IN THE MATTER OF * BEFORE THE

ANNE ARUNDEL MEDICAL * MARYLAND HEALTH

CENTER, INC. * CARE COMMISSION

* Docket No.: 15-02-2360

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INTERESTED PARTY DIMENSIONS HEALTH CORPORATION D/B/A PRINCE GEORGE'S HOSPITAL CENTER'S EXCEPTIONS TO REVISED RECOMMENDED DECISION

Dimensions Health Corporation d/b/a/ Prince George's Hospital Center ("PGHC"), by its undersigned attorneys, and pursuant to COMAR 10.24.01.09B, submits the following Exceptions to the Revised Recommended Decision issued March 3, 2017 in the above captioned matter.

The Revised Recommended Decision should be rejected because neither the applicant, Anne Arundel Medical Center ("AAMC"), nor the Reviewer appropriately considered the substantial negative impact that AAMC's proposed program will have on PGHC's existing program. The general review criteria to assess impact on existing providers and the health care delivery system, and the impact standard under the cardiac surgery chapter of the State Health Plan **required** AAMC to conduct that analysis. The Revised Recommended Decision should also be rejected because AAMC did not establish that its proposed program is financially feasible and the Reviewer misinterpreted the standard in finding that it did.

It is undisputed that PGHC has a resurgent cardiac surgery program that is a key component of the services currently offered at Prince George's Hospital Center. That program is also a key component for success of the recently approved Prince George's Regional Medical Center ("PGRMC"), a project that is strongly supported by Prince George's County, the State of Maryland, University of Maryland Medical System ("UMMS"), and numerous other stakeholders. A 2012 report of the University of Maryland School of Public Health entitled "Transforming Health in Prince George's County, Maryland: A Public Health Impact Study" found, among other things, that the establishment of a high-quality, academically affiliated regional medical center is necessary to achieve positive transformational change in the health care delivery system in the County that serves all people. This Commission has recently approved that regional medical center.

Together, the County and State are investing \$416 million to dramatically improve access to high quality, comprehensive healthcare services and reduce health care disparities in the Prince George's County region. In light of that effort, and the fact that the State Health Care Plan is designed to promote the efficient and cost effective utilization of health care resources by requiring applicants to fully analyze the impact on existing providers that a proposed program may have, it was incumbent upon AAMC to fully and accurately assess the impact that its proposed program would have on PGHC, and it was incumbent on the Reviewer to undertake a professional and thorough analysis of the assessment presented by AAMC. This is especially true because AAMC's

proposed program relies entirely on siphoning volume from existing programs, including PGHC.

PGHC submitted data demonstrating that AAMC's proposed program has a substantial likelihood of causing PGHC's annual volume of cardiac cases to drop below 100. As AAMC concedes, the State Health Plan is designed to avoid the siphoning of volume from an existing program, such as PGHC's, and causing it to drop below such a threshold. AAMC failed to submit any evidence demonstrating that its proposed program will not have this effect. If PGHC is not able to maintain sufficient annual volume to obtain a Certificate of Ongoing Performance within three years after commencing services in its relocated replacement hospital facility, the result could be closure of its program. That would leave the residents of Prince George's County to seek cardiac surgery care outside the County again, and result in a waste of the substantial investment of resources by the State, County and UMMS. To do so would fly in the face of the strong public policy reasons for this Commission's recent approval of the new Prince George's Regional Medical Center. For these reasons, the Commission should reject the Revised Recommended Decision.

I. RELEVANT REGULATIONS

The impact standard under the cardiac surgery chapter of the State Health Plan, COMAR 10.24.17.05A(2) provides:

(2) Impact.

- (a) A hospital that projects that cardiac surgery volume will shift from one or more existing cardiac surgery hospitals as a result of the relocation or establishment of cardiac surgery services shall quantify the shift in case volume and the estimated financial impact on the cardiac surgery program of each such hospital.
- (b) An applicant shall demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:
 - (i) Compromise the financial viability of cardiac surgery services at an affected hospital; or
 - (ii) Result in an existing cardiac surgery program with an annual volume of 200 or more cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 200 cardiac surgery cases; or
 - (iii) Result in an existing cardiac surgery program with an annual volume of 100 to 199 cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 100 cardiac surgery cases.

