secondary Service Area	3 2	-	-	-	-	<u>-</u>	-	-	2	2	-	-	<u> </u>	_	-	-	-	2
	Secondary Service Area	5	1	-	-	-	-	-	-	6	5	-	-	-	-	-	-	-	5
21108	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
	Upper Shore Areas	-	-	-	-	-		-	-	-	-	-	-		-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	1	-	-	-	-		-	-	1	1		-		-	-	-	-	1
	Upper Shore Areas			-					_	-		_				-	-		-
21612	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-
	Upper Shore Areas	2	-	-	-	-	-	-	1	3	2	1	-	-	-	-	-	1	4
	Upper Shore Areas Upper Shore Areas	2	_	-	-	-		-	1	2	2	1	-	-	-	-	-	- 1	2
	Upper Shore Areas Upper Shore Areas		_	-	-	-	<u>-</u>	_	_	3	-		-	-	-	-	-		-
	Upper Shore Areas									-									-
21625	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	2	-	-	-	-	-	1	-	3	2	-	-	-	-	-	-	-	2
	Upper Shore Areas			-	-	-	<u>-</u>	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	1	1	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	1	-	-	-	-	-	-	1	2	1	-	-	-	-	-	-	1	2
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	1	-	-	-	2
	Upper Shore Areas Upper Shore Areas	_		_		_	<u>-</u>	_		-	-		-	<u>-</u>	_		-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	1		-		_	<u>-</u>	-	-	1	1		-		_	-	-	-	1
	Upper Shore Areas	_	_	-	_	_		_	-	-	-	-	-		_	-	-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	1 2	-	-	-	- 1	-	-	-	3	1	-	-	-	1	-	-	-	1
	Upper Shore Areas	1		_		-		-	_	1	1	_	-		_		-		1
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-		-	-	-	-	1
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	2	-	-	-	-	<u>-</u>	-	1	3	2	-	-	<u> </u>	_	_	-	-	2
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	2	-	-	-	-	-	-	1	3	2	-	-	-	-	-	-	2	4
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	1	<u>-</u>	-	-	-	<u>-</u> -		-	1	1	_	-	-	-		-	-	1
	Upper Shore Areas	1		-					-	1	1		-			-	-		1
21673	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	1	-	-	_	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Area Sub Total	37	1	-		3	-	1	5	47	39	3	-		4	_	-	5	51
	Other Service Area	-		-	-	-	-		1	1	-		-	-	-	-	-	2	2
	Other Service Area	1	1	-	1	-	1	-	-	4	1	1	-	1	-	1	-	-	4
	Other Service Area	-	_	-	-	-	1	-	-	1	-	-	-	-	-	1	-	-	1
	Other Service Area Other Service Area	-		-	_	_		-	1	1	-		-	-	-	-	-	1	1
	Other Service Area	-							-	-	-	-	-	-	-	-	-	-	-
20763	Other Service Area	_		-	_	-	_	-	-	-	-	1	_	-	_	-	-	_	1
	Other Service Area	1	-	-	-	-	-	-	1	2	1	-	-	-	-	-	-	1	2
	Other Service Area	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other Service Area Other Service Area	1	1		-		-	_	-	2	1	2	-	-	-	-	-		3
	Other Service Area	1	1						1	3	1	1						1	3
21032	Other Service Area	1	-	-	-	-	-	-	-	1	1	-	-	1	-	-	-	-	2
	Other Service Area	-	-	-	-	-	-	-	1	1	-	1	-	-	-	-	-	1	2
	Other Service Area Other Service Area	3	-	-	-	-	-	-	2	5	3	-	-	-	-	-	-	3	6
	Other Service Area	3	2	1	-	-	<u>-</u>	1	-	7	3	1	-	-	-	-	1	-	5
	Other Service Area	1		-		_		-	1	2	1	1	_		-		-	2	4
