ANNE ARUNDEL MEDICAL CENTER

CERTIFICATE OF NEED APPLICATION

Response to Exceptions to Revised Recommended Decision

MARCH 16, 2017

Anne Arundel Medical Center

Anne Arundel Medical Center

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IN THE MATTER OF	*	
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	*	
* * * * * *	*	* * * * *

ANNE ARUNDEL MEDICAL CENTER
RESPONSE TO EXCEPTIONS TO REVISED RECOMMENDED DECISION

Anne Arundel Medical Center, Inc. ("**AAMC**"), by its undersigned counsel, hereby responds to the March 10, 2017 exceptions filed to Commissioner Tanio's March 3, 2017 revised recommended decision (the "**Revised 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 Revised Recommended Decision. Commissioner Tanio continues to "recommend approval of the stronger AAMC application and to recommend denial of BWMC's weaker proposal…"[1] Quite simply, AAMC's application satisfies all relevant criteria imposed by the Cardiac Chapter of the State Health Plan ("**Cardiac Chapter"**), while BWMC's does not.

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[1] DI # 121GF at 122.

Commissioner Tanio persuasively articulates how, because of its size, location, and large service area, AAMC is well positioned to attain the cardiac surgery volumes required by the Cardiac Chapter. AAMC is not only the third busiest hospital in the entire State of Maryland[2], but importantly it is also located outside of both the Baltimore and Washington metropolitan areas, both of which already have multiple hospitals offering cardiac surgery services. In short, Commissioner Tanio correctly concludes that AAMC, in collaboration with Johns Hopkins Medicine, has the 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.

In response to the Revised Recommended Decision, BWMC, MedStar and PGHC have filed exceptions which merely repeat tired, baseless, last-ditch and unpersuasive arguments that each has previously made in an effort to thwart AAMC's ability to launch a much-needed cardiac surgery program in Anne Arundel County. AAMC has grouped these scatter-shot exceptions to the Revised Recommended Decision into eight categories, corresponding to the relevant State Health Plan criteria, and, as more fully described below, responds to those exceptions in the order of the State Health Plan.

1. Volume.

Commissioner Tanio's use of a simple alternative framework, referred to in this Response as the "Forecast Model", to test the volume projections of AAMC and BWMC is sensible. Contrary to BWMC's claims, Commissioner Tanio had no obligation to accept uncritically the predictions set forth by AAMC or BWMC in their applications. Commissioner

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[2] HSCRC, FY 2017 User Fees Estimate, Updated 11-1-2016, available at: http://www.hscrc.state.md.us/documents/Hospitals/gbr-tpr-update/fy17/HSCRC-FY2017-User-Fees-Estimate-11-1-16.xls.

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

2. Impact.

AAMC agrees that the residents of Prince George's County deserve access to high quality health care, and recognizes the substantial investment made by the State and County in PGHC. However, Commissioner Tanio rightly concluded that AAMC's proposed cardiac surgery program can co-exist with a sustainable program at PGHC. There are enough cardiac surgery cases to sustain both programs, and the lack of overlap in their respective referral sources means 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. Cost Effectiveness.

Commissioner Tanio correctly and thoroughly concluded that AAMC met the cost effectiveness standard in the Cardiac Chapter. AAMC projects "one of the lowest charges per case in Maryland" for cardiac surgery.[3] Also, by AAMC treating cardiac surgery patients at AAMC at low cost, instead of transferring those patients to MedStar's District of Columbia Washington Hospital Center, AAMC will be materially helping the State of Maryland meet the difficult Medicare cost test that Maryland must meet to maintain the State's federal waiver that allows the Health Services Cost Review Commission ("**HSCRC**") to continue to set rates for Maryland hospitals.[4]

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[3] DI # 121GF at 57.

4. 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 Revised 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.

5. Need.

The State Health Plan required Commissioner Tanio to assess the need for AAMC's proposed cardiac surgery program by measuring whether its volumes would meet the minimum volume threshold in light of regional trends in population and cardiac surgery volumes. Commissioner Tanio 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 that included input from all stakeholders and the Legislature.

6. Financial Feasibility.

Commissioner Tanio correctly found that AAMC's proposed program would be economically sustainable when considered from a conventional accounting perspective, and in harmony with the overall financial feasibility of AAMC as a hospital. Commissioner Tanio's conclusion is also in complete alignment with the HSCRC, which has similarly opined in this Review that a cardiac surgery program at AAMC is financially feasible.

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[4] Docket No. 15-02-2360, DI # 22 at Exhibit 4.

7. Comparative Review.

Commissioner Tanio did not need to make a comparative review, because he found that BWMC did not meet the minimum volume standard. Moreover, BWMC's complaints in this regard amount to nothing more than BWMC wishing that Commissioner Tanio had rejected BWMC's application in a separate decision as opposed to issuing one Revised Recommended Decision addressing both applications simultaneously.

8. Due Process.

BWMC and MedStar have trivialized important constitutional protections because they are disappointed with the result of the Revised Recommended Decision. BWMC has had ample opportunity to comment *ad nauseam* in regard to non-controversial data that has been properly put into the record, the truthfulness and integrity which has never challenged.

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

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

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

BWMC argues that Commissioner Tanio applied an alternative forecast model ("Forecast Model") as the standard for assessing minimum volume that is inconsistent with the standards in the State Health Plan and constitutes impermissible rulemaking.[5] BWMC is wrong and misses the point. Commissioner Tanio's Forecast 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. The Forecast 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 Commissioner Tanio explained:

> Based on my review of the applications, I constructed a simple alternative forecast model at the hospital service-area level, in order to provide a more direct comparison of the applicants' market potential. I do not intend this exercise as a rejection of each applicant's response to this standard. Rather, my intention is to provide a more balanced perspective, allowing for comparison of the applications on the basis of consistent assumptions, grounded in actual experience. The main attraction of this approach is that, first, it relies on established inpatient service areas, which both applicants obviously 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. My model's key moving parts are the population use rate, which is projected to be declining, consistent with the SHP regional forecast model at the time these applications were filed, and observed cardiac market share.[6]

Contrary to BWMC's arguments, the Forecast Model was not intended to – and did not – establish a "new" or "threshold" standard,[7] and there has been no change in Commission policy that would be appropriate for formal rulemaking. BWMC's reliance on *CBS Inc. v. Comptroller*

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[5] BWMC Exceptions at 5-10, 15-28.

[6] DI #121GF at 29-30.

[7] BWMC Exceptions at 8, 10.

of the Treasury, 319 Md. 687 (1990),[8] is misplaced. In *CBS, Inc.*, the Comptroller insisted that CBS use a method of apportioning advertising receipts that was a "substantial deviation" from the way in which the Comptroller for years had interpreted a regulation on apportionment of receipts and that had not been challenged in previous audits of CBS's taxes. *Id.* at 697-98. In that case, the Court determined that the Comptroller was effectively announcing "a substantially new generally applicable policy . . . [which] amounted to a change in a generally applicable rule" that should be promulgated under the Administrative Procedure Act. *Id.* at 698-99. Here, by contrast, there is no regulatory history from which Commissioner Tanio could deviate; this is the first cardiac surgery review under the 2014 version of the Cardiac Chapter.

Commissioner Tanio is not changing the State Health Plan or the way in which an applicant establishes minimum volume under COMAR 10.24.17.05A(1). Rather, he simply used the Forecast Model to test AAMC's and BWMC's projections and assumptions made in their respective forecast models.[9] Because the Forecast 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 Forecast Model enabled Commissioner 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 at least 200 adult open heart surgery cases in the second full year of operation, while BWMC did not. The Commission should adopt Commissioner Tanio's Revised Recommended Decision.

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[8] BWMC Exceptions at 9-10.

[9] DI #121GF at 29-30.

B. The Forecast Model Is A Conventional And Logically Sound Framework For Testing The Applicants' Volume Projections, And It Shows That AAMC's Projections Are Substantially More Robust Than BWMC's Projections.