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

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

Financial feasibility is assessed pursuant to COMAR 10.24.17.05A(7) which provides that:

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

- (b) An applicant shall document that: ...
- (ii) Its revenue estimates for cardiac surgery are consistent with utilization projections and account for current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, for cardiac surgery, as experienced by similar hospitals; ...
- (iv) Within three years or less of initiating a new or relocated cardiac surgery program, it will generate excess revenues over total expenses for cardiac surgery, if utilization forecasts are achieved for cardiac surgery services.

II. SPECIFIC EXCEPTIONS¹

- A. The finding that the proposed program at AAMC is not likely to cause the annual volume of cardiac surgery cases at PGHC to drop below 100 (Revised Recommended Decision p. 44) is not based on any substantial factual basis and was erroneous.
- **B.** The finding that the proposed program at AAMC is not likely to cause the annual volume at PGHC to drop below 100 does not meet the standard of COMAR 10.24.17.05A(2) that an applicant demonstrate that other providers will not be negatively affected to a degree that will compromise the financial viability of cardiac surgery services at an affected hospital or result in an existing program

¹ PGHC incorporates by reference the Exceptions and arguments of Baltimore Washington Medical Center and the other Interested Parties.

- with an annual volume of 100 to 199 dropping below an annual volume of 100 cases.
- C. Although acknowledging that the issue of how a new program at AAMC would affect the ability of PGHC to rebuild its existing program is one of "legitimate concern" (Revised Recommended Decision p. 44), and that "a program at AAMC is likely to incrementally constrain the growth potential of the existing program at PGHC," (Revised Recommended Decision p. 45) the Reviewer finds that the markets that will be tapped are "sufficiently large" enough. *Id.* There was no showing by AAMC in its application or responses that this is the case and there is no substantial evidence to support the finding.
 - The Revised Recommended decision admits that a program at AAMC is likely to draw cases from PGHC. Revised Recommended Decision p. 45.
 - 2. The Revised Recommended Decision also admits that the new program at AAMC would be aggressively seeking to pull cases away from Washington, DC hospitals, as would the program at PGHC, but without any substantial basis, concludes summarily that:
 - a. the cases pulled by AAMC from Washington, DC hospitals will "primarily be patients from the Annapolis area" and
 - b. "most of" the Prince George's residents will shift from the Washington, DC hospitals to PGHC. *Id.*

- D. The Revised Recommended Decision should be rejected because the Reviewer failed to require AAMC to address the required impact analysis based on existing volume and quality of the existing cardiac surgery program at PGHC at the time of Commission action on the application.
- E. The general CON review criterion, COMAR 10.24.01.08G(3)(f), required AAMC to include PGHC's existing cardiac surgery program in calculating the impact of its proposed project on existing health care providers and the health care delivery system, yet AAMC failed to do so. Therefore, its application should not be recommended for approval.
- F. The Reviewer found, contrary to the report requested from and received from the Health Services Cost Review Commission ("HSCRC"), that "the markets that will be tapped for cases by PGHC and AAMC are sufficiently large that each can reach the target level of 200 cases per annum without having an unacceptable impact on other programs." Revised Recommended Decision p. 120. This finding was not based on substantial evidence and was erroneous.
- G. The Reviewer misconstrued the financial feasibility requirements of COMAR 10.24.17.05A(7), and his finding that the AAMC application met this standard for a cardiac surgery services should be rejected. Revised Recommended Decision p. 95-100.
- H. The Reviewer erred in denying the Motion for Recusal and to Strike Recommended decision.

III. ARGUMENT

A. AAMC in its application and responses, and the Reviewer in his Revised Recommended Decision, failed to provide any analysis based on substantial evidence, of the impact of the proposed program at AAMC on the existing program at PGHC.

As noted by the Reviewer, the Cardiac Surgery Chapter of the State Health Plan, COMAR 10.24.17, is applicable in this case. Revised Recommended Decision p. 14. One of the Standards for Review of a Certificate of Need for a Cardiac Surgery Program includes analysis of the impact of the proposed program on existing programs. COMAR 10.24.17.05A(2). Implicit in that standard is the principle that each review must give some deference to existing programs, and ensure that there will either be no negative effect on those existing programs, or only a minimal effect with an offsetting benefit.

The first requirement of this Standard is that an applicant that projects a shift from one or more existing programs **quantify** the shift and the estimated financial impact on the cardiac surgery program of each affected hospital. COMAR 10.24.17.05A(2)(a). AAMC's application made no such analysis or quantification with respect to the effect its proposed program would have on the existing program at PGHC. DI#3AA, p. 87-98. PGHC noted the absence of this required analysis in its Comments filed July 27, 2015. DI#30GF, p. 5, 8-12.

