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January 19, 2017

VIA EMAIL

Craig Tanio, M.D.
Chair/Reviewer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: AAMC Response to Exceptions to Recommended Decision

Dear Commissioner Tanio:

Pursuant to your letter of December 30, 2016 and COMAR 10.24.01.09(B), enclosed please find Anne Arundel Medical Center, Inc.'s response to exceptions.

The required paper copies will follow.

Sincerely,

Jonathan Montgomery/dms

Jonathan Montgomery

Enclosures

cc: Jinlene Chan, M.D., Health Officer, Anne Arundel County (via email)
Paul Parker, Director, Center for Health Care Facilities Planning & Development, MHCC (via email)
Suellen Wideman, Esq., Assistant Attorney General, MHCC (via email)
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Steve R. Schuh, Anne Arundel County Executive (via email)
Kevin R. McDonald, Chief, Certificate of Need, MHCC (via email)
Anne Arundel Medical Center (via email for Internal Distribution)

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ANNE ARUNDEL MEDICAL CENTER	*	
Docket No. 15-02-2360	*	
* * * * * * *		BEFORE THE
IN THE MATTER OF UNIVERSITY	*	MARYLAND HEALTH CARE
OF MARYLAND BALTIMORE	*	COMMISSION
WASHINGTON MEDICAL CENTER	*	
Docket No. 15-02-2361	*	

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ANNE ARUNDEL MEDICAL CENTER
RESPONSE TO EXCEPTIONS TO RECOMMENDED DECISION

Anne Arundel Medical Center, Inc. ("**AAMC**"), by its undersigned counsel, hereby responds to the January 11, 2017, exceptions filed to Chairman Tanio's December 30, 2016, recommended decision (the "**Recommended Decision**") in regard to the above-captioned Baltimore Upper Shore Cardiac Surgery Review (the "**Review**"). In particular, AAMC responds to the exceptions filed by (1) University of Maryland Baltimore Washington Medical Center ("**BWMC**"); (2) Dimensions Health Corporation d/b/a Prince George's Hospital Center ("**PGHC**"); and (3) Medstar Health, Inc. ("**MedStar**").

I. SUMMARY

AAMC endorses the Recommended Decision by Chairman Tanio. As set forth in the Recommended Decision, Chairman Tanio duly finds that AAMC's application to establish a new cardiac surgery program satisfies all of the criteria imposed by the Cardiac Chapter of the State Health Plan ("**Cardiac Chapter**"), while the competing application of BWMC does not. Chairman Tanio persuasively articulates how, because of its size, location, and larger service area, AAMC is better positioned than BWMC to attain the cardiac surgery case volumes required

by the Cardiac Chapter. In that context, Chairman Tanio prudently recommends that only one proposed program – that of AAMC – receive approval, given the geographic proximity of the two hospitals. In short, Chairman Tanio correctly concludes that AAMC, in collaboration with Johns Hopkins Medicine, has the greatest potential to establish a low-cost, high-performance cardiac surgery program, improving access to cardiac surgery services for patients in Anne Arundel County and the broader Baltimore Upper Shore region.

As explained more fully below, the exceptions filed by BWMC, Medstar, and PGHC are baseless and, in many cases, disingenuous and constitute a last ditch effort to thwart the Commission's vote on AAMC's request to launch a much-needed cardiac surgery program in Anne Arundel County. AAMC has grouped the scatter-shot exceptions to the Recommended Decision into five categories, corresponding to the relevant State Health Plan criteria – volume, impact, need, financial feasibility, and access – and has addressed each in turn.

1. Volume

Chairman Tanio's use of a simple alternative framework, referred to in this Response as the "Credibility Model," to test the volume projections of AAMC and BWMC was sensible. Contrary to BWMC's claims, Chairman Tanio had no obligation to accept uncritically the predictions set forth by AAMC and BWMC in their applications. Chairman Tanio, instead, used a conventional service area analysis to demonstrate that AAMC's proposed cardiac surgery program would likely achieve the volume necessary for a sustainable, high-quality program, while BWMC's proposal would not.

Chairman Tanio's use of the Credibility Model was within his discretion in this Review. Chairman Tanio did not override or violate the projection methodologies permitted in the State Health Plan. Rather, he used the Credibility Model to *test* the credibility of the parties' projections on an "apples to apples" basis.

Chairman Tanio also did not violate anyone's constitutional rights to due process. Chairman Tanio complied with the Administrative Procedure Act by taking notice of non-controversial data – such as the audited financial statements of the applicants and publicly available population and discharge data – and by giving the parties an opportunity to respond through the exception process.

2. Impact

AAMC agrees that the residents of Prince George's County deserve access to high quality health care, and it recognizes the substantial investment made by the State and County in PGHC. However, Chairman Tanio rightly concluded that AAMC's proposed cardiac surgery program can coexist with a sustainable program at PGHC. There are enough cardiac surgery cases to sustain both programs, and the lack of overlap in referral sources ensures that AAMC's program will have, at most, a minimal impact on PGHC's program. The people of Anne Arundel County also deserve a cardiac surgery program to meet their needs. Unsupported, speculative, and fanciful objections should not stand in the way.

3. Need

The State Health Plan required Chairman Tanio to assess the need for AAMC's proposed cardiac surgery program by measuring whether its volumes would meet the minimum threshold in light of regional trends in population and cardiac surgery volumes. He did just that. MedStar's exception to his analysis is nothing more than a complaint about the standards established by the State Health Plan following a transparent and extensive review which included input by all stakeholders and the Legislature.

4. Financial Feasibility

Chairman Tanio found that AAMC's proposed program would be low charge, economically sustainable when considered from a conventional accounting perspective, and in

harmony with the overall financial feasibility of AAMC as a hospital. Chairman Tanio is also in complete alignment with the Health Services Cost Review Commission ("**HSCRC**"), which has similarly opined in this Review that a cardiac surgery program at AAMC is financially feasible.

5. Access

AAMC established in this Review that its patients, and the residents of Anne Arundel County and the larger region, face significant disruptions to needed cardiac care. Commissioner Tanio did not give undue weight to AAMC's essentially unrebutted case in this regard. The Recommended Decision clearly states that access considerations are "secondary" to the decision. However, the Commission should still recognize that a cardiac surgery program at AAMC will bring real and measurable benefits to the spectrum of care received by cardiac patients and their families.

The Commission should respect the thoroughness and thoughtfulness of Chairman Tanio and Staff in this multi-year review, and adopt the Recommended Decision.

II. CHAIRMAN TANIO CORRECTLY CONCLUDED THAT AAMC HAS DEMONSTRATED THE ABILITY TO MEET THE MINIMUM VOLUMES STANDARD, WHILE BWMC HAS NOT.

A. Chairman Tanio's Alternative Model – Referred To Herein As The Credibility Model – Is A Framework For Testing The Minimum Volume Projections By AAMC and BWMC, Not A Substitute Methodology For Determining Minimum Volume.

BWMC argues that Chairman Tanio applied an alternative forecast model ("Credibility Model") as the standard for assessing minimum volume and that his Credibility Model is inconsistent with the standards in the State Health Plan.[1] BWMC misses the point. Chairman Tanio's Credibility Model is a framework for *testing* the minimum volume projections by AAMC and BWMC, using more conservative service area and market share assumptions than those used by the applicants, not a replacement methodology for determining minimum volume.

[1] BWMC Exceptions at 5-10.

The Credibility Model is consistent with both applicants' CON applications and the State Health Plan in its use of conventional zip-code defined inpatient service areas, population use rate, and observed cardiac market share to assess whether the applicants are likely to achieve the minimum 200 cardiac surgery cases necessary to sustain a cardiac surgery program. As Chairman Tanio explained:

> Based on my review of the applications, I constructed a simple alternative forecast model at the hospital service-area level, like the applicants. This is not a rejection of the applicants' response to this standard. It is intended to provide some balance and allows both applications to be compared with consistent standards. The main attraction of this approach is that, first, it relies on established inpatient service areas, which both applicants used to inform their service area definitions but only as one factor. Second, it uses observed cardiac market shares within an identically constructed service area for similar existing programs. So, the model's key moving parts are the population use rate, which is projected to be declining, consistent with the SHP model at the time these applications were filed, and observed cardiac market share.[2]

Because the Credibility Model is a framework for testing the applicants' minimum volume projections, and not a replacement methodology for determining minimum volume, it should be evaluated in the context of its findings regarding the soundness of the volume projections by AAMC and BWMC. In essence, the Credibility Model enabled Chairman Tanio to compare "apples to apples" and "oranges to oranges" and to test the reasonableness of each applicant's projections. He concluded that AAMC presented information and analyses that demonstrate the ability to meet a projected volume of 200 adult open heart surgery cases in the second full year of operation, while BWMC did not. The Commission should adopt his Recommended Decision.