	Other Service Area	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other Service Area Other Service Area	2 1	1 1	-	-	-		-	3 2	6 4	2	1	-	-	-	-	- 1	3	6
	Other Service Area	1	1	_	<u> </u>	-	<u>-</u>	_	1	3	1	1	-	-	_	-		1	3
	e Area Sub Total	16	8	1	1	-	2	1	14	43	16	11	-	2	-	2	2	19	52
Grand Total		145	17	8	1	3	2	5	23	204	151	21	11	2	4	2	7	30	228



556

-2.6% -2.6% -2.6% -2.6% -2.6% -2.6% -2.6% -2.6% -2.3% -2.3% -2.3% -2.3% -2.3% -2.3% -2.3% 80.0% 25.0% 25.0% 25.0% 25.0% 25.0% 25.0% 25.0% 80.0% 30.0% 30.0% 30.0% 30.0% 30.0% 30.0% 30.0% 8 9 142 197 104 54 8 17 10 33 145 568 193 102 52 16 34

		197	104	54	8	17	10	33	145	568	193	102	52	8	16	9	34	142	556
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Zip Code	Service Area	u		N MEM			ADV	SJMC	SP	BWMC SHIFT	u		UNION MEM			ADV	SJMC	SP	BWMC SHIFT
Zip code	Service Area	ОММС	표	UNION	SINAI	PRMC	WASH	UM SJ	с ноsp	NMC	ОММС	王	NON	SINAI	PRMC	WASH	UM SJ	с ноsp	NM(
21060	Primary Service Area	5	<u> </u>	<u>5</u>	IS -	-	<u></u>	<u> </u>	<u>ā</u>	<u>n</u> 17	5 15	<u> </u>	<u>5</u>	<u>.</u>	<u>-</u>	≥	<u>5</u>	<u> </u>	<u></u>
	Primary Service Area	22	1	1	-	-	-	-	_	24	21	1	1	-	-	-	1	1	25
	Primary Service Area	21	2	2	1	-	-	1	2	29	21	2	2	-	-	-	1	2	28
	Primary Service Area Primary Service Area	6	1	3		-	-	1	-	7	6	2	1 4	-	-	_	-	-	7
	ice Area Sub Total	<i>67</i>	5		1	-	-	2	2	85	66	6	9	-	-	-	3	3	87
	Secondary Service Area	3	-	-	-	-	-	-	-	3	3	1	-	-	-	-	-	1	5
	Secondary Service Area	2	-	-	-	-	-	-	-	2	2	1	-	-	-	-	-	-	3
	Secondary Service Area Secondary Service Area	6	-	1		-		- 1	1	6 9	5 6	1	- 1	<u> </u>	-	-	- 1	1	6
	Secondary Service Area	3	1	-		1		-	1	6	3	1	-		-	-	-	1	5
	Secondary Service Area	7	1	-	-	-	-	-	3	11	8	1	-	-	-	-	-	2	11
	Secondary Service Area	1	-	1	-	-	-	-	-	2	1	-	1	-	-	-	-	-	2
	Secondary Service Area ervice Area Sub Total	4 32	2 4	2 4	-	1	-	3 4	5	11 50	4 32	1 6	3 5		-	-	3 4	- 5	11 52
	Upper Shore Areas	6	1	1	-	2	-	-	-	10	7	1	-	-	2	-	-	-	10
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	1	-	-	-		-	-	-	1	1 -	-	-	-	-		-	-	-
21612	Upper Shore Areas									-					-				-
	Upper Shore Areas	2	-	-	-	-	-	-	2	4	2	1	-	-	-	-	-	3	6
	Upper Shore Areas Upper Shore Areas	2	- 1	-	_	-	-	1	2	6	2	1	-	-	-	-	-	2	3
	Upper Shore Areas	-	-	-				-	-	-	-	-	-		-		-	-	-
21624	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	2	-	-	-		-	-	-	2	1	-	-	-	-	-	-	-	1
21632	Upper Shore Areas	2								2	1				-				1
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	1	-	-	-	-	<u>-</u>	-	- 1	1	1	-	-	<u>-</u>	-	-	-	- 1	1
	Upper Shore Areas	1	-	-	-	1		-	-	2	1	-	-		1	-	-	-	2
21640	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	-	-	-	-	-	<u> </u>	-	-	-	-	-	-		-	-	-	-	_
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
21649	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas Upper Shore Areas	-	-	-	-	-	<u>-</u>	-	-	-	-	-	-	<u>-</u>	-	-	-	-	-