AAMC's response to this deficiency was that, because no AAMC inpatients or cardiac patients were transferred to PGHC from AAMC, it could reasonably conclude that its proposed cardiac surgery center would have no impact on the existing program at

PGHC. Revised Recommended Decision p. 41. AAMC claims this methodology is "sensible" because it "reflects the preferences of those patients and physicians whom AAMC will seek to serve." DI#45GF, p. 25. What it does not reflect, however, and what the Reviewer acknowledges elsewhere in his Revised Recommended Decision, is that the proposed program at AAMC would be in direct competition with PGHC for patients currently obtaining cardiac surgery care in Washington, DC. Revised Recommended Decision p. 45. AAMC's so-called justification, therefore, falls flat.

The finding that the proposed program at AAMC is not likely to cause the annual volume at PGHC to drop below 100 (Revised Recommended Decision p. 44) is not based on any substantial factual basis. AAMC's CON application did not address the impact of its proposed new program on PGHC. PGHC highlighted AAMC's failure and AAMC responded that an impact analysis was not required because the PGHC program did not then have the current volume and STS rating that would trigger the requirement for that impact analysis. PGHC moved to supplement the record to show that, before Commission action on the AAMC application, (1) the volume of cardiac surgery cases at PGHC was above 100 cases annually; and (2) PGHC has had a 2 Star or better STS rating in the three most recent composite rating periods.

The Reviewer accepted PGHC'S Supplemental Comments to AAMC's CON ("the Supplemental Comments"), filed June 24, 2016, (DI#62GF) with the additional evidence, over AAMC's objection. Yet, AAMC *never* actually analyzed whether its proposed program would cause the annual volume at PGHC to drop below 100. The Reviewer

should have recommended denial of AAMC's CON application based on that failure alone. Instead, despite his concession that "a program at AAMC is likely to incrementally constrain the growth potential of the existing program at PGHC" (Revised Recommended Decision p. 45), the Reviewer arbitrarily concludes, without any evidentiary basis, that "the establishment of a cardiac surgery program at AAMC and/or BWMC would not be likely to cause PGHC's annual volume to drop below 100 cases."

Id at 44. The Reviewer claims that although AAMC's proposed program will "draw some cases from PGHC's service area . . . these will primarily be patients from the Annapolis area that has not historically been developed as a source of patients for PGHC." *Id.* at 45. That assumption is not only speculative - it is contradicted by the record evidence. DI# 62GF, p. 9.

The Reviewer's determination that "AAMC will be aggressively seeking to pull cases away from District of Columbia hospitals[,]" and his finding that "the cardiac surgery cases most likely to shift from use of District of Columbia hospitals to PGHC are residents of Prince George's County, most of whom will continue to be a primary market for PGHC and District of Columbia hospitals, with AAMC or BWMC functioning as second-order providers" is equally unfounded. Revised Recommended Decision p. 45.

Again, there are no facts in the record supporting these assumptions. Indeed, the Revised Recommended Decision does not refer to *anything* in the record to support these findings.

B. The burden of proof is on the applicant.

The finding that the proposed program at AAMC is not likely to cause the annual volume at PGHC to drop below 100 does not meet the standard of COMAR 10.24.17.05A(2) that *an applicant demonstrate* that other providers will not be negatively affected to a degree that will compromise the financial viability of cardiac surgery services at an affected hospital or result in an existing program with an annual volume of 100 to 199 dropping below an annual volume of 100 cases. It is important to note that the burden of showing this effect is on the applicant. COMAR 10.24.01.08G(1). It is not the burden of an interested party such as PGHC to prove the impact. In this case, AAMC has produced no evidence on this question and has steadfastly insisted it does not need to. Any evidence on this issue that has been presented, has been presented by other parties, and shows that the impact of the proposed program at AAMC will be detrimental to the success of the existing program at PGHC.

C. There is no basis in the record for the finding that the "market is sufficient" to sustain an additional cardiac surgery program at AAMC.