B. The Credibility Model Is A Conventional And Logically Sound Framework For Testing The Applicants' Volume Projections, And It Shows That

[2] Recommended Decision at 27.

AAMC's Projections Are Substantially More Robust Than BWMC's Projections.

The Credibility Model starts by assessing each applicant's baseline market – the populations from which each cardiac surgery program would potentially derive their patients. Chairman Tanio used, as the baseline market, the applicants' observed 85% relevance medical/surgical/gynecological/addictions ("MSGA") service areas, consisting of a group of zip code areas that contributed, ranked by highest to lowest frequency, 85% of MSGA discharges.[3] Chairman Tanio concluded that BWMC has a much smaller MSGA service area (15 zip codes with a 2015 estimated population of 335,000) than AAMC (39 zip code areas with an estimated 2015 adult population of 674,000).[4] He also concluded that BWMC has a much larger overlap

[3] Although BWMC questions the use of the MSGA service area as the relevant baseline market for cardiac surgery cases (BWMC's Exceptions at 10-18), Chairman Tanio's approach is the conventional method for assessing a hospital's ability to build volume. Both BWMC and AAMC used zip-code based service areas in their volume projections, although they were customized service areas for a cardiac surgery project. (Exhibit 23 to AAMC's Response to Second Set of Completeness Questions; DI #8BW, Exhibit 44). Chairman Tanio noted that the MSGA service areas developed for both applicants using the Credibility Model were smaller geographically and had smaller populations than the service areas defined by the applicants in their CON applications. (Recommended Decision at 27). In other words, Chairman Tanio applied the more conservative service area assumptions to both applicants' projections.

BWMC purports to use a linear regression analysis to challenge the strength of the correlation between a hospital's MSGA service area population size and open heart surgery discharges (BWMC's Exceptions at 17-18 & Exhibit 1). BWMC's analysis is fatally flawed. First, BWMC excludes from the analysis the two academic hospitals with the greatest MSGA service area population bases and the largest number of open heart surgery discharges, JHH and UMMC, thereby skewing the analysis and reducing the number of observations in an already limited regression analysis (based on eight hospitals and a single snapshot of time). If one incudes JHH and UMMC in the regression analysis, the resulting correlation between MSGA service area population size and open heart surgery discharges is much stronger: R^2 = .7834, as compared with the 0.1503 calculated by BWMC. *See* Exhibit 1 hereto. Second, BWMC's conclusion that $y = 0.0001x + 205.75$, with "x" representing the MSGA service area population, is nonsensical. If the MSGA service population is 0, under BWMC's formula, there would still be 206 cardiac surgery patients. Assuming a standard error rate of 50%, BWMC's formula would still show 103 cardiac surgery patients for an MSGA service area with a population size of 0.

[4] Recommended Decision at 29.

AAMC and BWMC both replicated Chairman Tanio's calculation of the applicants' MSGA service areas and both concluded that, while Chairman Tanio correctly determined BWMC's MSGA service area, AAMC's MSGA area is actually slightly larger than Chairman Tanio calculated: it consists of 41 (not 39) zip codes, including 20785 and 21629, which together add 37,180 to the adult population figure for AAMC's MSGA service area. *See* Exhibit 2 hereto and BWMC's Exceptions at 41. This

with the AAMC service area (73%) than AAMC has with the BWMC service area (36%), meaning it would be harder for BWMC to capture sufficient cases if both programs were approved. These findings are significant because they show that AAMC has a more expansive service area and a larger population from which to draw potential patients than does BWMC.[5] While not the only factor to be considered, this factor further supports the argument that AAMC represents the location with the greater opportunity for a successful cardiac surgery program.

The Credibility Model next assumes a normative cardiac surgery market share range of 18% to 20% for surgery cases originating in each hospital's MSGA service area, with a best case scenario of 25%, based on the recent comparable experience of three suburban community hospitals – Suburban, Washington Adventist, and UM St. Joseph's.[6] While BWMC quibbles with the comparability of these three suburban hospitals to AAMC and BWMC,[7] BWMC, again, misses the point.

Chairman Tanio admits that "[p]erfect comparability is not achievable."[8] He selected the maximum figure of 25% market share to test the volume projections of AAMC and BWMC because (1) that figure "allows for a marker of 'best case scenario' success in building a referral base that has some credibility based on the analyses provided by the applicants with respect to

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calculation merely strengthens Chairman Tanio's conclusions regarding the comparative strength of the applicants' volume projections.

[5] BWMC argues that, because it sits in a more densely populated area and has a stronger market share in its surrounding zip codes than AAMC, it is more likely to capture cardiac surgery cases than AAMC. (BWMC Exceptions at 11). This argument is without merit. BWMC, with its close proximity to Baltimore City, is competing with several nearby hospitals with high market shares in cardiac surgery, including UMMC and JHH. AAMC, by contrast, is located more than 30 miles from JHH and nearly 30 miles from the other large urban center, the District of Columbia, with the cardiac surgery program at Washington Hospital Center. Moreover, AAMC is already drawing patients from geographical areas that do not have competing cardiac surgery programs, including the Eastern Shore. Because of its geographical location and its already established, broad-based service area, AAMC is demonstrably better positioned than is BWMC to draw patients to a new cardiac surgery program.

[6] Recommended Decision at 29.

[7] BWMC Exceptions at 21-24.

[8] Recommended Decision at 29.

their update of service lines in their service areas"; (2) AAMC is somewhat unique as a potential cardiac surgery site in Maryland in that "[i]t has suburban and exurban characteristics and its size and the size of its service area set it apart from other existing hospitals"; and (3) the 25% figure "is substantially more conservative than the 40% market share projected by AAMC in Year 3 or the market share implied in the BWMC analysis."[9]

The third step in the Credibility Model consists of an adjustment for the fact that any cardiac surgery hospital will draw some patients from beyond its established 85% relevance MSGA service area.[10] Chairman Tanio noted that, "[o]n average, Maryland's cardiac surgery hospitals have only generated about 75% of their total cardiac surgery case volume from their 85% relevance MSGA service areas, and the most comparable suburban hospitals have only generated about 66% of their cardiac surgery volume from their MSGA service area."[11] Accordingly, Chairman Tanio assumed that AAMC and BWMC would generate 66% of their cardiac surgery volume from their MSGA service areas and 34% from outside those service areas.[12]

Applying the foregoing assumptions and adjustments, Chairman Tanio concluded that AAMC has presented information and analyses that demonstrate its ability to meet the minimum volume threshold, whereas BWMC has not. Specifically, he found that, if AAMC were able to penetrate the cardiac surgery market in its established MSGA service area at levels comparable

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[9] *Id.* In light of these statements, BWMC's suggestion that AAMC will not be able to achieve the 22% market share necessary to capture 200 cardiac surgery cases under the Credibility Model (BWMC Exceptions at 9 n.3 and 28) is without merit. Indeed, AAMC expects to receive the majority of its cardiac surgery patients from internally-generated cases, based on AAMC's past experience in transferring patients requiring cardiac surgery to other hospitals.

[10] Recommended Decision at 30.

[11] *Id.*

[12] BWMC's argument that Chairman Tanio should have assumed that the hospitals would generate 78.8%, rather than 66%, of their cardiac surgery volume from within their MSGA service areas (BWMC's Exceptions at 20-21) does not help BWMC's position, as BWMC itself would admittedly not meet the 200 threshold under that assumption. *Id.*

to that of most existing cardiac surgery hospitals (18-20%), it could project an ability to generate a case volume that approaches 200 open heart surgery cases per year.[13] If AAMC were able to capture a 25% market share, it would be likely to generate a case volume of 200 or more cases per year.[14] Chairman Tanio noted that the 25% market rate was the rate AAMC projected to achieve in its larger defined service area in the first year of operation but was far more conservative than the 40% rate AAMC projected for its third year.[15]

By contrast, even if BWMC achieved the high market rate of 25% in its MSGA service area, it could only hope to capture 126 open heart surgery cases per year.[16] BWMC would have to achieve a 40% market share within its MSGA service area to hit the 200-case minimum – a market share penetration well above the normative levels for existing comparable cardiac surgery hospitals.[17]

Chairman Tanio's conclusion that AAMC's projections for meeting the 200-case threshold are more robust than BWMC's projections is bolstered by other factors, including AAMC's size, its geographical location, the scope of its service area, its historic referral patterns, and its cost structure relative to BWMC:

> I find that the information and analysis provided by the applicants indicates that a cardiac surgery program located at AAMC is likely

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[13] Recommended Decision at 31.