The Forecast Model starts by assessing each applicant's baseline market – the populations from which each cardiac surgery program would potentially derive its patients. Commissioner 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.[10] Commissioner 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). He also concluded that BWMC has a much larger overlap 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.[11]

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[10] Although BWMC questions the use of the MSGA service area as the relevant baseline market for cardiac surgery cases, BWMC's Exceptions at 15-22, Commissioner 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. Commissioner Tanio noted that the MSGA service areas developed for both applicants using the Forecast Model were smaller geographically and had smaller populations than the service areas defined by the applicants in their CON applications. DI #121GF at 30. In other words, Commissioner Tanio applied the more conservative service area assumptions to both applicants' projections.

[11] 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 16. 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,

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 Forecast 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.[12] While BWMC quibbles with the comparability of these three suburban hospitals to AAMC and BWMC,[13] BWMC, again, misses the point.

Commissioner Tanio appropriately recognizes that "[p]erfect comparability is not achievable."[14] 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 their uptake 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."[15]

The third step in the Forecast Model consists of an adjustment for the fact that any cardiac surgery hospital will draw some patients from beyond its established 85% relevance

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broad-based service area, AAMC is demonstrably better positioned than is BWMC to draw patients to a new cardiac surgery program.

[12] DI #121GF at 32.

[13] BWMC Exceptions at 22-25.

[14] DI #121GF at 32.

[15] *Id.* at 32-33.

MSGA service area.[16] Commissioner 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. The most comparable non-urban hospitals, used as a benchmark for service area market share, have only generated about 66% of their cardiac surgery volume from their MSGA service areas."[17] Accordingly, Commissioner 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.[18]

Applying the foregoing assumptions and adjustments, Commissioner 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 to that of most existing cardiac surgery hospitals (18-20%), it could project an ability to generate a case volume of 200 or more cardiac surgery cases per year.[19] If AAMC were able to capture a 25% market share, it would be likely to generate a case volume of 200 to 215 or more cases, if developing a program at the same time as BWMC, and 250 to 260 cases, if authorized to develop a program without a competing program at BWMC.[20] Commissioner 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.[21]

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[16] DI #121GF at 33.

[17] *Id.*

[18] BWMC's argument that Commissioner 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 24, does not help BWMC's position, as BWMC itself would admittedly not meet the 200-case threshold under that assumption. *Id.*

[19] DI #121GF at 34.

[20] *Id.*

[21] DI #121GF at 34. 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

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.[22] 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.[23]

Commissioner 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 a cardiac surgery program located at AAMC is likely to have a lower cost-to-effectiveness ratio than a program located at BWMC. This finding rests on the fact that AAMC is a larger hospital that has a larger service area population than BWMC. Also, because of AAMC's location and historic referral patterns, it is in a stronger position, geographically, than BWMC, to shift cardiac surgery market share from two metropolitan areas. Thus, AAMC has the ability on its own to build a larger volume of cases than BWMC. Additionally, AAMC is a lower charge hospital that will be able to provide cardiac surgery at a lower charge than BWMC. Finally, AAMC's service area population, on average, resides at a greater distance from existing cardiac surgery programs than BWMC's service area population. The greater distance from existing programs increases the improved access benefit for the AAMC proposed program when compared to the BWMC proposed program.[24]

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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. Revised Recommended Decision at 19-20; 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. Revised Recommended Decision at 19; 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." DI #121GF at 78.

[22] DI #121GF at 34.

[23] *Id.* at 34-35.

[24] DI #121GF at 108.

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

C. Commissioner Tanio Was Not Required To Accept BWMC's Projections to Meet the Minimum Standard, 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.[25] 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.[26] By 2021, BWMC predicted a caseload of 270 cases, with 56% of the cases (150) coming from UMMC and the remaining 44% coming from other Maryland and District of Columbia Hospitals.[27]

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.[28] 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[29] 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.[30]

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[25] DI #8BW, Exhibit 44.

[26] *Id.*

[27] *Id.*

[28] BWMC notes that only 27% of UMMC's cases originate in BWMC's service area. Docket No. 15-02-2361, DI#2 at 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, Docket No. 15-02-2361, DI #8 at 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. Docket No. 15-02-2361 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%). Docket No. 15-02-2361, DI #8 at 3.

Despite these manifest weaknesses, BWMC argues that Commissioner Tanio was required to find that BWMC's volume projections met the standard of COMAR 10.24.17.05A(1) because although Commissioner Tanio stated that his use of the Forecast Model was not intended as "a rejection of each applicant's response,"[31] he failed to consider the deliberate shifting of cases from UMMC to BWMC as the primary driver of volume. BWMC's Exceptions at 28-39. This argument is specious.

Commissioner 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 – Commissioner Tanio was required to test each program's forecasts and underlying assumptions critically. Although he found that "both applicants took reasonable approaches to the development of forecasts" for cardiac surgery demand,[32] he concluded that both applicants' underlying assumptions about service area and market share were not sufficiently conservative, particularly given the prior decline in the use rate of cardiac surgery.[33]

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[29] DI #28GF at 10.

[30] *Id.*

[31] DI #121GF at 29.

In testing BWMC's forecasts through the use of a more conservative MSGA service area from the Forecast Model, Commissioner Tanio concluded that BWMC would need to achieve a 40% market share in its service area 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.[34] He also concluded that AAMC was far better situated than BWMC – by size, internal case load, geographical location, historic referral patterns, scope of service area, and comparative cost – to draw patients from outside BWMC's service area.[35]

BWMC complains that Commissioner Tanio failed to consider the fact that BWMC could potentially meet the volume threshold simply by shifting cases from UMMC to BWMC.[36] While Commissioner Tanio would have been well within his rights to disregard 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 Commissioner Tanio *did* consider this claim:

> I reached this conclusion [that BWMC has not demonstrated an ability to meet a projected minimum volume of 200 cardiac surgery cases in the second full year of operation] after considering BWMC's analysis and testing its basic structure with more conservative service area and market area assumptions.

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[32] DI #121GF at 29.

[33] *Id.*

[34] DI #121GF at 34-35.

[35] DI #121GF at 34-35, 79, and 108.

[36] BWMC Exceptions at 36-39.

> That test indicates that BWMC, even in a single new program scenario and working with a high level of integration as a component of the UMMC Cardiac Surgery Division, would need to: far exceed the recently observed performance of the most similar non-urban cardiac surgery programs in Maryland; and quickly establish a strong position of some dominance as a provider of cardiac surgery in its service area.[37]

Commissioner Tanio concluded that AAMC could succeed at a cardiac surgery program with far less support from its affiliation partner, Johns Hopkins Medicine, than BWMC would require from UMMC to succeed. As Commissioner Tanio explained:

> BWMC did not demonstrate that its proposed program can generate at least 200 cardiac surgery cases per year from 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 BWMC program, producing a very high market share for BWMC. However, my analysis shows that this collaborative support would need to be much stronger in the case of BWMC than the support required of JHH for the proposed AAMC program. This results primarily from AAMC's larger service area. Furthermore, AAMC has locational advantages over BWMC with respect to service area 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.[38]

In short, Commissioner Tanio was not required to accept BWMC's claimed ability to shift cases from UMMC, nor was he required to accept that even if BWMC could shift cases, it would be enough to meet the minimum 200 cardiac surgery cases per year. Commissioner Tanio reasonably concluded, based on all the information and analyses presented, and as tested by the

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[37] DI #121GF at 35.

[38] DI #121GF at 79.

Forecast Model, that BWMC did not demonstrate an ability to meet the minimum 200 cardiac surgery cases per year.

D. The Revised Recommended Decision's Approach To Minimum Volume Is Consistent With This Commission's Previous Reviews Of Cardiac Surgery CON Applications.