Although acknowledging that the issue of how a new program at AAMC will affect the ability of PGHC to rebuild its existing program is one of "legitimate concern" (Revised Recommended Decision p. 44), the Reviewer finds that the markets that will be tapped by a new program at AAMC and the existing program at PGHC are "sufficiently large" enough. *Id.* There is no showing by AAMC in its application or responses that this is the case and there is no substantial evidence to support the finding. First, there is

serious question about the available markets being sufficiently large to support another cardiac surgery program in such close proximity to PGHC. The Reviewer excuses AAMC's initial failure to address this issue because of the low volume at PGHC in calendar year 2015. *Id.* However, the Reviewer acknowledged that the standard requires consideration of the impact on a hospital meeting the volume and quality thresholds in the two most recent STS rating cycles prior to Commission action, and because of that he accepted into the record PGHC's June 24, 2016 filing updating its data and comments. DI#62GF. That submission showed that, due to its efforts in rebuilding its cardiac surgery program, PGHC has, in the last calendar and fiscal years prior to this Recommended Decision, reached a volume of over 100 cardiac surgery cases for the year, and exceeded the required quality ratings. DI#62GF p. 4-5.

PGIIC illustrated, in its supplemental comments, that analysis of the zip codes for the cardiac surgery cases performed at PGHC between July 2014 and June 2016, showed that a significant portion of the growth PGHC has been able to accomplish in its cardiac surgery program will be jeopardized by the proposed AAMC program, with its service area that includes a number of zip codes in Prince George's County. It is obvious that a significant portion of the growth PGHC has been able to accomplish in the last year, in its cardiac surgery program, will be jeopardized by the proposed AAMC program with its service area significantly overlapping the geographical source of much of the PGHC patient population for cardiac surgery. With 40% of the cardiac surgery cases at PGHC in this period coming from the intended service area of the proposed

AAMC program, it cannot be denied that the impact of that proposed program would be to reduce the volume at PGHC to below 100 cases per year. DI#62GF p. 8-10. AAMC must not be allowed to define its cardiac surgery service area as including part of Prince George's County on the one hand, and then on the other, deny that its proposed program will shift any patients from PGHC to AAMC.

PGHC requested, at the time of its Motion to Supplement, that AAMC be required to show, in light of the data presented, the effect its proposed program would have on PGHC. However, the Reviewer did not require that AAMC do so. Consequently, the Commission has undisputed evidence in the record that there is a substantial likelihood that the proposed program at AAMC will negatively affect the volume at PGHC and has a significant chance of causing it to drop below 100 cases annually, rather than growing as it otherwise would, to the goal of 200+ cases per year.

The Revised Recommended Decision admits that a program at AAMC is likely to draw cases from PGHC's service area and incrementally constrain its growth potential. Revised Recommended Decision p. 45. Those findings are directly contradictory to the assertions of AAMC that its program would not draw cases away from PGHC, but the Revised Recommended Decision does not acknowledge this inconsistency, nor does it recognize that this finding is further basis to find that AAMC has not complied with COMAR 10.24.17.05A(2).

Despite these admissions, and despite a finding that there is not sufficient volume in the larger area to justify a program at BWMC, the Reviewer nonetheless found that

there is sufficient volume in the more limited geographic area that includes the overlapping service areas of PGHC and AAMC to justify allowing AAMC to open a new program in direct competition with PGHC. To reach this conclusion, the Reviewer refers to the existence of 3470 cardiac surgery cases in an area larger than the one to be served by PGHC and AAMC, even including the District of Columbia and Northern Virginia. There is no evidence or analysis in the record of where any of these cases will be treated, as between PGHC and AAMC, if treated at either. This volume alone cannot justify AAMC's proposed program.

The Revised Recommended decision also admits that the new program at AAMC would be aggressively seeking to pull cases away from Washington, DC hospitals, as would the program at PGHC, but without any evidence or substantial basis, concludes summarily that:

- 1) the cases pulled by AAMC from Washington, DC will "primarily be patients from the Annapolis area" and
- 2) "most of" the Prince George's residents will shift from the Washington, DC hospitals to PGHC.

Revised Recommended Decision p. 45. The success of the proposed AAMC program indeed depends largely on its ability to pull hundreds of cases involving Maryland residents from MedStar Washington Hospital Center. PGHC also bases a good deal of its projected growth on doing the same thing. The Reviewer's findings that "most of" the

cases going to PGHC will be Prince George's residents and that AAMC will pull "primarily" from the Annapolis area have no basis in the record.