[14] *Id.*

[15] Recommended Decision at 31. AAMC's ability to achieve a 25% market share within its MSGA service area finds substantial support in the record. More than 200 patients per year at AAMC require transfer to other hospitals for cardiac surgery. The majority of these patients can be expected to remain at AAMC for cardiac surgery if the hospital offers this service. (Recommended Decision at 17; DI # 3AA, p. 80). Moreover, AAMC's existing base of affiliated cardiologists is projected to generate a volume of cardiac surgery cases in excess of 200 per year, even if use rates decline as assumed in the SHP volume projections. (Recommended Decision at 16; DI #3AA, pp. 78-79). AAMC's partnership with JHH "provides an additional level of confidence that [AAMC] will be able to reach this use level." (Recommended Decision at 75).

[16] Recommended Decision at 31.

[17] *Id.*

> to have a lower cost to effectiveness ratio associated with its proposed cardiac surgery program than a program located at BWMC. This finding rests on the fact that AAMC is a larger hospital and has a larger service area population than BWMC and, because of its location and historic referral patterns, will be in a stronger position, geographically, than BWMC to shift cardiac surgery market share from two metropolitan areas. Therefore, it is likely to be able to build a larger volume of cases than BWMC without consideration of the efforts of the collaborating partner hospitals in assisting with establishment of case volume. Additionally, AAMC is a lower charge hospital than BWMC and the record establishes that it is likely to be able to provide cardiac surgery at a lower charge than BWMC. Lastly, the service area population of AAMC, on average, resides at a greater distance from existing cardiac surgery programs than the service area population of BWMC. The greater distance from existing programs increases the improved access benefit for the AAMC program when compared to the BWMC program.[18]

Chairman Tanio's Recommended Decision is well-reasoned, supported by substantial evidence, and consistent with the State Health Plan. The Commission should adopt the Recommended Decision.

C. Chairman Tanio Was Not Required To Accept BWMC's Volume Projections, As BWMC Contends.

In its CON application, BWMC projected that it would achieve its minimum volume requirement primarily by shifting cardiac surgery cases from UMMC to BWMC. In the first year of operation, BWMC projected a total of 84 cases, with 76% of the cases (64) coming from UMMC and 24% (20) coming from other Maryland and District of Columbia hospitals.[19] By the second year of operation, BWMC forecast a total of 204 cases, with 71% of the cases (145) shifting from UMMC and the remaining 29% of the cases (59) shifting from other Maryland and District of Columbia hospitals.[20] By 2021, BWMC predicted a caseload of 270 cases, with only

[18] Recommended Decision at 103.

[19] DI #8BW, Exhibit 44.

[20] *Id.*

56% of the cases (150) coming from UMMC and the remaining 44% coming from other Maryland and District of Columbia Hospitals.[21]

BWMC's projections are, as a matter of common sense, both arbitrary and high, given that BWMC is located only 13 miles from UMMC and other Baltimore-area competitors. The projections are also belied by BWMC's underlying assumption that BWMC could capture, at most, only 17.92 % of UMMC's cardiac surgery caseload.[22] Moreover, in responding to the second set of completeness questions, BWMC admitted that it had no credible basis for its assumption that it will have a 50% market share of the cardiac surgery market in its service area[23] and that it had no established referral pattern from non-UMMC hospitals and a low existing market share in peripheral regions of the service area, such as Prince George's County, southern Anne Arundel County, and the Eastern Shore counties.[24]

Despite these manifest weaknesses, BWMC argues that Chairman Tanio was required to find that BWMC's volume projections met the standard of COMAR 10.24.17.05A(1) because Chairman Tanio stated that both applicants' volume projections were "practical and sufficiently documented"[25] and that the Credibility Model was not "a rejection of the applicants' response."[26] (*See* BWMC's Exceptions at 29-30, 32-33). This argument is specious.

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[21] *Id.*

[22] BWMC notes that only 27% of UMMC's cases originate in BWMC's service area. (Application at p. 45). Of those, only 83% are "non-severe" cases, meaning those cases that BWMC would perform under the division of labor between UMMC and BWMC whereby UMMC will retain all cases deemed "severe" by pre-operative screening. (BWMC's Response to Second Round of Completeness Questions ("Completeness II") at p. 2). Of those in-area, non-severe cardiac cases that UMMC otherwise would perform, BWMC expects UMMC to retain 20% of the cases for various reasons. (Completeness II at p. 3). Thus, BWMC does not expect to perform more than 17.92% of all cases UMMC would perform (17.92% = 27% x 83% x 80%). (Completeness II at p. 3).

[23] DI #28GF, p. 10.

[24] *Id.*

[25] Recommended Decision at 26.

[26] Recommended Decision at 27.

Chairman Tanio was not required to blindly accept the forecasts and predictions set forth by the two applicants. As the person charged with determining whether, as a matter of sound public policy, the proposed programs met the requirements of the State Health Plan – whether each program could establish the ability to meet the 200-case threshold, whether each would adversely affect existing cardiac surgery programs, whether the benefits each program brought to the Maryland health care system exceeded the costs to the system, whether each program was financially feasible, and whether, if both programs satisfied all of the State Health Plan requirements, one was comparatively better than the other – Chairman Tanio was required to test each program's forecasts and underlying assumptions critically. Although he found both applicants' projections to be "practical and sufficiently documented" and "reasonable,"[27] he concluded that both applicants' underlying assumptions about service area and market share were not sufficiently conservative, particularly given the decline in the use rate of cardiac surgery and the "sober[ing]" example of Suburban, the most recent hospital to be granted a CON to perform cardiac surgery, whose annual case volume has remained between 200 and 250 cases for several years.[28]

In testing BWMC's forecasts through the use of a more conservative MSGA service area from the Credibility Forecast, Chairman Tanio concluded that BWMC would need to achieve a 40% market share in its service area in order to capture the required 200 cases – a market share far in excess of the normative experience of comparable cardiac surgery suburban hospitals in the region.[29] He also concluded that AAMC was far better situated than BWMC – by size,

[27] Recommended Decision at 26.

[28] Recommended Decision at 27.

[29] Recommended Decision at 32.

internal case load, geographical location, historic referral patterns, scope of service area, and comparative cost – to draw patients from outside BWMC's service area.[30]

BWMC complains that Chairman Tanio failed to consider the fact that BWMC could potentially meet the volume threshold simply by shifting cases from UMMC to BWMC.[31] While Chairman Tanio would have been well within his rights in disregarding BWMC's claim that it could meet the volume threshold simply by shifting cases from UMMC – based on common sense, given the proximity of the two programs, or BWMC's underlying assumption that it could capture, at most, only 17.92% of UMMC's cardiac surgery caseload, or UMMC's admitted concern about the need to support the cardiac surgery program at PGHC by sending cases there – the fact is that Chairman Tanio did consider this claim. However, he did so in a comparative context, concluding that AAMC could succeed at a cardiac surgery program with far less support from its affiliation partner, Johns Hopkins Medicine, than BWMC would require of UMMC to succeed. As Chairman Tanio explained:

> BWMC did not demonstrate that its proposed program can generate at least 200 open heart surgery cases per year form its proposed service area. For BWMC to be able to do so would require an exceptional level of penetration of its market and an even higher level of market share in the alternative service area definition that I used to test both applicants' demand assessments, i.e., the observed MSGA service area providing 85% of MSGA discharges by order of frequency. 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 suburban program, producing a very high BWMC market share. However, my analysis shows that this collaborative support would need to be much strong in the case of BWMC than the support that would be required of JHH for the proposed AAMC project. This results primarily from AAMC's larger service area. Furthermore, AAMC has locational advantages over BWMC with respect to service area

[30] Recommended Decision at 31, 75, 76, 103.

[31] BWMC Exceptions at 36-39.