Contrary to BWMC's argument, Commissioner Tanio's review of the applicants' minimum volume projections is consistent with this Commission's prior decisions. The decisions provided by BWMC identify a variety of information and data used by cardiac surgery CON applicants to demonstrate the ability to meet minimum volume requirements, but more importantly these decisions all demonstrate *a critical review* – not just blind acceptance – of the information presented, to ensure that the applicants met all of the criteria for a CON. *See, e.g.*, *In re Metropolitan Washington Open Heart Surgery Review*, Docket Nos. 04-15-2133, 04-16-2135, and 04-15-2134, p. 53 (July 21, 2005) (observing that while two of the three hospitals under consideration submitted physician surveys to help demonstrate the ability to maintain the required minimum volume, "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"); *In the Matter of Sacred Heart Hospital*, Docket No. 97-01-2012, p. 19 (Aug. 31, 1999) (noting that hospital's volume projections were "confirmed by the HRPC's own projections"); *In re St. Agnes Hospital , Sinai Hospital, Franklin Square Hospital, and Maryland General Hospital*, Docket Nos. 86-24-1369, 86-24-1371, 86-03-1372, and 86-24-1373, p. 51 (Jan. 23, 1990) (stating that the Commission "is skeptical" of the hospital's projections).

BWMC argues that since the Commission has perhaps only concluded once in many years that an applicant failed to meet the minimum volume standard,[39] then BWMC must have also demonstrated that it will meet the minimum volume standard. Even if it were true that the

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[39] BWMC Exceptions at 13.

Commission rarely rejects an application for failing to meet the minimum volume standard, BWMC's assertion is absurd that, therefore, BWMC must have also met the standard.

As with this Commission's prior decisions, Commissioner Tanio did not simply accept the applicants' projections on minimum volume, but reviewed them with a critical eye. In this case, Commissioner Tanio's review included testing the parties' assumptions and projections to determine whether he agreed with those projections, particularly with respect to the applicants' projected market share levels beyond their ability to shift cases from affiliated hospitals. The Commissioner's diligence was appropriate, particularly in light of Suburban Hospital's failure to achieve the volumes it projected in the Commission's most recent cardiac surgery CON review. As Commissioner Tanio noted, Suburban Hospital's "relatively stable" case volume of 200-250 cases per year, despite its projections that it would achieve at least 350 cases, is a "relevant point of reference for soberly assessing what each proposed new market entrant can achieve."[40] While Commissioner Tanio's review may have taken a somewhat different form than prior cardiac surgery CON proceedings, it was entirely consistent with the Commission's history of diligent and critical review of all CON applicants.

III. COMMISSIONER TANIO CORRECTLY CONCLUDED THAT ANY IMPACT OF AAMC'S PROGRAM ON PGHC'S CARDIAC SURGERY PROGRAM 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. Commissioner Tanio appropriately rejected those arguments in the Revised Recommended Decision. His conclusion is correct.

BWMC, PGHC and MedStar point to the standard (hereinafter referred to as "standard (iii)") that addresses whether AAMC's proposed cardiac surgery program will "result in an existing cardiac surgery program with an annual volume of 100 to 199 open heart surgery cases and 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."[41]

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[40] DI #121GF at 29.

Clearly, at the time AAMC filed its application, PGHC did not have 100 open heart cases,[42] and did not have the requisite scores.[43] One year later, however, Commissioner Tanio generously allowed PGHC to add information to the record of this review with respect to PGHC's most recent cardiac surgery performance.[44] PGHC has further attempted to provide additional updates to its star ratings pursuant to its Exceptions to the Revised Recommended Decision.[45]

Whether PGHC is entitled to the protections of standard (iii) is still questionable inasmuch as standard (iii) is not clear if the required 100 to 199 open heart 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. Moreover, it is still questionable whether PGHC has even met the star ratings required by standard (iii), because standard (iii) is not clear as to whether rating cycles are every six months, every year, every calendar year or every fiscal year.

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[41] COMAR 10.24.17.05(A)(2)(b)(iii).

[42] DI #121GF at p. 44.

[43] DI #30GF at 15.

[44] Notwithstanding that such updated information did not impact Commissioner Tanio's conclusion with respect to AAMC's impact on PGHC, 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 comments, those updates should have been excluded. Moreover, such exclusion would have been proper because AAMC was required under 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. (DI #66GF at 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.

[45] PGHC's Exceptions to Revised Recommended Decision, footnote 2 at 16.

Nevertheless, even if one assumes *arguendo* that PGHC's cardiac surgery program is entitled to the protections of standard (iii), any conclusion that AAMC's proposed program would cause PGHC to fall below the applicable threshold lacks all real world credibility.[46]

PGHC forecasts that it will capture between 30 - 40% of the cardiac surgery market share in Prince George's County.[47] That is, it acknowledges that 60-70% of County cardiac patients will seek care elsewhere. Accordingly, whether 60-70% 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] Contrary to PGHC's complaints, AAMC has previously addressed the updated data provided by PGHC, showing that any impact on PGHC would be negligible, even in light of the updated data.[49] Moreover, as Commissioner Tanio concluded,[50] the record amply supports, and the chart below shows, the answer to the second question is that in the aggregate there are more than enough, in fact over 1,000, cardiac surgery patients in Prince George's County and Anne Arundel County to support both programs.

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[46] BWMC, PGHC and MedStar also complain that AAMC has not addressed the impact that AAMC's open heart surgery program would have on PGHC, notwithstanding that: (a) PGHC has admitted that it did not meet standard (iii) at the time of AAMC's application; (b) Commissioner Tanio has concluded that "AAMC cannot be faulted for not quantifying a case shift from PGHC to AAMC in its CON application, given that PGHC's case volume was so negligible during the timeframe in which AAMC was preparing its application," (DI #121GF at 44.); (c) AAMC timely showed in its Response to Dimensions' Motion to Supplement its Comments, DI #66GF at 2 – 7, that such impact would be negligible at worst; and (d) Commissioner Tanio explicitly instructed AAMC not to amend its application in response to the HSCRC's letter of August 24, 2016, in any way other than to address the 50% variable cost factor (Tanio October 28, 2016 letter to Montgomery and Dame, DI #90GF at 1 – 4).

[47] PGHC's Motion to Supplement its Comment, DI #61GF at 9.

Cardiac Surgery Discharges
Age 15+ Years
Prince George's County and Anne Arundel County
CY2010-2015[51]

Prince George's County	2010	2011	2012	2013	2014	2015
Adult Population	688,558	693,219	698,152	703,372	714,124	724,315
# Adult Cardiac Surgery Discharges	538	473	446	481	523	550
Cardiac Surgery Discharges per 100,000 pop	78.1	68.2	63.9	68.4	73.2	75.9

Anne Arundel County	2010	2011	2012	2013	2014	2015
Adult Population	419,314	423,388	427,619	432,014	438,598	443,911
# Adult Cardiac Surgery Discharges	522	567	444	512	500	528
Cardiac Surgery Discharges per 100,000 pop	124.5	133.9	103.8	118.5	114.0	118.9

In fact, PGHC has already contended in its own CON application that there are even more cardiac surgery patients in Prince George's County than the applicable discharge data reflects, because there is also a large number of patients in need of this service who have not had access to the care.[52] In that regard, PGHC has told the Commission that it believes that the appropriate Prince George's County cardiac surgery use rate should actually be 87 per 100,000 in population,[53] meaning that there should be well over 600 Prince George's County cardiac surgery patients per year from which PGHC can draw.

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[48] Docket No. 15-02-2360, DI #3 at 91.

[49] DI #66GF at 2 – 7.

[50] DI #121GF at pp. 44 – 45.

[51] The data source for the population data is based on single-year estimates from Nielsen-Claritas, with estimates for 2013, 2014 and 2015 based on 2010 Census and estimates for 2011 and 2012 reflecting average annual growth from 2010- 2013. The data sources for cardiac surgery volume are the HSCRC Abstract data for Maryland hospitals and the DCHA Abstract data for Washington, D.C. hospitals. The DCHA CY2015 data represents 6 months data, January – June, annualized, and Maryland hospital CY2015 data is based on 12 months data using ICD9 to ICD10 crosswalk to define cardiac surgery for October – December 2015.

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.

IV. COMMISSIONER TANIO CORRECTLY AND THOROUGHLY CONCLUDED THAT AAMC'S PROGRAM WILL BE COST EFFECTIVE, DELIVERING SUBSTANTIAL SAVINGS TO CARDIAC PATIENTS AND THE HEALTH CARE SYSTEM.