PGHC is entitled, as an existing program that has undertaken substantial rebuilding efforts, to the protection afforded by the State Health Plan - i.e. that any proposed new program have to show that it will not have a detrimental effect on the ability of an existing program to maintain levels of sustainable volume. PGHC needs to continue to grow, not just maintain volume. Yet, the Reviewer erroneously discusses tradeoffs and "weighing of benefits" (Revised Recommended Decision p. 45) between a viable program at PGHC and an additional program at AAMC. The impact standard is intended to protect existing, successful, programs like PGHC's, and to require that an applicant for a new program affirmatively show that it will not have the effect of reducing (in this case) PGHC volume to below 100 nor compromise the financial viability of its services. COMAR 10.24.17.05A(2). There was no such showing in this case. The Reviewer, instead, discussed whether the market is large enough to allow AAMC's proposed program and PGHC's existing program to both reach a volume of 200 annual cardiac surgery cases. Id. That is not the relevant issue, however. AAMC was required to demonstrate that its program would not drop PGHC's program below 100 cases. The issue is not whether the market can sustain an additional program, it is the effect that an additional program will likely have on an existing program.

D. The Revised Recommended Decision should be rejected because the Reviewer failed to require AAMC to address the required impact analysis based on existing volume and quality of the existing cardiac surgery program at PGHC at the time of Commission action on the application.

As PGHC noted in its Supplemental Comments, COMAR 10.24.17.05A(2)(b)(iii) requires that a proposed new program will not result in an existing program, with the requisite volume and STS composite score "prior to Commission action on an application," dropping below an annual volume of 100 cardiac surgery cases. DI#62GF. Based on this regulation, the Reviewer accepted PGHC's Motion to Supplement its Comments to show that it had reached an annual volume of 100 cases and had been given a three star rating from STS for 2015, which is granted to approximately 10 percent of programs nation-wide. Revised Recommended Decision p. 44. Clearly, based on these Supplemental Comments, PGHC is a hospital entitled to the protection of COMAR 10.24.17.05A(2)(b)(iii) prior to Commission action on the application. Therefore, the Reviewer should have required that AAMC address the impact analysis with regard to PGHC. Having failed to do so, the finding that the establishment of a cardiac surgery

² AAMC's comment that PGHC had only shown a sufficient STS rating for 1 ½ years is misplaced. COMAR 10.24.17.05A(2) refers to achieving the requisite rating in 2 of the 3 most recent rating cycles, which occur twice per year. PGHC's initial Comments included PGHC's most recent rating - - for the second half of 2014. The Supplemental Comments demonstrated that PGHC had achieved a 3 star rating for the two cycles in 2015. Thus, in its Comments and Supplemental Comments, PGHC conclusively showed that it had achieved the requisite rating (and more) for 2 of the three most recent cycles. PGHC also received a 3 star rating for the most recent rating cycle of July 1, 2015 through June 30, 2016.

program at AAMC would not be likely to cause PGHC's annual volume to drop below 100 cases is erroneous and without a factual basis and the Commission should reject it.

E. AAMC in its application and responses, and the Reviewer in his Revised Recommended Decision, failed to provide an analysis, based on substantial evidence, of the impact of the proposed project on PGHC.

"In reviewing a Certificate of Need application, the burden of proof that the project meets the applicable criteria for review, by a preponderance of the evidence, rests with the applicant." COMAR 10.24.01.08G(1). AAMC did not meet that burden of proof with regard to the impact of its proposed project, nor did the Reviewer address AAMC's failure to do so. COMAR 10.24.01.08G(3)(f) provides that:

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

(emphasis added).

On July 15, 2016 the Reviewer requested that the HSCRC review and comment on the financial feasibility and underlying assumptions of the proposed program at AAMC as well as the proposed program at Baltimore Washington Medical Center. DI#64GF. In its response, the HSCRC noted specifically that, "AAMC draws some of its patients from Prince George's County, and this could impact the DHS [Dimensions Health System] program." The HSCRC pointed out that changes in volume levels at Washington Hospital Center resulting from a new program at AAMC may impact available capacity

at Washington Hospital Center, "making it more difficult for DHS to grow its volumes in the face of this increased capacity. Thus, there is the potential to directly or indirectly impact program volumes at DHS, and, therefore, its financial performance." DI#68GF, p. 3 (emphasis added).

After receipt of this response from the HSCRC, the Reviewer invited AAMC to revise its application and it did so on November 7, 2016. DI# 3AA. The Modified CON addressed COMAR 10.24.01.08G(3)(f), but only in part. *See* DI# 3AA p.16. Most importantly, the Modified CON did not even purport to address the impact of the proposed project on PGHC's existing program, despite that impact having been noted by the HSCRC. Similarly, it did not adequately or correctly address the impact on costs of the health care delivery system.