> and market share. AAMC's location in Annapolis gives it more upside potential for shifting cases from two metropolitan areas, Baltimore and the District of Columbia, while BWMC is more anchored in the Baltimore Market.[32]

In short, BWMC's claimed ability to shift cases from UMMC, even if accepted as true, does not outweigh the many advantages held by AAMC in its comparative ability to succeed at a new cardiac surgery program.

D. Chairman Tanio Did Not Violate BWMC's Due Process Rights By Entering Into The Record, Shortly Before Issuing His Recommended Decision, Population Data By Zip Code Areas Prepared By Nielsen Claritas And The Applicants' Audited Financial Statements.

BWMC complains that Chairman Tanio violated its due process rights by admitting into the record, shortly before his release of the Recommended Decision, new evidence in the form of (1) estimated and projected population data, by zip code areas, prepared by Nielsen Claritas, and (2) audited financial statements of the applicant hospitals,[33] which Chairman Tanio then used in applying his Credibility Model to test the applicants' minimum volume projections.[34] BWMC contends that the admission and use of such data violated BWMC's due process rights because BWMC has not had a meaningful opportunity to contest the data, citing an opinion by the Circuit Court for Baltimore City in *In The Matter of Petition of Clarksburg Community Hospital, Inc.*, Case No. 24-C-11-001046. BWMC's argument is misplaced, and the *Clarksburg* decision is simply wrong.

It is well established that an administrative agency has broad discretion to consider evidence submitted before a final decision by the agency – even if the evidence is first admitted in connection with exceptions to a recommended but-not-yet-final decision. In *Mehrling v. Nationwide Insurance Company*, 371 Md. 40 (2002), the Maryland Court of Appeals held that,

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[32] Recommended Decision at 75.

[33] DI #97GF, #98GF.

[34] BWMC Exceptions at 40-41.

under the Administrative Procedures Act ("APA"), the entire administrative record consists of all transcripts, documents, information, and materials that were before the final decision maker at the time of his or her decision – even evidence first admitted in exceptions to a recommended decision.[35] The Court reasoned as follows:

> First, it is the function of the court on judicial review of an agency's action to review the 'final decision' in a contested case. APA § 10-222(a)(1). Where, as here, the administrative agency retained the authority to make the final decision, we review the final decision of the agency, and not the ALJ's recommended decision. It follows then, that the 'entire' administrative record consists of all materials and information the agency had before it at the time it reached its final decision. This notion is consistent with the principle that an 'administrative agency has broad discretion to consider evidence admitted after the close of an evidentiary hearing as long as there is compliance with procedural due process. *Maryland State Police v. Ziegler*, 330 Md. 540, 557 (1993), 625 A.3d 914, 922 (citing *Schultz v. Pritts*, 291 Md. 1, 7-10, 432 A.2d 1319, 1323-24 (1981) (documentary evidence submitted to the agency several days after the hearing but before the agency's decision); *Montgomery County v. Nat'l Capital Realty*, 267 Md. 364, 375-76, 297 A.2d 675, 681-82 (1972) (documentary evidence submitted to and considered by the zoning body after the hearing). An agency's ability to consider post-hearing evidence necessarily contemplates that such evidence becomes a part of the administrative record.
>
> Second, as part of the administrative process the APA (and complementary regulations) provide a party with a 'last chance' opportunity to persuade the agency that an ALJ's proposed decision should be 'affirmed, reversed, or remanded.' APA § 10-216(a)(1). In this regard, a party aggrieved by the ALJ's recommended decision may file exceptions. Moreover, under APA § 10-218(9), exceptions are deemed part of the record that is before the agency in making its final determination. As petitioner correctly points out, there is nothing in the statute or corresponding regulations that would preclude a party from offering new evidence in support of the party's exceptions, subject to satisfaction of due process consideration before such evidence may be admitted. Respondent offers no cases, and we are aware of none that have construed so narrowly these provisions. Indeed, it would appear that filing exceptions is the only appropriate method

[35] *Mehrling*, 371 Md. at 60.

> for a party to present post-hearing evidence for an agency's possible consideration. We merely recognize that written exceptions are a part of the administrative process, and therefore, evidence offered in exceptions may become, unless properly rejected by the agency, a part of the administrative record, subject to the final administrative decision maker's ruling on whether to admit and consider such evidence.

Mehrling, 371 Md. at 60-61 (internal citations and footnotes omitted). If it is permissible to offer new evidence into the record for the first time in connection with exceptions to a recommended decision, *a fortiori*, it is permissible to enter evidence into the record *before* the issuance of the recommended decision. Moreover, Chairman Tanio was entitled to take judicial notice of the data pursuant to Md. Code Ann., State Govt., § 10-213(h)(1).[36]

BWMC's complaint that it has not had a meaningful opportunity to address the new evidence is disingenuous. BWMC does not contest the accuracy of the data entered into the

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[36] BWMC also complains that the following data is missing from the record: (1) the 2020 population data from Nielsen Claritas; (2) the discharge database for D.C. hospitals; (3) the CY 2020 utilization projections; and (4) the data used by Chairman Tanio to arrive at the 39 zip codes in AAMC's 85% MSGA service area. (BWMC Exceptions at 41). BWMC's complaints are disingenuous and without merit. With regard to (1), Chairman Tanio supplied the 2020 population projections in his Recommended Decision: "The observed MSGA service area of AAMC has an estimated 2015 adult population of about 674,000 which is projected to increase to about 713,000 by 2020…The actual MSGA service area of BWMC has an estimated 2015 population of only 335,000, projected to move to 352,000 by 2020." (Recommended Decision at 27). Moreover, this data is readily available for purchase from Nielsen Claritas. With regard to (2), BWMC argues that the data in Tables 4, 5, 6, and 7 of the Recommended Decision purport to come from the HSCRC Discharge Data Base but appear to include data from the discharge database for D.C. hospitals. Consistent with the CON regulations, Chairman Tanio used data from the HSCRC discharge database and the District of Columbia Hospital Association, which data is readily available from the Commission. With regard to (3), BWMC argues that it was improper for Chairman Tanio to rely upon cardiac surgery utilization projections for CY 2020, given that the most recent cardiac surgery utilization rates published in the Maryland Register are for CY 2019, and COMAR 12.24.17.05A(1) requires applicants to rely upon the most recent utilization projections. BWMC's argument is misplaced. The COMAR section cited by BWMC applies to the data that applicants must use in their CON applications, not to data a Reviewer may use to test the reasonableness of the applicants' projections. Moreover, cardiac surgery utilization projections for CY2020 are easily derived from the formula set forth in the State Health Plan. With respect to (4), BWMC states that, when it tried to replicate Chairman Tanio's calculation of AAMC's MSGA service area, it came up with 41 zip code areas, rather than 39 as Chairman Tanio found. Based on this discrepancy, BWMC concludes that it is missing data. However, AAMC also replicated Chairman Tanio's calculation of AAMC's MSGA service area and, like BWMC, determined that there are 41 zip code areas in that service area, not 39. *See* Exhibit 2 hereto. In short, there is no missing data. Chairman Tanio simply made a small error in calculating AAMC's MSGA service area.

record and/or cited by Chairman Tanio in his Recommended Decision – data which is readily available to the public and with which BWMC should be thoroughly familiar, as in the case of its own audited financial statements. BWMC's real complaint is with Chairman Tanio's use of the data in connection with the Credibility Model to test the applicants' volume projections. BWMC will have had ample opportunity – through its 82-page written exceptions and in oral argument before the Commission on January 26, 2017 – to address any objections it has to that use.

Finally, BWMC's argument that Chairman Tanio's use of the new data in his Credibility Model to test the applicants' volume projections somehow creates a genuine issue of material fact, giving rise to the right to an evidentiary hearing,[37] is absurd. There is not a genuine issue of material fact in this case as to whether the parties have demonstrated an ability to reach 200 open heart surgery cases in the second full year of operation, as BWMC asserts. The parties' projections and forecasts are just that – predictions about what may happen in the future – not facts that happened in the past. Similarly, Chairman Tanio's determination as to whether the parties' predictions are likely to materialize is also a prediction. This is not the sort of situation where an agency must determine whether a person engaged in a past act of misconduct. This is a situation where the Commission must consider the record before it, including the applicants' projections, weigh the evidence and various policy considerations, and make a judgment about the future. Therefore, no evidentiary hearing is required. Indeed, under COMAR 10.24.01.10D, the decision whether to hold an evidentiary hearing is left to the discretion of the Reviewer.[38] Chairman Tanio found no need for such a hearing.

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[37] BWMC Exceptions at 43-44.