AAMC fulfilled the State Health Plan's mandate to "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."[54] In particular, AAMC quantified its program's cost savings "for cardiac surgery patients in its proposed service area" as compared to existing providers.[55] As Commissioner Tanio recognized, AAMC projects "one of the lowest charges per case in Maryland" for cardiac surgery, at "an estimated $37,501 charge per case."[56] Commissioner

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[52] Exhibit 26 of PGHC's CON application, at p. 48, attached hereto as Exhibit 1.

[53] *Id.*

[54] COMAR 10.24.17.05(A)(4).

[55] COMAR 10.24.17.05(A)(4)(b).

[56] DI #121GF at 57.

Tanio "concluded that AAMC brings the highest potential for establishment of a lower charge program that can also be high performing."[57]

MedStar blindly asserts that Commissioner Tanio failed "to assess the cost-effectiveness of AAMC's program under the scenario of maintaining the status quo number of cardiac surgery programs."[58] On the contrary, Commissioner Tanio comprehensively analyzed this question,[59] summarizing MedStar's defense of the status quo, and expressly weighing the cost of expanding "the number of cardiac surgery programs" against savings generated by "a new cardiac surgery program [that] will charge less for the cases that would have otherwise been performed at the higher charge existing programs…"[60]

MedStar also asserts that Commissioner Tanio failed to focus on whether AAMC would "have lower charges than existing providers for lower intensity cases…"[61] Again, to the contrary, as noted by Commissioner Tanio, AAMC's advantageous charge per case figure is adjusted for case mix (i.e., acuity).[62] Moreover, AAMC's original application derived a comparatively much higher charge figure for MedStar Washington Hospital Center for cases with the same acuity.[63] MedStar has not disputed AAMC's figures, even though AAMC challenged Medstar to do so over eighteen months ago, when MedStar first made this argument.[64]

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[57] DI #121GF at 122.

[58] MedStar Exception at 10.

[59] *See, e.g.,* DI #121GF at p.62-65

[60] DI #121GF at 64.

[61] MedStar Exception at 11.

[62] DI #121GF at 59.

[63] Docket No. 15-02-2360, DI #3 at 109, Chart 15.

[64] DI #45GF at 23.

MedStar also implies that Commissioner Tanio should have treated Prince George's Regional Medical Center (PGRMC) as an "existing alternative facilit[y]" for the purpose of determining whether AAMC would be more cost-effective than existing providers,[65] even though PGRMC is not an existing alternative facility. This argument refutes itself. In any event, AAMC has projected that its cardiac surgery cases will primarily derive from volume otherwise referred to major cardiac surgery centers (Washington Hospital Center and Johns Hopkins Hospital), and not from Dimensions' volume.

Commissioner Tanio's analysis ultimately concluded that AAMC's proposed cardiac surgery program would produce substantial savings for cardiac surgery patients and for the overall health care delivery system. Contrary to MedStar's objections, this analysis was thorough and should be adopted by the full Commission.

V. COMMISSIONER TANIO CORRECTLY CONSIDERED ACCESS TO CARE IN THE CONTEXT OF THE OVERALL REVIEW AND AS SECONDARY SUPPORT FOR HIS REVISED 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.[66] These disruptions include pre-operative and post-operative gaps in care due to long travel times. They 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.[67]

While Commissioner 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."[68]

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[65] MedStar Exception at 11 (citing COMAR 10.24.08(G)(3)(c)).

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

[67] *See* Docket No. 15-02-2360, DI #3 at 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, DI #45GF at 12-16.

Commissioner 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.

First, the Revised Recommended Decision clearly states that access considerations are "secondary"[69] to the decision. Commissioner Tanio acknowledged 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."[70] Commissioner Tanio did not ignore that sentence; he cited it, discussed it, and incorporated it into the Revised Recommended Decision.[71] Commissioner Tanio merely refused to use that narrow sentence as a talisman to ward off any consideration whatsoever of the real world barriers to effective cardiac care faced by patients in AAMC's region.

Second, Commissioner Tanio would not have reached a different outcome even if he gave no weight whatsoever to AAMC's case on access. Commissioner Tanio found that AAMC met all other criteria of the Cardiac Chapter, while BWMC failed to meet the minimum volume standard, among other standards. On that basis, AAMC's application should have been approved, and BWMC's application denied. 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.[72]

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[68] DI #121GF at 73.

[69] DI #121GF at 73.

[70] COMAR 10.24.17.03

[71] DI #121GF at 73 (noting the relevant State Health Plan language regarding geographic access barriers).

[72] MedStar's implication to the contrary (*See* MedStar Exception at 10) is incorrect.

Third, Commissioner'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, Maryland's general CON standards ask applicants to analyze "the impact of the proposed project… on geographic and demographic access to services…"[73] 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."[74]

In that regard, AAMC demonstrated access barriers beyond patient travel times for cardiac surgery. For example, Commissioner Tanio credited AAMC with identifying "specific issues with transfer of patients" needing cardiac surgery from AAMC to other hospitals, especially in regard to Washington Hospital Center.[75]

Finally, Commissioner Tanio could have given even more weight to AAMC's access case under the State Health Plan than he did. That is, the Revised 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 region***…"[76] Accordingly, the Revised Recommended Decision could have harmonized the Cardiac Chapter by allowing AAMC to "[d]emonstrate that access barriers exist…"[77] in its particular region, notwithstanding the lack of a geographic access problem generally in Maryland.

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

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

[75] DI #121GF at 72.

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

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

VI. COMMISSIONER 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.

Commissioner Tanio properly found that the Cardiac Chapter applies a need analysis to proposed cardiac surgery programs.[78] The Cardiac Chapter section titled "Need" requires a proposed program to demonstrate that it "can generate at least 200 cardiac surgery cases per year."[79] Commissioner Tanio correctly found that AAMC satisfied this need criterion.[80]

MedStar objects that Commissioner Tanio should have instead attempted an untethered divination of whether "unmet needs" exist in AAMC's region, rather than relying on the objective standard set forth in the "Need" section of the Cardiac Chapter.[81]

MedStar's objection has a fatal flaw: Maryland's CON rules required Commissioner Tanio to "consider the applicable need analysis in the State Health Plan"[82] – which he did. An "unmet needs" analysis is only performed "[i]f no State Health Plan need analysis is applicable."[83]

Recognizing this obstacle, MedStar argues that the Cardiac Chapter standard titled "Need" – and which expressly requires applicants to perform a "need analysis" through projections from regional utilization trends[84] and the hospital's existing cardiac surgery referrals[85] – "does not establish an applicable need analysis…"[86]

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[78] DI #121GF at 105.

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

[80] DI #121GF at 105.

[81] MedStar Exception at 4 (citing COMAR 10.24.01.08(G)(3)(b)).

[82] COMAR 10.24.01.08(G)(3)(b)

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

MedStar's argument turns on a false dichotomy between establishing that a new program would serve a high volume of patients, and establishing that those patients need that program. MedStar may as well argue that a yardstick doesn't measure distance because MedStar prefers the metric system. It is perfectly reasonable to conclude that if, in over 200 cases per year, cardiac patients and their referring cardiologists would use a new cardiac surgery program over an existing program, then that new program meets a "need" that existing programs do not. This 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"[87] by establishing an objective threshold for new programs at 200 cases per year.

Tellingly, MedStar offers no coherent alternative to the Cardiac Chapter's objective need standard. Instead, Medstar offers an inchoate list of proposed need factors (such as "capacity at existing providers")[88] with no way for Commissioner Tanio to measure the factors or weigh the factors against each other. As Commissioner Tanio notes, for example, a "capacity" oriented approach "is an elusive concept for a service that only requires hospital surgical facilities and an adequate staff to expand almost any existing cardiac surgery program" and is "at odds with the need standard in the Cardiac Surgery Chapter…"[89] And even this partial list creates tension with MedStar's opposition to AAMC proposed program:

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

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

[86] MedStar Exception at 4.

[87] COMAR 10.24.17.03.

[88] MedStar Exception at 5.

[89] DI #121GF at 114. *See also* AAMC Response to Comments, DI #45GF at 4 (noting that 2001 version of the Cardiac Chapter defined need using the notion of excess capacity, while the 2014 version does not).