1. Impact on PGHC's Existing Program.

PGHC has worked hard to reduce the out-migration of Prince George's County residents for health care services. Among the most important of services to be provided in Prince George's County is a full array of cardiovascular health care, including cardiac surgery. UMMS and PGHC have made large investments of resources in these services, and the investment is beginning to bear impressive results with a substantially increased volume of cardiac surgery cases for County residents, as well as recognition for the quality of the care provided.

The Supplemental Comments filed June 24, 2016, (DI#62GF) highlighted the continued growth of PGHC's existing cardiac surgery program. At that time, PGHC had

over 100 cardiac surgery cases in Calendar Year 2015 and in FY 2016. *Id.* At the same time, PGHC was awarded a 3 Star Composite Rating - the highest possible rating - for the Composite Quality Ranking for isolated CABG from the Society of Thoracic Surgeons. *Id.* PGHC's Motion to Supplement also highlighted the fact that 39% of PGHC's cardiac surgery cases from July 2014 to June 2016 came from the intended service area of the proposed AAMC program. *Id.* at 8.

Notwithstanding this showing by PGHC in its Supplemental Comments, the Modified CON filed later by AAMC still failed to address the impact of the proposed program on PGHC's existing program. It did so despite: (1) the evidence produced by PGHC of the volume and quality of its existing program which entitled it to protection; (2) the HSCRC's opinion; and (3) the fact that AAMC acknowledged that its proposed cardiac surgery program would have an impact on OHS Hospitals from as far away as Baltimore, including St. Joseph's Medical Center, which AAMC projected to have only *one* affected case. Revised Exhibit 39. No explanation was provided for the omission of any discussion or consideration of the impact on PGHC.

AAMC's failure to include an analysis of its proposed program's impact on PGHC's existing program was consistent with AAMC's failure to show that approval of its application would not negatively affect PGHC's existing program by causing PGHC's annualized cardiac surgery volume to drop below 100 cases. *See* COMAR 10.24.1705A(2)(b)(iii). Nonetheless, the Reviewer - without any showing by AAMC and contrary to the opinion of the HSCRC that "there is the potential to directly or

performance" - found that the markets that would be tapped for cases were sufficiently large that there would be no impact on the existing PGHC program. This finding is without substantial evidence, and contrary to all evidence that is in the record.

2. The Impact on Costs to The Health Care Delivery System.

"demonstrate that AAMC's proposed cardiac surgery service would generate even greater savings to the health care delivery system than originally projected." *See* the Modified CON at 16. The Reviewer found that "AAMC's proposed project will have a positive impact on charges for and access to cardiac surgery and a positive impact on health systems costs and would not result in increased costs or charges at existing facilities that outweigh these positive impacts." Revised Recommended Decision p. 121. The assumptions underlying AAMC's projected total health care expenditure saving and the Reviewer's finding are inaccurate.

As discussed above, AAMC completely failed to acknowledge that, if its CON Application were approved, AAMC's new program would shift patients away from PGHC's existing program. To the extent that AAMC shifts cases from PGHC rather than from MedStar Washington Hospital Center, the savings to the health care system will not be as significant as projected by AAMC, because PGHC will receive 50% VCF while Washington DC hospitals would receive nothing for volume loss. Accordingly, AAMC

failed to accurately calculate the impact of this shift on overall savings. The finding by the Reviewer on this point, therefore, is not based on substantial evidence.

Second, AAMC fails to account for the fact that patients who would otherwise go to Washington, D.C. hospitals for care are going, and will continue to go in increasing numbers, to PGHC. Accordingly, AAMC's estimate of 227 cases being transferred to it from D.C. hospitals is unsubstantiated. Third, to the extent that AAMC's proposed program did shift cases from D.C. hospitals, that shift would create capacity in those hospitals to take cases that would otherwise have gone to PGHC. This last effect was the one noted by the HSCRC, discussed above. The Reviewer's ultimate finding on this issue, quoted above, is based, at least in part, on his initial finding that "the markets that will be tapped for cases by PGHC and AAMC are sufficiently large that each can reach the target level of 200 cases per annum without having an unacceptable impact on other programs." Revised Recommended Decision p. 120. As discussed above, this finding is unsupported by any substantial evidence, and fails to give deference to the existing program at PGHC, as required by the standard.

F. The Reviewer failed to give PGHC the protection afforded by the State Health Plan to an existing program.

The general review criterion for assessing impact on existing providers and the health care delivery system requires that:

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographical and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care system.

COMAR 10.24.01.08G(3)(f).