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	2 1	-	-	-	-	-	-	-	2	2	-	-	-	1	-	-	-	3
	Upper Shore Areas	1	-	-	-	-		-	-	1	1	-	-		-	-	-	-	1
21660	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	3	-	-		-	<u>-</u>	-	-	3	3	-	-	<u> </u>	1	-	-	1	5
	Upper Shore Areas	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Upper Shore Areas	2	1	-	-	-	-	-	2	5	2	-	1	-	-	-	-	2	5
	Upper Shore Areas Upper Shore Areas	- 1	-	-	-	-	-	-	-	- 1	- 1	-	-	-	-	-	-	-	1
	Upper Shore Areas									-	-		-		-		-		-
21671	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1
	Upper Shore Areas Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	-	-	-	1	-	2
	Upper Shore Areas	1	-	-	-	-	-	-	-	1	1	-	-	<u>-</u>	-	-	-	-	1
21679	Upper Shore Areas	-		-		-		-	-	-	-	_	-	-	-	-	-	-	-
	Area Sub Total	41	3	1	-	3	-	1	7	56	40	3	1	-	5	-	1	10	60
	Other Service Area Other Service Area	1	3	-	1		1	-	2	6	1	1	-	1	-	1	-	2	4
20724	Other Service Area		-		-		1			1		1			-	1			2
	Other Service Area	-	-	-	_	-	1	-	1	2	-	-	-	-	-	-	-	1	1
	Other Service Area Other Service Area	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	1	1
	Other Service Area	-	1	-	-	-	-	-	-	1		1	-	-	-		-		1
20764	Other Service Area	1	-	-	-	-	-	-	1	2	1	1	-	-	-	-	-	1	3
	Other Service Area	-	-	-	-	-	-	-	-	-	-	1	-	-	-	1	-	-	2
	Other Service Area Other Service Area	1	- 1	-		-	-	-	-	2	1	1	-	-	-	-	-	-	2
	Other Service Area	1	1						2	4	1	1	-					2	4
21032	Other Service Area	1	-	-	-	-	-	-	-	1	1	1	-	-	-	-	1	-	3
	Other Service Area	-	1	-	-	-	-	-	2	3	-	1	-	-	-	-	-	2	3
	Other Service Area Other Service Area	- 4	-	-		-	<u>-</u>	-	3	7	3 -	1	-	-	-		-	4	8
	Other Service Area	3	2	1				1		7	3	1	1	1			1		7
21114	Other Service Area	1	1	-	_	-	-	-	2	4	1	1	-	-	-	-	-	2	4
	Other Service Area Other Service Area	2	2	-	-	-	-	-	- 4	- 8	2	2	-	-	-	-	-	- 5	- 9
	Other Service Area	1	1	-	-	-	-	-	3	5	1	1	-	-	-		-	4	6
21409	Other Service Area	1	1	-	-	-	-	-	1	3	1	1		_	-	-	-	1	3
Other Service	e 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
Grana Tolai		15/	20	14	2	4	3	ð	30	250	154	21	10	2	5	3	10	45	264

Grand Total



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					FY21 S	SHIFT TO B	WMC			
Zip Code	Service Area	UMMC	НН	UNION MEM	SINAI	PRMC	WASH ADV	UM SJMC	DC HOSP	BWMC SHIFT
21060	Primary Service Area	15	1	1	-	-	-	1	-	18
21061	Primary Service Area	20	1	1	-	-	-	1	2	25
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 Serv	vice Area Sub Total	64	6	10	-	-	-	4	5	89
21054	Secondary Service Area	3	1	-	-	-	-	-	1	5
21076	Secondary Service Area	2	1	_	_	_	_	_		3
21090	Secondary Service Area	5	1	_	_	_	_	_		6
21108	Secondary Service Area	6	-	1		_	_	1	1	9
		3		1		_		1		6
21113	Secondary Service Area	7	1		1	-	-	-	1	
21146	Secondary Service Area		1	-	-	-	-	-	3	11
21226	Secondary Service Area	1	-	1	-	-	-	-	-	2
21227	Secondary Service Area	4	1	4	-	-	-	3	-	12
Secondary Se	ervice Area Sub Total	31	6	6	1	-	-	4	6	54