- MedStar suggests focusing on "capacity at existing providers" but the very data offered by MedStar shows that Johns Hopkins – AAMC's partner in establishing cardiac surgery at AAMC, and thus in shifting cases from Johns Hopkins Hospital to AAMC – has seen tremendous volume growth. Per Medstar, cardiac surgery volumes at Johns Hopkins Hospital increased by over 30% from CY 2009 to CY 2015 (from 969 cases to 1262 cases).[90]
- Medstar suggests focusing on "actual utilization" but acknowledges that actual cardiac surgery volumes have increased substantially since 2012.[91] MedStar gives no reason to believe that these increases will abate, other than a self-serving characterization of the "current uptick" as a mere "normalizing" of volumes from previous declines.[92]
- MedStar suggests focusing on "access barriers", but elsewhere argues that the Commission is precluded from considering AAMC's essentially unrefuted case that chronic transfer delays imposed by existing providers - and other disruptions to continuity of care for AAMC's cardiac patients - constitute an access barrier.[93]
- MedStar suggests focusing on "referral trends"[94] but ignores data showing that AAMC's Heart Institute continues to generate an increasing number of cardiac surgery referrals.

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[90] MedStar Exception at 5 (chart 1).

[91] MedStar Exception at 5 (Chart 1).

[92] MedStar Exception at 6.

[93] MedStar Exception at 9-10 (citing State Health Plan on *geographic* access to care in Maryland).

[94] MedStar Exceptions at 5.

In sum, MedStar's real objection is not that Commissioner Tanio misapplied the Cardiac Chapter, but that Commissioner Tanio did not substitute MedStar's preferred methodology for the text and logic of the Cardiac Chapter itself. The Commission should reject this objection.

VII. COMMISSIONER TANIO CORRECTLY CONCLUDED THAT AAMC'S PROGRAM WILL BE FINANCIALLY FEASIBLE.

In his Revised Recommended Decision, Commissioner Tanio finds that AAMC's proposed cardiac surgery program "is financially feasible"[95] in compliance with the Cardiac Chapter's financial feasibility requirement.[96] Commissioner Tanio is correct.

A. AAMC's Proposed Program is Financially Feasible Under Conventional Accounting Principles

Commissioner 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."[97]

The "conventional accounting perspective" 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,[98] 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. Moreover, the standard asks applicants to perform the feasibility analysis using revenue estimates that account for "current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, ***for cardiac surgery***"[99] in particular, rather than for the hospital as a whole.

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[95] DI #121GF at 100.

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

[97] DI #121GF at 99.

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

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

BWMC misreads this portion of the regulation to imply a "retained revenue"[100] metric, allowing BWMC to mischaracterize AAMC's projected cardiac service line revenue as mere "billable charges"[101] that are not "retained revenue." In fact, AAMC's service line revenue projections do account for cardiac-specific contractual adjustments, reimbursement rates, etc. AAMC would bill ***and collect*** for cardiac surgery, just as AAMC actually requests and really receives reimbursement for other services performed at the hospital.

Moreover, the feasibility standard nowhere qualifies the word "revenue" with the word "retained." Nor does the standard reference "incremental" or "marginal" revenue or any similar concept. Rather, subparagraph (b)(iv) of the standard evaluates whether AAMC can "***generate*** excess revenues over expenses for cardiac surgery."[102] To generate means to "bring into existence" or "originate"[103], not retain. "Generate" implies a front-end evaluation of revenue brought in by the service line, while "retain" is a back-end concept implying an evaluation of how the revenue ultimately impacts the hospital's bottom line. A "conventional accounting perspective" best fits the actual words of the feasibility standard.

A "conventional accounting perspective" is also the best reading of the feasibility standard 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 generate 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.[104] 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.[105]

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[100] BWMC Exceptions at 65.

[101] For example, *see* BWMC Exceptions at 65.

[102] COMAR 10.17.24.17.05(A)(7)(b)(iv)(emphasis added).

[103] *Generate*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (3d ed. 2002).

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 for cardiac surgery.[106] As a result, to offset the 50% of the revenue generated by its proposed program which will not increase its GBR, AAMC may need to reduce charges elsewhere, achieve volume efficiencies (such as by reducing unnecessary readmissions or improving population health), or find other efficiencies. It is possible that AAMC could apply 100% of its cardiac surgery revenue to its GBR budget, if AAMC does not earn as much as it estimates it will earn elsewhere in the hospital, or if it finds these other efficiencies.[107]

In sum, the GBR process does not ***erase*** AAMC's projected cardiac surgery revenues, but in fact ***presupposes*** that such revenue exists.

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[104] BWMC recognized this distinction earlier in this Review. In its August 10, 2015 filing, Docket No. 15-02-2361, DI #17, 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).

[105] AAMC also observed this distinction when calculating the savings AAMC's program would generate. Throughout this Review, AAMC has carefully delineated (a) savings it would deliver for cardiac surgery patients and payers (measured by revenue generated by the cardiac surgery program), from (b) savings it would deliver for the health care delivery system as a whole (measured by the ultimate effect of the proposed program on overall revenue at AAMC and its competitors). That is, AAMC has consistently distinguished between revenue generated from cardiac surgery on the one hand, and the impact of the project on overall hospital budgets at AAMC and elsewhere, on the other. AAMC is not trying to have its cake and eat it too, as BWMC suggests. *Cf.* Medstar Exceptions at 67.

[106] 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.

[107] 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.

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.

Finally, 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. As Commissioner Tanio noted, the "'blinders on' interpretation of subparagraph (b)(iv) is an artifact of" the GBR treatment of market shifts.[108] In the long-term, "the dynamic of case volume shifting from one hospital to another will have no actual force or particular relevancy in looking at the performance of the involved hospitals."[109] That is, if AAMC now performed the exact volume of cardiac surgery cases it projects to shift from existing providers, generated the exact revenue from those cases it predicts, and thereby incurred the exact expenses it predicts, AAMC would be financially feasible on ***any*** interpretation of the Cardiac Chapter.[110] Commissioner Tanio found it "highly likely" that a new cardiac surgery program at AAMC would be "operating 'in the black'" in the long run.[111]

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[108] DI #121GF at 100.

[109] DI #121GF at 100.

[110] Over the more than two year history of this Review, AAMC has submitted various financial projections for its proposed cardiac surgery program, and has revised those projections after relevant rulings and clarifications, such as Commissioner Tanio's project status conference and the HSCRC's August 2016 memorandum. BWMC quibbles at length with the evolution of these projections (BWMC Exceptions at 54-57) – including by reference to material stricken from the record. Ultimately, however, BWMC recognizes that "AAMC's Table J-2" (AAMC's most recent financial projection incorporating the HSCRC market shift adjustment policy) "complied with the Reviewer's direction" and with COMAR 10.24.17.05(A)(7)(b)(ii). BWMC and AAMC

B. Commissioner Tanio's Harmonization of the Feasibility Standard is Persuasive and Lawful

As reflected in the Revised Recommended Decision, Commissioner Tanio reasonably recognizes this overarching mandate for hospital feasibility as an essential thrust of the Cardiac Chapter's financial feasibility standard. Commissioner Tanio rejects an "overly rigid"[112] interpretation of the feasibility standard. Rather, Commissioner Tanio found that the applicants fulfilled the mandate that a new "cardiac surgery program shall be financially feasible"[113] by demonstrating that each "proposed 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."[114]

The interested parties are wrong to accuse Commissioner Tanio of writing subparagraph (b)(iv) of the feasibility standard out of the Cardiac Chapter, for the following reasons.

First, as noted above, subparagraph (b)(iv) is at least silent as to whether to measure "revenue….for cardiac surgery" by conventional accounting for the service line, or by overall impact to GBR budgets. Although BWMC states that the feasibility standard requires AAMC to demonstrate "retained revenue"[115] over expenses, the standard nowhere contains the word "retained."