[38] COMAR 10.24.01.01D provides, in pertinent part, that an evidentiary hearing may be held in the following circumstances:

> (4) The Commission may hold an evidentiary hearing in a Certificate of Need review for a proposed new facility or service if, in the judgment of the reviewer, an evidentiary hearing is

III. PGHC HAS NOT MET THE PROGRAM REQUIREMENTS NECESSARY TO REQUIRE THE COMMISSION TO CONSIDER THE IMPACT OF AAMC'S PROGRAM ON PGHC'S CARDIAC SURGERY PROGRAM AND, EVEN IF PGHC DID MEET THOSE REQUIREMENTS, CHAIRMAN TANIO CORRECTLY CONCLUDED THAT THE IMPACT WOULD BE MINIMAL.

BWMC, PGHC, and MedStar have each implausibly asserted that AAMC's proposed cardiac surgery program will have a devastating and impermissibly negative impact on PGHC's cardiac surgery program. Chairman Tanio appropriately rejected that argument in the Recommended Decision. His conclusion is correct.

As a preliminary matter, PGHC does not meet the program criteria necessary for the Commission to even consider the impact of a new cardiac surgery program on PGHC under the applicable standard. Specifically, the applicable standard requires AAMC to demonstrate that its proposed cardiac surgery program will not negatively affect another program "**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

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appropriate due to the magnitude of impact the proposed project would have on the existing health care system, by meeting the requirements of this subsection and of §D(5) of this regulation. The project, if approved, would result in one of the following:

(a) A significant increase in public costs, or in costs and charges paid by a substantial number of patients and third-party payors;

(b) A significant decrease in the availability and overall quality of health care services in the affected area in a manner not consistent with policies or need projections set forth in the State Health Plan, such as by causing a loss of reasonable access to an essential medical service by a substantial number of patients;

(c) An additional demand on limited resources available to support health care facilities or medical services in a proposed service area that has existing budgetary and competitive constraints, such as a high penetration of managed care, or a high level of existing excess capacity; or

(d) Any impact that the reviewer concludes may be sufficiently serious to merit an evidentiary hearing.

(5) An evidentiary hearing will assist the reviewer in resolving questions of material fact or witness credibility.

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."[39]

With respect to (i) above, there is nothing in the record to indicate that an AAMC cardiac surgery program would threaten the financial viability of cardiac surgery services at PGHC. PGHC has already shown that its cardiac surgery services can survive through periods of very low cardiac surgery volumes. In fact, PGHC has maintained its cardiac surgery program through two recent calendar years in which twenty or fewer cardiac surgery cases were performed at the hospital.

With respect to (ii) above, PGHC admits that its cardiac surgery program "does not currently have 200 cardiac surgery cases per year . . ."[40]

With respect to (iii) above, PGHC admits that, at the time it first commented on AAMC's CON application, PGHC had "not received an STS-ACSD Composite Score for CABG of two stars or higher for two of the three most recent rating cycles."[41] One year later, however, Chairman Tanio erroneously allowed PGHC to add information to the record of this review with respect to PGHC's more recent cardiac surgery performance. [42] Nevertheless, that new

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[39] COMAR 10.24.17.05(A)(2)(b)(i), (ii) and (iii) (emphasis added).

[40] PGHC's July 27, 2015, Comments to AAMC's Application, at 18.

[41] *Id.* at 15.

[42] Notwithstanding that such updated information did not impact Chairman Tanio's conclusion with respect to Standard (iii), Commission Tanio should not have permitted PGHC to add the information to the record of this review. In ruling on motions in PGHC's own application for its replacement hospital facility in Largo, Commissioner Moffit reasoned that COMAR 10.24.01.08(F)(3) – limiting an applicant to only one response to comments – "evidences regulatory intent that those seeking interested party status [such as PGHC in this review] are permitted to file only one set of comments on an application." (Commissioner Moffit, "Ruling on Pending Motions and Requests", Docket No. 13-2351 (07/08/2016) at p. 3.) Accordingly, since PGHC's updated information was submitted one year after its original

information did not change the fact that PGHC still has "not received an STS-ACSD Composite Score for CABG of two stars or higher for **two** of the three most recent rating cycles." (emphasis supplied.)

In PGHC's Motion to Supplement its Comments, PGHC states that it received a two star Composite Quality Rating for "the second half" of calendar year 2014.[43] It also stated that it had a three star rating "for quality outcomes" for the calendar year 2015.[44] However, STS Composite Ratings are reported for isolated CABG in **one year intervals.** Therefore, based on the record in this case, PGHC has not had a two star rating for the required **two** cycles.[45] As a consequence, the Commission need not consider the impact of AAMC's proposed program on PGHC.

Even if PGHC could somehow clarify or correct the ambiguity as to whether it meets standard (iii), Chairman Tanio correctly concluded that AAMC's proposed program will not have an impermissible impact on PGHC. Indeed, any conclusion that AAMC's proposed program would cause PGHC to fall below applicable thresholds lacks all real world credibility.[46]

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comments, those updates should have been excluded. Moreover, such exclusion would have been proper because AAMC was required under the State Health Plan to make all of its projections based on data no newer than 2013, notwithstanding that cardiac surgery use rates in both Baltimore Upper Shore region and the Metro Washington region have increased since that time. (Anne Arundel Medical Center Response to Dimensions' Motion to Supplement Comments, Schedule 2.) Quite simply, admitting PGHC's updated information was an error because CON reviews would never end if the State Health Plan allowed for continuous updates, as opposed to the use of data from prescribed, finite time periods.

[43] PGHC's Motion to Supplement its Comments at p.5.

[44] *Id.* at p. 6.

[45] It is also questionable whether PGHC meets the first prong of standard (iii), namely having an annual volume of 100 to 199 open heart surgery cases, inasmuch as standard (iii) is not clear if those 100 to 199 open heart surgery cases are to be performed prior to AAMC's application, for the year immediately prior to the Commission taking action on that application, or for two of the three most recent years prior to the Commission taking action. If the requirement pertains to the year prior to AAMC's application, or pertains to the two out of three years prior to the Commission taking action on the application, then PGHC also fails that prong of standard (iii).

[46] PGHC also complains that AAMC has not addressed the impact that AAMC's open heart surgery program would have on PGHC, notwithstanding the fact that PGHC has admitted that it did not meet standard (iii) at the time of AAMC's application, and notwithstanding the fact that AAMC timely

PGHC forecasts that it will capture between 30 to 40% of the cardiac surgery market share in Prince George's County.[47] Accordingly, whether 60 to 70% of the non-PGHC patients residing in Prince George's County go to other hospitals, including AAMC, or to other hospitals, not including AAMC, is irrelevant.

The only relevant questions are (1) how many patients will PGHC lose to AAMC if AAMC has a program, and (2) are there enough cardiac surgery patients in Prince George's County to make the answer to the first question inconsequential? The resounding answer to the first question is "none" or, at the very worst, "a precious few," given the lack of overlap between cardiologists who refer to each institution.[48] Moreover, as Chairman Tanio concluded, and the record amply supports, the answer to the second question is that there are more than enough cardiac surgery patients in Prince George's County and Anne Arundel County to support both programs[49] and, therefore, even if one were to assume some minimal impact from AAMC, that impact will necessarily be inconsequential to PGHC.

Finally, while AAMC is mindful of the large investment made by the State of Maryland and Prince George's County in PGHC, it would simply be bad public policy to allow some theoretical and fanciful impact on PGHC to prevent the creation of a needed Anne Arundel County cardiac surgery program at AAMC.

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showed, in its Response to Dimensions' Motion to Supplement its Comments at pp. 2 – 7, that such impact would be negligible at worst.

[47] PGHC's Motion to Supplement its Comments at p. 9.

[48] AAMC Application at p. 91.

[49] Recommended Decision at p. 41. *See also* Exhibit 3 hereto, showing the large number of adult cardiac discharges in Prince George's County from 2010 through 2015.

IV. CHAIRMAN TANIO CORRECTLY REJECTED MEDSTAR'S ARGUMENT THAT THE NEED ANALYSIS IN THE STATE HEALTH PLAN REQUIRES ANYTHING MORE THAN A "DEMONSTRATION THAT THE PROPOSED NEW PROGRAM CAN GENERATE AT LEAST 200 OPEN HEART SURGERY CASES PER YEAR."