21601	Upper Shore Areas	5	1	1	-	2	-	-	-	9
21606	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21607	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21609	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21610	Upper Shore Areas	-	-	-	-	_	-	_	-	
21612	Upper Shore Areas		_	_	_	_	_	_	_	
21617	Upper Shore Areas	2	1		_	_	_	_	2	5
21619	Upper Shore Areas	2	-	-	_		_	_	1	3
21619		2						1	2	
21620	Upper Shore Areas	1	1	-	-	- 1	-	1		6
	Upper Shore Areas	-	-	-	-	1	-	-	-	1
21624	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21625	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21628	Upper Shore Areas	-	-	-]	-	-	-	-	-	-
21629	Upper Shore Areas	2	-	-	-	-	-	-	-	2
21632	Upper Shore Areas	2			-	_		-		2
21635	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21636	Upper Shore Areas	1	_	-	_	_	_	-	-	1
21638	Upper Shore Areas	1	_	_	_	_	_	_	1	2
21639	Upper Shore Areas	1	_	_	_	1	_	_		2
21640	Upper Shore Areas		_							
-		-			-	-	-	-		
21641	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21644	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21645	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21647	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21649	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21650	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21651	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21652	Upper Shore Areas	_	-	-	-	_	_	-	-	-
21653	Upper Shore Areas	_	_	_	_	_	_	_	_	
21654	Upper Shore Areas	1	_	_	_	_	_	_	_	1
21655	Upper Shore Areas	2	_			1	_			3
		1	-	-		т	-	-	-	
21657	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21658	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21660	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21661	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21662	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21663	Upper Shore Areas	2	-	-	-	-	-	-	1	3
21665	Upper Shore Areas	-	-	-	-	-	-	-	-	-
21666	Upper Shore Areas	2	-	-	-	-	-	-	2	4
21667	Upper Shore Areas		-	_	_	_	-	_	-	
21668	Upper Shore Areas	1			_	_	_	_		1
		1	-	-	-	-	-	-	-	
21670	Upper Shore Areas	-	-		-	-	-	-		-
21671	Upper Shore Areas	1	-		-	1	-	-		2
21673	Upper Shore Areas	1	-	-	-	-	-	-	-	1
21676	Upper Shore Areas	1	-	-	-	_	-	-	-	1
21678	Upper Shore Areas	1	-	-]	-	-	-	-	1	2
21679	Upper Shore Areas		-		-	_	-	-		-
Upper Shore	Area Sub Total	39	3	1	-	6	-	1	10	60
20711	Other Service Area	-	-	-	-	-	-	-	2	2
20723	Other Service Area	1	2	_	1	_	1	_	-	5
20724	Other Service Area	_	1	_	_	_	2	_	_	3
20724	5 5 C. 110C / 11 CU	-			_		_		1	1
2.1.7.	Other Service Area	_	_			_	_		1	
	Other Service Area	-	ì							
20751	Other Service Area	-	-	-	-	-	-	-		1
20751 20755	Other Service Area Other Service Area	-	-	-	-	-	-	-	-	-
20751 20755 20763	Other Service Area Other Service Area Other Service Area	-	- 1		- -	-	-	-	-	- 1