BWMC itself skirts the supposedly unambiguous plain language of the feasibility standard when defending the feasibility of its own proposed program. BWMC has admitted that

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now simply disagree about the relevance of the HSCRC's market shift adjustment policy to the Cardiac Chapter's financial feasibility standard at COMAR 10.24.17.05(A)(7)(b)(iv).

[111] DI #121GF at 100.

[112] DI #121GF at 99.

[113] COMAR 10.24.17.05(A)(7)

[114] DI #121GF at 99.

[115] BWMC Exceptions at 65.

its proposed program, standing alone, would not retain revenue from cardiac surgery exceeding its total cardiac surgery expenses.[116] BWMC has instead asked that the Commission to accept a substitute: that "the UM Division of Cardiac Surgery…would be financially feasible."[117] 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 cardiac surgery program"[118] 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"[119] because the UM Division of Cardiac Surgery performs many hundreds of cases, and in any event has already existed for more than two years.[120] The Commission should reject this selective and illogical literalism.

Second, Commissioner Tanio's reading of the feasibility standard avoids generating an internal contradiction created by the interested parties' interpretation. The interested parties' reading of subparagraph (b)(iv) would render meaningless the standard's parallel requirement that a proposed program "not jeopardize the financial viability of the hospital."[121] As Commissioner Tanio persuasively notes, "[i]f the only test of financial feasibility were adequate documentation that the program will be profitable"[122] then there would be no reason to inquire as to the overall financial viability of the hospital – for how could a profitable service risk the hospital's financial viability?[123]

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[116] Docket No. 15-02-2361, DI #17 at 7.

[117] BWMC Exceptions at 52.

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

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

[120] And wouldn't AAMC be entitled to the same flexibility? Why not evaluate AAMC's proposed program in conjunction with the high volume and highly feasible cardiac surgery sites already affiliated with AAMC's partner in this project, Johns Hopkins Medicine? Or, why not evaluate the feasibility of AAMC's Heart Institute as a whole, given AAMC's excellent performance in medical cardiology and PCI?

[121] COMAR 10.24.17.05(A)(7)

[122] DI #121GF at 99.

Similarly, the interested parties' reading of the feasibility standard would render this entire Review process illusory. The HSCRC has indicated that it will apply the market shift adjustment policy to volume generated by a new cardiac surgery program – meaning that a hospital establishing a new program receives a GBR Budget increase equivalent to only about half the revenue the program generates. Under a 50% variable cost factor for new revenue, any new service would operate at a loss, on the interested parties' view, unless expenses are implausibly low. The Commission could not approve ***any*** plausible new program under the interested parties' reading. The Commission should instead "adopt that construction which avoids an illogical or unreasonable result, or one which is inconsistent with common sense." *Spangler v. McQuitty*, 449 Md. 33, 50, 141 A.3d 156, 166 (2016).

In that regard, Maryland courts "do not read regulatory language in a vacuum, ***nor do we confine strictly our interpretation of a regulation's plain language to the isolated section alone.*** Rather, the plain language must be viewed within the context of the regulatory scheme to which it belongs, considering the purpose, aim, or policy of the agency in enacting the regulation. We presume that the agency intends its enactments to operate together as a consistent and harmonious body of law, and, thus, we seek to reconcile and harmonize the parts of a regulation, to the extent possible consistent with the regulation's object and scope." *Kor-Ko Ltd. v. Maryland Dep't of the Env't*, 152 A.3d 841 (Md. 2017) (internal citations and quotations omitted)(emphasis added).

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[123] A contrary reading also risks conflating the overall hospital feasibility analysis with the service line feasibility analysis – as explained above, even taking into account fixed market share adjustment percentages, whether or not a hospital's GBR budget will actually decline as a result of a market shift adjustment for cardiac surgery depends on outside factors – such as a hospital's market share changes for other services, or policies implemented to reduce readmissions.

Finally, Commissioner Tanio's reasonable approach to the financial feasibility standard places it in harmony with HSCRC policies that "were only firmly enunciated in August 2016."[124] The HSCRC has authority to set financial policy for hospitals in Maryland. The HSCRC's August 24, 2016 memorandum 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…"[125] 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"[126]; (2) "capacity from reduced avoidable utilization"[127]; 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."[128] 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.

Instead, the Commission should exercise its broad discretion to interpret and apply its own rules. Maryland courts "respect the agency's expertise in its field. When an agency interprets its own regulations or the statute the agency was created to administer, we are especially mindful of that agency's expertise in its field. Compared with a question of statutory interpretation, when the construction of an administrative regulation rather than a statute is in issue, deference is even more clearly in order. We grant such deference to an agency's interpretation of its regulations because agency rules are designed to serve the specific needs of the agency, are promulgated by the agency, and are utilized on a day-to-day basis by the agency. …. Because an agency is best able to discern its intent in promulgating a regulation, the agency's expertise is more pertinent to the interpretation of an agency's rule than to the interpretation of its governing statute." *Kor-Ko Ltd. v. Maryland Dep't of the Env't,* 152 A.3d 841 (Md. 2017)(internal citations and quotations omitted).

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[124] DI #121GF at 99.

[125] DI #68GF at 2.

[126] *Id.*

[127] *Id.*

[128] *Id.*

The Commission should respect its own mandate and purpose by refusing the "blinders-on" approach offered by BWMC, MedStar, and Dimensions. The Commission should recognize, just as Commissioner Tanio recognized, that AAMC's proposed cardiac surgery service would be financially feasible.

VIII. COMMISSIONER TANIO DID NOT PERFORM AN IMPROPER COMPARATIVE REVIEW.

BWMC acknowledges that Commissioner Tanio was correct when he found that he did not need to make a comparative review pursuant to COMAR 10.24.17(8) of the applications of AAMC and BWMC. The comparative review in that section is applicable when "all policies and standards have been met by all applicants." Because Commissioner Tanio found that BWMC did not meet the minimum volume standard, he correctly determined not to make a COMAR 10.24.17(8) comparative review. "Because I did not find that both applicants have met all policies and standards, this standard is not applicable in this comparative review."[129] Hence, Commissioner Tanio clearly set forth that he understood and applied the review framework.

BWMC goes on, however, to assert that the recommendation should be rejected in its entirety as "arbitrary and capricious," "an impermissible abuse of authority," and a violation of "due process rights" because of three statements scattered at pages 3, 45 and 122 of the Revised Recommended Decision in which BWMC contends both applicants are mentioned and compared.[130] Reduced to its simplest form, BWMC asserts, without citation to any authority, that Commissioner Tanio was prohibited from any recognition that there were two applications in front of him, and from any characterization which in any way contrasted the approaches in each of those applications. BWMC's argument would have required Commissioner Tanio to write two separate recommendations, one for each applicant, each pretending that the other applicant did not exist. BWMC's suggestion requiring such a sanitized approach is impractical, illogical and wrong.

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[129] DI # 121GF at 100.

Commissioner Tanio found that AAMC met the projected minimum volume requirements for cardiac surgery, and BWMC did not. That finding, in and of itself, took BWMC out of the running for a CON as a matter of law. Having reached that conclusion, anything Commissioner Tanio said about BWMC's application in comparison to AAMC's was meaningless to BWMC and AAMC, because the only remaining issue before Commissioner Tanio was whether AAMC satisfied the other requirements for receiving a CON. Hence, any statements made contrasting the two applications were observations that could not have been material to the ultimate recommendation, and could not have harmed BWMC in any way.

Further, an analysis of the statements relied on BWMC reflects their benign nature. To support its argument that Commissioner Tanio improperly compared the two applications, BWMC relies on a statement made in both the introduction and recommendation section of the Revised Recommended Decision (but not in the analysis of any factor) referring to AAMC's application as stronger than BWMC's. First, this assertion is true – AAMC's application met the projected minimum volume requirements and BWMC's did not. Second, BWMC conveniently ignores Commissioner Tanio's unequivocal statements reflecting the basis for his decision in the first sentence of ensuing paragraphs of his Revised Recommended Decision. "The basis for my recommendation that the Commission approve the AAMC project, with conditions, is my finding that AAMC complied with all applicable State Health Plan standards in this review."[131] "The basis for my recommendation that the Commission deny the BWMC application is my finding that BWMC did not comply with all of the applicable State Health Plan standards."[132] While BWMC may disagree with those conclusions, it should not disingenuously assert that Commissioner Tanio applied a comparative test outside the State Health Plan standards in reaching his recommendations when it is obvious that he both knew the law and applied it.