Chairman Tanio properly found that the Cardiac Chapter applies a need analysis to proposed cardiac surgery programs.[50] The Cardiac Chapter heading titled "Need" requires a proposed program to demonstrate that it "can generate at least 200 cardiac surgery cases per year."[51] Chairman Tanio then correctly found that AAMC satisfied this need criterion.[52]

MedStar objects that this Cardiac Chapter standard titled "Need" – and which expressly requires applicants to perform a "need analysis" through projections from regional utilization trends[53] and the hospital's existing cardiac surgery referrals[54] – does not apply a need analysis.[55] To state MedStar's argument is to refute it.[56] MedStar may as well argue that a yardstick doesn't measure distance because MedStar prefers the metric system.

Moreover, MedStar's Exception relies on two faulty arguments that Chairman Tanio properly rejected.

First, MedStar wrongly argues that the need analysis in the Cardiac Chapter must include a subjective, untethered divination of the "unmet needs" of the service area population. In fact, the CON rules only call for that subjective analysis "[i]f no State Health Plan need analysis is

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[50] Recommended Decision at p. 100.

[51] COMAR 10.24.17.05(A)(6)(a).

[52] Recommended Decision at 100.

[53] *See* COMAR 10.24.17.05(A)(6)(b).

[54] *See* COMAR 10.24.17.05(A)(6)(c).

[55] MedStar Exception at 3.

[56] As the Recommended Decision notes, the "title and wording" of the Need standard at COMAR 10.24.17.05(A)(6) "clearly indicate that it was intended to serve the purpose…of defining an applicable need analysis for projects involving the establishment of a new cardiac surgery program or the relocation of an existing cardiac surgery program." (Recommended Decision at 100).

applicable."[57] The subjective analysis is a fallback, or backup, if the Cardiac Chapter somehow failed to include a need methodology.

Second, MedStar suggests that the Cardiac Chapter standard titled "Need" cannot constitute a need criteria, since "any applicant that can project over 200 procedures by year two would" satisfy that need standard.[58] But why is that a problem? It is perfectly reasonable to conclude that if, in over 200 cases, cardiac patients would prefer a new cardiac surgery program over any existing program, then that new program meets a "need" that existing programs do not.[59] This objective standard reflects the balance sought by the Commission to make "[c]ardiac surgery… geographically accessible consistent with efficiently meeting the health care needs of patients."[60] In that regard, the Cardiac Chapter, adopted in 2014, represents a definitive break from methodologies MedStar would like the Commission to have adopted, but which the Commission did not adopt, such as an analysis of "excess capacity" at existing programs.[61]

In sum, MedStar's real objection is not to the Recommended Decision's application of the Cardiac Chapter, but to the text and logic of the Cardiac Chapter itself – an objection the Commission should reject.

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[57] COMAR 10.24.01.08(G)(3)(b).

[58] MedStar Exception at 4.

[59] For example, Chairman Tanio recognizes the case AAMC made that "reduction in travel time can produce tangible benefits in terms of more timely service and better coordinated care and care management." Recommended Decision at 69.

[60] COMAR 10.24.17.03.

[61] *Contrast* AAMC Response to Comments at p. 4 (noting that 2001 version of the Cardiac Chapter defined need using the notion of excess capacity, while the 2014 version does not) *with* MedStar Exceptions at 4 (suggesting that "capacity at existing providers" is an essential component of any need analysis).

V. CHAIRMAN TANIO CORRECTLY CONCLUDED THAT AAMC MET THE FINANCIAL FEASIBILITY STANDARD IN THE CARDIAC CHAPTER OF THE STATE HEALTH PLAN.

In his Recommended Decision, Chairman Tanio finds that AAMC's proposed cardiac surgery program "is financially feasible"[62] in compliance with the Cardiac Chapter's financial feasibility requirement.[63] Chairman Tanio reaches this accurate conclusion in two ways, both of which are valid.

First, Chairman Tanio finds that both BWMC and AAMC "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."[64]

Using a "conventional accounting perspective" to evaluate the feasibility of a new cardiac surgery program is sensible within the context of Maryland's global budget revenue ("**GBR**") system for hospital finance. Under the GBR system, the HSCRC sets the amount of revenue the hospital is allowed to earn annually. At the same time, each hospital's individual service lines still generates revenue (at HSCRC-approved rates) standing alone. Indeed, a hospital's GBR budget is the ***aggregate*** of the revenue generated by each of its independent service lines.[65] If the revenue generated by one service line increases, then the revenue generated by other service lines must decrease to keep a hospital's overall revenue within its GBR budget, unless the HSCRC otherwise permits. In this Review, the HSCRC has said that it will permit AAMC to raise its GBR budget by an amount equal to 50% of the revenue AAMC will generate from its

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[62] Recommended Decision at 96.

[63] COMAR 10.24.17.05(A)(7).

[64] Recommended Decision at 95; *see also* AAMC Modification at Table J-1.

[65] BWMC recognized this distinction earlier in this Review. In its August 10, 2015 filing, BWMC noted that its "cardiac surgery charges to payers will increase by $11.8 million but the allowable GBR adjustment for UM BWMC will only be $4.6 million after consideration of the 50% revenue variability factor." (internal citations omitted).

proposed cardiac surgery program. [66] As a result, to offset 50% of the revenue generated by its proposed program, AAMC may need to reduce charges elsewhere, achieve volume efficiencies (such as by reducing unnecessary readmissions or improving population health), or find other efficiencies. [67] That is, the GBR process does not ***erase*** AAMC's projected cardiac surgery revenues, but in fact ***presupposes*** that such revenue exists.

An analogy may be helpful. Suppose a pharmacy has a regular customer who normally spends $50 weekly at the store. The customer has a heart attack, and now needs to buy heart medication at the cost of $10 every week. However, the customer can only afford to increase weekly pharmacy spending by $5. The customer buys the medication, but economizes on other items, now spending $55 total per week at the pharmacy. How much revenue did the pharmacy generate from this customer ***for heart medication***? BWMC's logic would suggest $5. In reality, the pharmacy's heart medication sales generated $10 in revenue.

The "conventional accounting perspective" also fits the Cardiac Chapter's feasibility standard. To evaluate whether a new cardiac surgery program would "generate excess revenues over expenses for cardiac surgery" within three years,[68] the Commission should compare the amount that the cardiac surgery program would collect from patients and payers for cardiac surgery with the expenses the program would generate in providing cardiac surgery. The standard identifies ***cardiac surgery*** revenues and expenses specifically, ***not*** overall hospital revenues. Moreover, the standard asks applicants to perform the feasibility analysis using

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[66] The process of rate realignment across the facility will also have a *de minimis* feedback effect on AAMC's proposed cardiac surgery program as well, as decreases in unit rates at the hospital level will decrease AAMC's charge per case for cardiac surgery (and thus revenue for cardiac surgery) since those unit rates compose, in part, such charge per case figure.

[67] Taken literally, the HSCRC will not cap AAMC's cardiac surgery revenue. Rather, the HSCRC will adjust AAMC's global budget upwards by only 50% of that revenue. It is possible AAMC could keep 100% of its cardiac surgery revenue, if AAMC does not earn as much as it estimates it will earn elsewhere in the hospital.

[68] COMAR 10.24.17.05(A)(7)(b)(iv).

revenue estimates that account for "current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, ***for cardiac surgery***"[69] in particular, rather than for the hospital as a whole. BWMC's characterization of cardiac surgery revenue as "billable charges" gives an incomplete picture.[70] AAMC would bill ***and collect*** for cardiac surgery, just as AAMC actually requests and really receives reimbursement for other services performed at the hospital. Using a "conventional accounting perspective" ultimately enables the Commission to evaluate the feasibility of a proposed program on its own merits by focusing on revenue and expense intrinsic to the program.

Second, as reflected in the Recommended Decision, Chairman Tanio reasonably recognizes this overarching mandate for hospital viability as the essential thrust of the Cardiac Chapter's financial feasibility standard. Chairman Tanio rejects an "overly rigid"[71] interpretation of the subsidiary requirement that an applicant "generate excess revenues over expenses for cardiac surgery" within three years.[72] Chairman Tanio persuasively notes that, in the context of the GBR system and HSCRC revenue policies that "were only firmly enunciated in August 2016" (two years after the Cardiac Chapter was adopted), ***no new program*** could generate marginal revenue for the overall hospital greater than the marginal expenses associated with the new program.[73]

Chairman Tanio's sensible approach to the financial feasibility standard places it in harmony with the HSCRC's guidance during this review. The HSCRC has authority to set financial policy for hospitals in Maryland. The HSCRC's August 24, 2016 memorandum (the

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[69] COMAR 10.24.17.05(A)(7)(b)(ii) (emphasis added).