20751 20755 20763 20764	Other Service Area Other Service Area Other Service Area Other Service Area	- - - - 1	- 1 1	- - -	- - -	- - -	-	- - -	-	- 1 3
20751 20755 20763 20764 20776	Other Service Area Other Service Area Other Service Area		- 1			-	-	-	-	- 1
20751 20755 20763 20764	Other Service Area Other Service Area Other Service Area Other Service Area		- 1 1			- - - -	-	- - - -	-	- 1 3
20751 20755 20763 20764 20776	Other Service Area		- 1 1			- - - - -	- - -	- - - - -	-	- 1 3
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20751 20755 20763 20764 20776 20778 20794 21012 21032	Other Service Area	1 - - 1	1 1 1 1 - 1 1		- - -		-	-	- 1 - - - 2	1 3 1 - 2 4
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035	Other Service Area	1 - - 1 1 1	1 1 1 1 - 1 1 1		- - - -		-	- - - - - - - -	- 1 - - - 2 - 2	- 1 3 1 - 2 4 3 3
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037	Other Service Area	1 - - 1 1 1 - 3	1 1 1 1 1 1 1 1 1		- - - - 1	-	-	- - - - - - - - -	- - 1 - - - 2 - 2 4	- 1 3 1 - 2 4
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056	Other Service Area	1 	1 1 1 1 1 1 1 1 1	- - - - - -	- - - - 1	-	-	- - - - - - - - - - -	- - 1 - - - 2 - 2 4	1 3 1 - 2 4 3 3
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075	Other Service Area	1 	1 1 1 1 1 1 1 1 1		- - - - 1		-	- - - - - - - - 1	- - 1 - - 2 - 2 4 -	1 3 1 2 4 3 3 8
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114	Other Service Area	1 	1 1 1 1 1 1 1 1 1	- - - - - -	- - - - 1	- - - - - - - - - - - - -	-	- - - - - - - - 1	- - 1 - - - 2 - 2 4	- 1 3 1 - 2 4 3 3 8
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114 21140	Other Service Area	1 	1 1 1 1 1 1 1 1 1 1 1	- - - - - - -	- - - - 1	-	-	- - - - - - - - 1	- - 1 - - - 2 - 2 4 - - - 2	1 3 1 - 2 4 3 3 8 - 5
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114 21140 21401	Other Service Area	1 	1 1 1 1 1 1 1 1 1 1 1 1 1	- - - - - - -	- - - - 1	-	-	- -	- - 1 - - - 2 - 2 4 - - 2 - 2	1 3 1 - 2 4 3 3 8 - 5 4 -
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114 21140 21401 21403	Other Service Area	1 	1 1 1 1 1 1 1 1 1 1 1 1 1 2	- - - - - - -	- - - - 1	-	-	- - - - - - - - 1	- - 1 - - - 2 - 2 4 - - - 2	1 3 1 - 2 4 3 3 8 - 5
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114 21140 21401 21403 21409	Other Service Area	1 	1 1 1 1 1 1 1 1 1 1 1 1 2 2 2	- - - - - - - - - -	- - - 1 - - -	- - - - - - - - - - - - - - - -	-	- -	- - 1 - - 2 - 2 4 - - 2 - 2 4 - 1	1 3 1 - 2 4 3 3 8 - 5 4 -
20751 20755 20763 20764 20776 20778 20794 21012 21032 21035 21037 21056 21075 21114 21140 21401 21403 21409	Other Service Area	1 	1 1 1 1 1 1 1 1 1 1 1 1 1 2	- - - - - - - - - -	- - - 1 - - - -	-	-	- -	- - 1 - - - 2 - 2 4 - - 2 - 2 - 2	- 1 3 1 - 2 4 3 3 8 - 5 4 - 9

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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 2156 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