This criterion recognizes a level of deference that must be given to an existing program in the assessment and evaluation of any application for a new cardiac surgery program, yet the Revised Recommended Decision ignores all of the evidence in the record, from various parties, that the proposed program at AAMC will be harmful to PGHC.

Initially, AAMC admitted that it had not addressed the impact of its proposed program on PGHC. DI#3 AA, p. 94. AAMC even admitted that its proposed program would shift cardiac surgery patients who are residents of Prince George's County from hospitals such as Washington Hospital Center to AAMC. DI #3AA, p. 94. As discussed by PGHC in its comments to the application, those would include at least some patients who would otherwise have been recaptured by PGHC. DI #30GF, p. 12.

AAMC, in its response to the comments from PGHC, also acknowledged that the State Health Plan's impact standards "plainly protect programs with current volume from dropping below a certain threshold." DI#45GF, p. 27. The wording of the general impact criterion is clear that the **applicant** has a duty to provide information and analysis with respect to the effect of its proposed program on existing providers in the region, but AAMC never did so in its application. Indeed, it claimed it did not need to do so. DI#3AA, pp. 87-98.

In its application, AAMC considered it worth noting that it was, at that time, speculative whether Dimension's application for replacement and relocation of PGHC would be approved. The Commission has recently approved that application (Docket No. 13-16-2351). In doing so, Commissioner Moffit mentioned, among other things, the substantial success PGHC has had in rebuilding its cardiac surgery program. PGRMC Decision, p. 79. It is undeniable that the overall success of the PGRMC is of significant importance to the residents of Prince George's County, who have few local facilities for primary health care or hospital services, and to the delivery of health care in Prince George's County.

The proper analysis is not one that looks at whether "the markets that will be tapped for cases" by the proposed program and the existing program are "sufficiently large" enough, (Revised Recommended Decision p. 120) but whether the applicant has provided information and analysis to show the impact of its proposed program on existing programs. Where no information or analysis has been provided with respect to the closest nearby provider, the criterion cannot be said to have been met.

G. If the same assumptions used by the Reviewer in his Revised Recommended Decision with respect to his minimum volume analysis were used to analyze the impact of the proposed program at AAMC on PGHC, it would indicate that PGHC would not reach the goal of an annual volume of 200+ cases.

As discussed above, AAMC did not provide any concrete analysis of its impact on PGHC's program. In the Revised Recommended Decision, the Reviewer constructed an "alternative forecast model" (Revised Recommended Decision p. 29) and used it in

connection with the assessment of the applicants' compliance with the minimum volume standard. This new method of measuring a new program's ability to generate cardiac surgery volume was not proposed by either applicant and is subject to question with regard to its validity. Although the validity of that model for the purposes proposed is disputed, if the Commission accepts it, it should apply the same alternative methodology to assess the impact of the proposed program at AAMC on the existing program at PGHC.

The Revised Recommended Decision used the Alternative Model to assess the ability of two hospitals with overlapping 85% MSGA service areas (UM BWMC and AAMC) to generate at least 200 cardiac surgery cases each year. Likewise, AAMC and PGHC have overlapping 85% MSGA service areas. As indicated in Table 1 below, using CY 2014 data, AAMC and PGHC share seven zip codes in eastern Prince George's County.

Table 1
CY 2014 AAMC/PGHC 85% MSGA Service Areas

Anne Arundel Medical Center MSGA			Prince George's Hospital Center MSGA				
ZIP	Discharges	Running Total %	ZIP	Discharges	Running Total %		
21401	2,549	13.37%	20785	1,087	13.80		
21403	1,689	22.23%	20743	1,069	27.36		
21403	1,005	27.50%	20019	498	33.68		
21037	828	31.84%	20774	468	39.62		
20715	811	36.10%	20784	439	45.20		
21409	760	40.08%	20747	413	50.44		
	674	43.62%	20706	272	53.89		
21146 21114	666	47.11%	20710	270	57.32		
	566	50.08%	20721	233	60.27		
21666	519	52.80%	20772	195	62.75		
20716			20772	193	65.20		
21113	382	54.81%		164	67.28		
21054	367	56.73%	20746		68.84		
21032	344	58.54%	20020	123			
21122	340	60.32%	20716	115	70.30		
21035	334	62.07%	20715	110	71.70		
21619	294	63.61%	20781	107	73.05		
20711	281	65.09%	20748	95	74.26		
21617	261	66.46%	20744	88	75.38		
20721	250	67.77%	20032	86	76.47		
20774	239	69.02%	20720	86	77.56		
20764	233	70.24%	20722	75	78.51		
20772	229	71.45%	20745	75	79.46		
20776	210	72.55%	20782	74	80.40		
21061	204	73.62%	20783	74	81.34		
20720	201	74.67%	20770	71	82.24		
20733	187	75.65%	20002	70	83.13		
21108	183	76.61%	20735	59	83.88		
21144	180	77.56%	20712	54	84.57		
21638	149	78.34%	20740	53	85.24		
21140	140	79.07%					
21601	135	79.78%					
20751	132	80.47%					
20736	122	81,11%					
21658	117	81.73%					
	117	82.33%					
20639		82.86%					
21620	102	1	1				
20732	92	83.35%					
20778	92	83.83%					
20754	88	84.29%					
21060	87	84.75%					
20706	83	85.18%					
tal	16,240	85.18%	Total	6,716	85.34		