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[130] While the three statements forming the basis of BWMC's argument did not change from the original decision to the revised decision, BWMC did not previously assert this argument in its exceptions to the original decision.

The only other comment cited by BWMC as purportedly showing an improper comparative analysis of the two applications is a statement on page 45 of the Revised Recommended Decision which BWMC takes out of context. Commissioner Tanio addressed his analysis of the impact standard beginning on page 42 of the Revised Recommended Decision. In the first sentence of the last paragraph in that section, he concluded, after separately considering each application, that "I find that each applicant proposed a cardiac surgery program that complies with the specific requirements of the impact statement."[133] Commissioner Tanio analyzed independently, as he should have, whether each applicant satisfied the requirements of the impact standard, and concluded they each did.

That section's reference to public policy was innocuous. "I have determined 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 . . . . While a program at AAMC is likely to incrementally constrain the growth potential of the existing program at PGHC, as any competing program would be expected to do, I conclude that the market is sufficiently large to support both programs at a level of 200 cardiac surgery cases."[134] It is clear that taken in context, this statement has nothing to do with comparing the applications of BWMC and AAMC as BWMC mistakenly asserts, but instead relates to the impact of a new cardiac surgery program on existing cardiac surgery programs. BWMC's contention that Commissioner Tanio improperly compared AAMC's and BWMC's application as the basis of his decision is simply unsupported by the statements on which BWMC relies.

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[131] DI #121GF at 123.

[132] DI #121GF at 123.

[133] DI # 121GF at 45.

IX. COMMISSIONER TANIO PROPERLY ADMITTED THE DATA INTO THE RECORD SO THERE IS NO DUE PROCESS VIOLATION OR NEED FOR A HEARING.

BWMC complains that Commissioner Tanio violated its "due process" rights because it was "not given the opportunity to contest data before its entry into the record" prior to the original recommendation. BWMC has proffered absolutely no support for its "due process" argument. BWMC has not challenged the accuracy or integrity of the data that was admitted into the record, but only takes issue with how Commissioner Tanio used it in the Revised Recommended Decision. Moreover, BWMC's interpretation of the APA as requiring an opportunity to contest data prior to its admission into evidence is just wrong. In addition, BWMC has had plenty of opportunity to comment on the data. BWMC has, in fact, contested the admission of the data in at least four filings.[135] Finally, there is no reason for an evidentiary hearing.

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[134] DI #121GF at 45.

[135] BWMC objected to the use of the data in: (1) its Exceptions to the original recommendation; (2) a Motion to Strike The Recommended Decision and Data Entered Into The Record on December 30, 2016; (3) its Comments in Response to January 23, 2017 Ruling (denying the motion to strike and inviting additional comments on evidentiary matters); and (4) its Exceptions to the Revised Recommended Decision. It is hard to imagine why these four bites at the apple did not give BWMC all the opportunity it needed to respond to the data at issue.

A. BWMC does not contest the truthfulness or integrity of the data Commissioner Tanio used in his decision.

BWMC does not challenge the truthfulness or integrity of the data entered into the record.

The data BWMC refers to includes HSCRC and DC discharge rates. BWMC does not challenge the truthfulness or integrity of this data which is available to the public. As Commissioner Tanio observed in his January 23, 2017 letter order denying BWMC's Motion To Strike the Recommended Decision ("Motion to Strike"), he provided notice on October 5, 2016 of his intent to use the information, and directed the parties to where the data could be found if they did not already have access to it.[136] The notice was titled **"Notice of use of HSCRC Discharge Database and District of Columbia Discharge Database in this review."** No party objected.

The data BWMC refers to also includes CY 2015 and CY 2020 population projections. BWMC does not challenge the truthfulness or integrity of this data either. The data was entered into the record on December 30, 2016. As Commissioner Tanio explained in his January 23, 2017 letter order denying BWMC's Motion To Strike, BWMC is wrong to assert that the data was not in the record. Rather, access to the CY 2020 data (but not the 2015 data) was simply missing a "record layout key." Accordingly, he provided the parties until February 1 (later extended to February 3 at BWMC's request) to respond to that data.[137] In BWMC's Comments In Response To January 23, 2017 Ruling, ("BWMC's Evidentiary Comments")[138], BWMC said nary a word about the CY 2020 data other than to repeat its dissatisfaction with Commissioner Tanio's Forecast Model.[139]

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[136] DI #70GF at 4.

[137] DI #106GF.

[138] DI #112GF.

The data BWMC refers to also includes the Virginia Health Information Data Set. BWMC did not refer to this data in its Motion To Strike. However, Commissioner Tanio noted of his own volition in his January 23, 2007 letter order that this data, limited to 13 cases overall, "while not substantively altering my analysis," was not in the record. As with the 2020 population projections, he provided the parties until February 1 (later extended to February 3 at BWMC's request) to respond to that data.[140] In BWMC's Evidentiary Comments, BWMC argued that the Virginia data was unreliable because the Virginia data does not indicate how cardiac surgery is defined.[141] BWMC accordingly took advantage of its opportunity to comment on the evidence prior to the Revised Recommended Decision. In his Revised Recommended Decision,

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[139] MedStar is similarly wrong to argue that the Commission's February 6, 2015 utilization projections for cardiac surgery in the region (which projected regional volumes through CY 2019) forecloses Commissioner Tanio from projecting regional population and volume for CY 2020. *See* MedStar Exceptions at 12-14. *First*, the Cardiac Chapter required Commissioner Tanio to evaluate CY 2020 data. The Cardiac Chapter calls for Commissioner Tanio to analyze whether a proposed program can "demonstrate the ability to meet a projected volume of 200 open heart surgery cases in the second full year of operation…" COMAR 10.24.17.05(A)(1)(a). CY 2020 is likely the second full calendar year of operation for any program approved in this Review, as neither program is likely to open before CY 2018, even if approved this month. *Second,* the Forecast Model did not contradict the Cardiac Chapter's utilization model. The Revised Recommended Decision makes clear that Commissioner Tanio updated utilization estimate "using the Forecast Model in the Cardiac Surgery Chapter…that was effective on August 17, 2014" with minor adjustments to permit a "zip code area-level of analysis necessary for hospital service areas." DI # 121GF at 30. *Finally*, whether or not Commissioner Tanio's updates to the utilization forecasts were published in the Maryland Register is irrelevant, as the Commission has entered the data into the record and given interested parties and the applicants ample opportunity to be heard in disputing the projections.

[140] DI 105GF at 5.

[141] DI #112GF at 7.

Commissioner Tanio expressly identified the definition used,[142] rendering BWMC's objection moot.[143]

B. The Administrative Procedure Act does not require prior notice to introducing evidence and there is no time bar.

BWMC's due process argument is premised on the incorrect assertion that under the APA it should have received an opportunity to contest the evidence prior to its admission. BWMC improperly conflates two concepts – (1) the admission of evidence into the record as set forth in § 10-213(a) – (d); and (2) taking administrative notice of a fact outside the record that is judicially noticeable or within the specialized knowledge of the agency as set forth in § 10-213(h). The section of the APA quoted by BWMC clearly recognizes the distinction: "findings of fact must be based exclusively on evidence of record in the contested case proceeding *and* on matters officially noticed in that proceeding." § 10-214(a)(emphasis added).[144] The prior notice concept raised by BWMC applies only to administrative notice of a fact outside the record. In this case, because Commissioner Tanio did not take administrative notice of any fact outside the record, the prior notice provision in § 10-214(h)(2) on which BWMC relies has no application.[145]

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[142] "VHI-filtered dataset using the Cardiac Surgery definition of cardiac surgery effective August 17, 2014." DI #121GF at 45 n. 28.

[143] DI #121GF at 45 n. 28.