[70] For example, *see* BWMC Exceptions at 69.

[71] Recommended Decision at 95.

[72] COMAR 10.24.17.05(A)(7)(b)(iv).

[73] *See* Recommended Decision at 95 (emphasis added).

"**HSCRC Memo**") states that AAMC's proposed cardiac surgery service will be financially feasible. Specifically, the HSCRC has indicated that application of a 50% variable cost factor to AAMC's GBR Budget would not "impact the feasibility of the program" because "AAMC has other sources of revenue" in the GBR system "to apply to the project..."[74] These sources of funds may encompass a number of anticipated future adjustments to AAMC's GBR budget by the HSCRC, including (1) the "population adjustment"[75]; (2) "capacity from reduced avoidable utilization"[76]; and (3) AAMC's existing and anticipated operating margin, i.e. "reallocation of overhead already funded in the system as evidenced by [AAMC's] profits."[77] BWMC attempts to use the HSCRC's market shift policy as a bludgeon against AAMC, while refusing to recognize HSCRC's opinion that AAMC has other sources of revenue to apply to the cardiac surgery project to make it financially feasible.

BWMC's literalist assault on Chairman Tanio's reasoning also betrays enormous chutzpah and no small measure of hypocrisy. BWMC has admitted that "[a]s a stand-alone cardiac surgery program, [its] proposed project would not achieve excess revenue over total expenses within three years."[78] BWMC has instead asked that the Commission accept a substitute: that "the larger cardiac surgery program managed by the UM Division of Cardiac Surgery" would be financially feasible.[79] But what in the Cardiac Chapter text allows BWMC to conflate its expected performance with that of a conglomeration of existing cardiac programs? The Cardiac Chapter's feasibility standard addresses the feasibility of the "new or relocated

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[74] HSCRC Memo at 2.

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] BWMC Modified Application at 7.

[79] *Id. See also* BWMC Exceptions at p. 55.

cardiac surgery program"[80] itself. BWMC might as well argue that their "proposed cardiac surgery program will…attain a minimum annual volume of 200 open heart surgery cases by the end of the second year of operation"[81] because the UM Division of Cardiac Surgery performs many hundreds of cases, and in any event has already existed for more than two years. The Commission should reject BWMC's selective literalism.

Instead, the Commission should exercise its broad discretion to interpret and apply its own rules.[82] "Reviewing courts should give special deference to an agency's interpretation of its own regulations because the agency is best able to discern its intent in promulgating those regulations."[83]

In sum, AAMC's proposed cardiac surgery service would be financially feasible under either the GBR budget methodology or when considering its proposed program standing alone.

VI. CHAIRMAN TANIO CORRECTLY CONSIDERED ACCESS TO CARE IN THE CONTEXT OF THE OVERALL REVIEW AND AS SECONDARY SUPPORT FOR HIS RECOMMENDED DECISION TO APPROVE AAMC'S APPLICATION.

AAMC established in this Review that its patients, and the residents of Anne Arundel County and the larger region, face significant disruptions to needed cardiac care.[84] These disruptions include pre-operative and post-operative gaps in care due to long travel times. They

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[80] COMAR 10.24.17.05(A)(7).

[81] COMAR 10.24.17.05(A)(1)(a).

[82] BWMC suggests that the Commission's adoption of a revised Cardiac Chapter in November 2015 without change to the financial feasibility standard means the Commission is presumed to have considered, and ignored, how the standard interacts with the HSCRC's new market shift adjustment policy. *See* BWMC Exceptions at pp. 66-67. But this Review is the first opportunity the Commission has had to apply the financial feasibility standard to a live cardiac surgery review. Moreover, as the Recommended Decision notes, the HSCRC "only firmly enunciated in August 2016" how the market shift adjustment policy fits into the overall revenue allocations for new cardiac surgery programs *See* Recommended Decision at p. 95.

[83] Kim v. Maryland State Bd. of Physicians, 196 Md. App. 362, 372, 9 A.3d 534, 540 (2010), aff'd, 423 Md. 523, 32 A.3d 30 (2011) (citation omitted).

[84] The Cardiac Chapter's access standard is located at COMAR 10.17.24.05(A)(5).

also include breaks in continuity of care and communications and delays in care imposed by transfer delays, whereby AAMC patients with an urgent need for cardiac surgery have been refused or delayed transfer to hospitals authorized to perform cardiac surgery.[85]

While Chairman Tanio was "persuaded by AAMC's arguments that this reduction in travel time can produce tangible benefits in terms of more timely service and better coordinated care and care management", he did not make access to care a "preeminent consideration" but instead considered AAMC's case "in the context of the complete picture."[86] In this regard, Chairman Tanio noted the statement in the State Health Plan that "[g]eographic access to cardiac surgery services and elective PCI is not a problem in Maryland, with respect to patient travel time or survival."[87]

Chairman Tanio did not give undue weight to AAMC's essentially unrebutted case that the population it seeks to serve currently faces disruptions to timely care and care management that AAMC's proposed cardiac surgery program would mitigate.[88]

First, the Recommended Decision clearly states that access considerations are "secondary"[89] to the decision, especially in light of the sentence in the State Health Plan discussing geographic access.[90] Chairman Tanio did not ignore that which he cited, discussed, and incorporated into the Recommended Decision.

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[85] *See* AAMC Application at p. 82. Four case studies regarding transfer delays were enclosed with AAMC's Application as Exhibit 7(i), and an additional case was discussed in AAMC's August 25, 2015 response to interested party comments (pp. 12-16).

[86] Recommended Decision at 69.

[87] COMAR 10.24.17.03

[88] BWMC agrees [cite].

[89] Recommended Decision at 69.

[90] Recommended Decision at 68-69 (noting interested party arguments that the State Health Plan precludes consideration of access barriers).

Second, Chairman Tanio would not have reached a different outcome even if he gave no weight whatsoever to AAMC's case on access. Chairman Tanio found that AAMC met all other criteria of the Cardiac Chapter, while BWMC failed to meet the minimum volume standard, amongst other standards. On that basis, AAMC's application should have been approved, and BWMC's application denied.[91]

Third, Chairman Tanio's consideration of AAMC's case as part of the "complete picture" is thoroughly appropriate given that other applicable standards touch on the importance of care coordination and care effectiveness in evaluating whether to approve a new cardiac surgery program. For example, the Cardiac Chapter asks applicants to analyze how a new 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 care effectiveness shall include, but need not be limited to, the quality of care, care outcomes, and access to and availability of cardiac surgery services."[92] Moreover, the general CON standards ask applicants to analyze "the impact of the proposed project… on geographic and demographic access to services…"[93]

Finally, Chairman Tanio could have given even more weight to AAMC's access case under the State Health Plan. He did not do so. That is, the Recommended Decision was more conservative than it needed to be. While the State Health Plan includes a statement that access to cardiac surgery in Maryland as a whole is not a problem with respect to patient travel time or survival, the Cardiac Chapter also permits an applicant to "justify establishment of cardiac surgery services…based on inadequate access to cardiac surgery services in ***a health planning***

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[91] To win CON approval an applicant may – but need not – establish that access barriers to cardiac care exist in the region the applicant seeks to serve.

[92] COMAR 10.24.17.05(A)(4)(c).

[93] COMAR 10.24.01.08(G)(3)(f).

region..."[94] Accordingly, the Recommended Decision could have harmonized the Cardiac Chapter by allowing to AAMC to "[d]emonstrate that access barriers exist..."[95] in its particular region, notwithstanding the lack of a geographic access problem generally in Maryland.

VII. CONCLUSION

For the foregoing reasons, AAMC respectfully asks the Commission to deny the exceptions, adopt the Recommended Decision, and grant AAMC a certificate of need to establish a cardiac surgery service.

Respectfully submitted,

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[94] COMAR 10.24.17.05(A)(5)(a) (emphasis added).

[95] COMAR 10.24.17.05(A)(5)(a)(i).

ANNE ARUNDEL MEDICAL CENTER

CARDIAC SURGERY PROGRAM CERTIFICATE OF NEED APPLICATION

RESPONSE TO EXCEPTIONS TO RECOMMENDED DECISION

Attestation by Victoria W. Bayless

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the January 19, 2017 response to exceptions, and its attachments, of Anne Arundel Medical Center are true and correct to the best of my knowledge, information and belief.