[144] Maryland's highest court similarly emphasized the distinction between evidence admitted into the record and notice of facts outside the record in connection with a proceeding before the State Ethics Commission. "…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.'….MD. CODE REGS. 19A.01.03.10(E)(4)(d) provides that *[e]xcept as set forth in §E(4)(e) [taking official notice of fact]* and (f) [inadmissibility of settlement offers] of this regulation, all evidence, including records and documents in the possession of the Commission, of which the Commission desires to avail itself, shall be offered and made a part of the record of the case"(emphasis added). *Bereano v. State Ethics Com'n*, 403 Md. 716, 740 (2008).

[145] While the procedure for taking administrative notice of facts outside the record is not applicable here because no administrative notice was taken, it should be observed that the regulations for the Commission do not require prior notice before a fact is administratively noticed. "The reviewer may take administrative notice of all judicially cognizable facts to the same extent as courts of this State, either on the reviewer's own motion or at the request of a

As to evidence made of record, "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." § 10-213(a)(2). The APA does not provide a procedure for the parties to contest evidence prior to its inclusion in the record. Commissioner Tanio admitted the data on which he relied into the record.[146]

There is no time deadline prior to final decision in which evidence can be entered into the record. In *Mehrling v. Nationwide Insurance Company*, 371 Md. 40, 60 (2002), Maryland's highest Court held that 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. "[T]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." Clearly then, there is no prohibition on admitting evidence into the record before a recommendation is issued.[147]

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party. The reviewer may also take official notice, without meeting formal evidentiary rules, of general technical or scientific facts within the specialized knowledge of a member of the Commission. 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." Md. Code Regs. 10.24.01.11(g).

[146] Indeed, both parties, as well as the agency, have submitted evidence into the record without the opportunity of the other party to first review it.

[147] BWMC's continued reliance on the case of *In re Clarksburg Community Hospital* is misplaced for several reasons. First, the opinion is wrongly decided, as it misconstrues the APA which does not require notice before evidence is admitted. Perhaps neither party raised this issue in that proceeding. Second, as a circuit court opinion, the decision has no precedential value. *A. & H. Transportation, Inc. v. Save Way Stations*, 214 Md. 325, 338 (1957). Third, the *Clarksburg* decision is inconsistent with *Mehrling v. Nationwide Insurance Company.* Fourth, BWMC's attempt to distinguish *Merhling* defies common sense. The issue of what evidence may be admitted, and when, does not depend on whether the evidence is offered by a party or the agency. Indeed, it would be illogical if a party could offer evidence with its exceptions, but the agency with the presumed expertise in the subject matter could not add data into the record prior

Administrative agencies have broad discretion in what evidence to admit. "The presiding officer may admit probative evidence that reasonable and prudent individuals commonly accept in the conduct of their affairs and give probative effect to that evidence." § 10-213(b). "Administrative bodies are not ordinarily bound by the strict rules of evidence of a law court.... Procedural due process in administrative law is recognized to be a matter of greater flexibility than that of strictly judicial proceedings." *Cecil Cty. Dep't of Soc. Servs. v. Russell*, 159 Md. App. 594, 612–13 (2004) (internal citations and quotations omitted). With the Administrative Procedure Act, "the General Assembly implicitly recognized that the formal rules of evidence possess far greater utility in jury trials than an agency hearing before a presumably expert hearing office. Indeed, Section 10–213 of the State Government Article suggests an emphasis upon the informal rather than the formal." *Para v. 1691 Ltd. P'ship*, 211 Md. App. 335, 380–81 (2013) (internal citations and quotations omitted). Commissioner Tanio's decision to enter the data into the record and to use it as he did is entirely permissible and consistent with the discretion afforded him under the Administrative Procedure Act.

C. Even if Commissioner Tanio should have allowed BWMC an opportunity to contest the data at an earlier point, the failure to do so is harmless error.

Even if BWMC correctly posits that prior notice should have been given before the data was admitted into evidence (which is not the case), any failure to do so is harmless error. BWMC "has the burden of showing prejudice in addition to the alleged error." *See, e.g., Desser v. Department of Health & Mental Hygiene*, 77 Md. App. 1, 14 (1988)(holding that the Secretary of Personnel's admission of tax returns into the record was harmless error). BWMC has had plenty of opportunity to take issue with the use of the evidence by way of its motion to strike, its comments on the evidentiary ruling, and its exceptions. BWMC has not

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to making a recommendation. Finally, even if the *Clarksburg* decision was correctly decided, Commissioner Tanio has given BWMC more than sufficient opportunity to comment, rendering BWMC's argument moot.

even tried to demonstrate that it was prejudiced by the data when it had ample opportunity to review and contest the data after it was admitted to the record. And, as noted above, BWMC does not contend the data is faulty or misleading – it only does not like the way it was used. BWMC's argument as to methodology is one suited to be raised in exceptions, and not whether the evidence should have been entered in the first place. Just because BWMC thinks data is irrelevant does not make it so. BWMC should not be allowed to trivialize important constitutional protections like due process because it is disappointed in the result.

D. There is no basis for an evidentiary hearing.

BWMC's argument that Commissioner Tanio's use of the data in his Forecast Model to test the applicants' volume projections somehow creates a genuine issue of material fact, giving rise to the right to an evidentiary hearing must be rejected. The decision whether to hold an evidentiary hearing is left to the judgment of the Reviewer.[148] Commissioner Tanio did not find any need for such a hearing. Whether the parties have demonstrated an ability to reach 200 open heart surgery cases in the second full year of operation does not raise an issue of material fact or witness credibility. The parties' projections and forecasts are just that – predictions about what may happen in the future – not facts that happened in the past. Similarly, Commissioner Tanio's determination as to whether the parties' predictions are likely to materialize is also a prediction. This is not a situation where there are issues about witness credibility or the authentication of evidence. Therefore, there is no need for an evidentiary hearing, even if one had been requested.

X. CONCLUSION.

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[148] COMAR 10.24.01.01D. That section provides, in pertinent part, that an evidentiary hearing may be held "if, in the judgment of the reviewer, an evidentiary hearing is 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."

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

Respectfully submitted,

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ANNE ARUNDEL MEDICAL CENTER

CARDIAC SURGERY PROGRAM CERTIFICATE OF NEED APPLICATION

RESPONSE TO EXCEPTIONS TO REVISED RECOMMENDED DECISION

Attestation by Victoria W. Bayless

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the March 16, 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.

March 16, 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 REVISED 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 March 16, 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.

March 16, 2017
Date

Signature

Director, the Heart Institute at AAMC
Position/Title

ANNE ARUNDEL MEDICAL CENTER

CARDIAC SURGERY PROGRAM CERTIFICATE OF NEED APPLICATION

RESPONSE TO EXCEPTIONS TO REVISED RECOMMENDED DECISION

Attestation by Robert Reilly

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the March 16, 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.

March 16, 2017
Date

Signature

CFO, Anne Arundel Medical Center
Position/Title

Exhibit 1

Dimensions Healthcare System

Cardiovascular Program
Strategic Business Plan
FY2012 – FY2017

Business Plan Executive Summary

DHS/UMMS Executive Work Group

December 13, ~~2013~~ 2012 [correct typo]

PRINCE GEORGE'S COUNTY RESIDENTS EXPERIENCED HEART SURGERY AT A RATE APPROXIMATELY 40% LOWER THAN THE U.S. POPULATION

COMPARISON OF CARDIOVASCULAR USE RATE CALCULATIONS
(PER 1,000 POPULATION)

PROCEDURE / SOURCE	Claritas 2011 Estimates Prince George's County	Nat'l Hospital Discharge Summary Report 2010 (Nat'l Rate)	AHA 2012 Report (2009 Data) Nat'l Rate	Prince George's County Actual Experience Rate 2010	Use Rate Applied to 2016 Pop. Proj. Prince George's County
PCI	**2.69**	**2.02**	**2.44**	**1.72**	**1.99**
Cardiac Surgery	**1.02**	**1.09**	**1.25**	**0.64**	**.87**

Note: Cardiac Surgery includes CABG, Valves, and "other" major cardiothoracic procedures

Sources: Prince George's actual experience rate calculated from combined FY2010 HSCRC and District of Columbia Hospital Inpatient Database Reports.