January 19, 2017
Date

Signature

CEO, Anne Arundel Medical Center
Position/Title

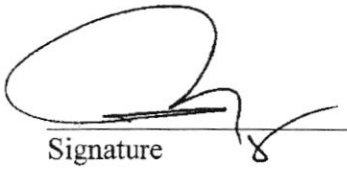
ANNE ARUNDEL MEDICAL CENTER

CARDIAC SURGERY PROGRAM CERTIFICATE OF NEED APPLICATION

RESPONSE TO EXCEPTIONS TO RECOMMENDED DECISION

Attestation by Robert Reilly

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the January 19, 2017 response to exceptions, and its attachments, of Anne Arundel Medical Center are true and correct to the best of my knowledge, information and belief.



January 19, 2017
Date

Signature

CFO, Anne Arundel Medical Center
Position/Title

ANNE ARUNDEL MEDICAL CENTER

CARDIAC SURGERY PROGRAM CERTIFICATE OF NEED APPLICATION

RESPONSE TO EXCEPTIONS TO RECOMMENDED DECISION

Attestation by Jerome Segal, M.D.

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the January 19, 2017 response to exceptions, and its attachments, of Anne Arundel Medical Center are true and correct to the best of my knowledge, information and belief.

January 19, 2017
Date

Signature

Director, the Heart Institute at AAMC
Position/Title

Exhibit 1

EXHIBIT 1

BWMC argues that the overall service area population is not a meaningful factor in determining program potential and is not a meaningful measure for evaluating whether volume targets will be met. BWMC submits a regression analysis to suggest that there is no correlation between a hospital's service area population and overall cardiac surgery volume.

BWMC's regression analysis excludes the two academic hospitals with the greatest service area population bases and the largest number of open heart surgery discharges, JHH and UMMC, thereby skewing the analysis and reducing the number of observations, weakening an already small number of observations for a regression analysis.

The attached regression analysis was prepared to include JHH and UMMC in the analysis. In order to produce a comparable analysis, AAMC prepared the revised regression using the same hospital MSGA 15+ populations and open heart volumes laid out in Table 6 of BWMC's Exceptions (page 19). AAMC was not able to verify BWMC's 85% MSGA service areas for the cardiac surgery hospitals. This was due to lack of clarification on how BWMC handled non-Maryland zip codes, international discharges (coded using zip code "77777" in the discharge database), or postal zip codes with no population that falls into a hospital's 85% MSGA service area as defined by total discharges. This was particularly an issue for JHH and UMMC due to the large number of international patients they treat, and for PGHC, Suburban, Washington Adventist, Western Maryland, and PRMC due to geographical proximity to Maryland's borders. In addition, BWMC does not specify whether they include open heart cases *within the MSGA area only* or whether they simply include hospital total volume in their analysis.

With these caveats, the attached regression analysis shows that the correlation between MSGA service area population size and open heart surgery discharges is much stronger: $R^2 = .7834$, as compared with the 0.1503 calculated by BWMC.

REVISED REGRESSION ANALYSIS

CY2014 DATA

SERVICE AREA DATA

Hospital	Service Area Population and OHS Discharges, CY14 MSGA Population (15+)	MSGA OHS Discharges (15+)
JHH	4,945,459	823
PGHC	770,160	28
PRMC	160,459	332
Sinai	1,338,031	243
UMSJMC	1,219,141	306
Suburban	1,401,045	186
UMMC	3,715,797	682
Union Memorial	1,535,290	450
WAH	1,023,776	145
Western MD	77,705	138
	16,186,863	3,333

Sources: (1) Population: Nielsen
(2) OHS Discharges: HSCRC Abstract Dataset

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.885074746
R Square	0.783357307
Adjusted R Square	0.75627697
Standard Error	124.5045509
Observations	10

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	448,411.03	448,411.03	28.93	0.00
Residual	8	124,011.07	15,501.38		
Total	9	572,422.10			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	98.62	58.77	1.68	0.13	(36.91)	234.15	(36.91)	234.15
X Variable 1	0.00	0.00	5.38	0.00	0.00	0.00	0.00	0.00

Exhibit 2

EXHIBIT 2

AAMC examined the raw HSCRC data for the CY2014 time period to corroborate the figures associated with the 85% MSGA service areas for AAMC and BWMC set forth in the Recommended Decision. The resulting excel spreadsheet is attached.

AAMC

- Our examination of AAMC's service area, based on 85% of its total inpatient volume, less normal newborns, corresponds to the service area defined in the Recommended Decision, with two exceptions:
  - Two zip codes fall in our analysis that do not appear in the service area map included in Recommended Decision (zip codes 20785 and 21629)
  - These two zip codes would add 37,180 to the adult (ages 15+) population figure and a total of 52 cardiac surgery discharges in the service area.

BWMC

- Our examination of BWMC's service area, based on 85% of its total inpatient volume, less normal newborns, corresponds to the service area defined in the Recommended Decision. This service area represents a population base of approximately 334,000 adult residents and 375 adult cardiac surgery cases.

AAMC 85% MSGA Service Area

Zip Code	Overlap with UM BWMC?	CY2015 Adult Population (Ages 15+)	CY2014 Total Cardiac Surgery Discharges
21401		32,913	38
21403		25,682	27
21037		17,381	16
21012		17,698	17
20715		21,321	21
21409		16,653	19
21114	Y	20,642	13
21146	Y	22,825	33
21666		10,180	15
20716		17,224	15
21113	Y	26,636	22
21122	Y	51,344	72
21054	Y	8,867	10
21032		7,747	8
21035		6,782	8
21061	Y	44,967	50
21619		5,130	6
20774		38,582	30
20711		5,424	14
21617		8,392	8
20721		24,027	12
20720		19,757	7
20772		37,410	33
20764		3,145	6
21144	Y	26,889	26
21108	Y	14,475	10
20776		3,585	4
20733		2,626	3
21060	Y	26,059	35
21638		4,157	9
21601		20,192	31
21140		2,856	1
21620		11,039	13
20639		12,157	13
20751		2,041	1
20736		7,609	11
21658		3,177	4
20732		8,333	9
20706		30,819	16
20754		5,888	9
20778		1,846	3
Subtotal MHCC		**674,477**	**698**
Additional Zip Codes We Found			
21629		7,746	14
20785		29,434	38
Subtotal		**37,180**	**52**
Total Including BRG Zips		**711,657**	**750**

UM BWMC 85% MSGA Service Area

Zip Code	Overlap with AAMC?	CY2015 Adult Population (Ages 15+)	CY2014 Total Cardiac Surgery Discharges
20794		12,797	13
21054	Y	8,867	10
21060	Y	26,059	35
21061	Y	44,967	50
21076		11,498	4
21090		8,399	8
21108	Y	14,475	10
21113	Y	26,636	22
21114	Y	20,642	13
21122	Y	51,344	72
21144	Y	26,889	26
21146	Y	22,825	33
21225		25,884	30
21226		5,986	8
21227		27,248	41
Total MHCC		**334,516**	**375**

UM BWMC Current Adult Cardiac 85% Service Area

Zip Code	Overlap with AAMC?	CY2015 Adult Population (Ages 15+)	CY2014 Total Cardiac Surgery Discharges
21061	Y	44,967	50
21122	Y	51,344	72
21060	Y	26,059	35
21144	Y	26,889	26
21146	Y	22,825	33
21113	Y	26,636	22
21108	Y	14,475	10
21225		25,884	30
21090		8,399	8
21076		11,498	4
21054	Y	8,867	10
Total		**267,843**	**300**

Exhibit 3

Prince George's County

Adult Cardiac Surgery Utilization

Actual

	2010	2011	2012	2013	2014	2015	
Adult Population	688,558	693,219	698,152	703,372	707,656	712,204	
# Adult Cardiac Surgery Discharges	538	473	446	481	523	561	
Cardiac Surgery Discharges per 100,000 population	78.13	68.23	63.88	68.38	73.91	78.77	
Average Annual % Change							0.53%

Re: Data sources:

(1) Population data: Nielsen-Claritas

(2)Cardiac surgery volume:

(a) HSCRC Abstract data

(b) DCHA Abstract data

Notes:

- DCHA CY2015 data represents 6 months data, Jan-June, annualized
- CY2015 data is based on an ICD9 to ICD10 crosswalk to define cardiac surgery