The Cardiac Surgery Discharges from the 85% Relevance MSGA Service Area were then calculated using the Reviewer's methodology and produced the results shown in Table 2 below.

Table 2
Cardiac Surgery volume projections for hospitals' 85% Relevance MSGA Service area - no overlap adjustment

Hospital	Projected	Cardiac Surg		es from 85% Area	Relevance N	/ISGA Service
Service Area	2015	2016	2017	2018	2019	2020
AAMC	714	703	694	685	676	668
PGHC	559	551	543	535	527	520

The projections for AAMC in Table 2 are the same calculated by the Reviewer in his Revised Recommended Decision at p. 31.

Using the Alternative Model, PGHC then used the Reviewer's methodology to calculate projected cardiac surgery discharges from the 85% MSGA service areas of AAMC and PGHC. This was calculated by applying the Health Planning Regions' projected use rates to the projected population for each zip code. The Reviewer also assumed that discharges in the shared zip codes would be split evenly (50/50) between the two service areas. The projected discharges in each service area, after adjusting for the shared zip codes, are shown in Table 3 below.

Table 3
Projected Cardiac Surgery Discharges from the 85% MSGA Service Areas reflecting shared zip code adjustment

Hospital Service	Projecte	ed Cardiac		scharges fr rvice Area	om 85% Re	elevance
Area	2015	2016	2017	2018	2019	2020
AAMC	632	622	612	602	592	583
PGHC	486	479	472	465	458	451

Next, PGHC calculated the projected cardiac surgery discharges for AAMC and PGHC within their respective 85% MSGA service areas at the same three levels of market share that the Reviewer used in the Alternative Model. The results are shown in Table 4 below.

Table 4
Projected Cardiac Surgery Discharges from 85% MSGA Service Area
by Selected Market Share Levels

Market Share Assumption		Projected Cardiac Surgery Discharges from 85% Relevance MSGA Service Area							
		2015	2016	2017	2018	2019	2020		
18%	AAMC		114	112	110	108	107	105	
	PGHC		88	86	85	84	82	81	
20%	AAMC		126	124	122	120	118	117	
	PGHC		97	96	94	93	92	90	
25%	AAMC		158	155	153	150	148	146	
	PGHC		122	120	118	116	114	113	

Applying the Reviewer's assumption that the hospitals will derive 66% of their cardiac surgery volume from their 85% MSGA service areas and the remainder from outside their service areas, PGHC then calculated the total projected cardiac surgery volume for AAMC and PGHC assuming they co-exist with overlapping service areas. These results are shown in Table 5 below.

Table 5
Projected Cardiac Surgery Discharge from Inside and Outside
85% MSGA Service Area by Selected Market Share Levels

Market Share Assumption		Projected Cardiac Surgery Discharges from 85% Relevance MSGA Service Area							
			2015	2016	2017	2018	2019	2020	
18%	AAMC		172	170	167	164	162	159	
	PGHC		133	131	129	127	125	123	
20%	AAMC		192	188	185	182	180	177	
	PGHC		147	145	143	141	139	137	
25%	AAMC		239	235	232	228	224	221	
	PGHC		184	181	179	176	173	171	

In contrast, Table 6, following the Alternative Model's methodology, demonstrates that PGHC will achieve 200 or more annual cases by 2017, assuming that its program continues and that AAMC's proposed application is denied.

Table 6
PGHC's Projected Volume

Market Share Assumption	Projected Volume						
	2017		JATE I				
18%	148						
20%	165						
25%	206						

Thus, the unsubstantiated finding in the Revised Recommended Decision that the proposed program at AAMC would not have a substantial impact on PGHC's existing program is not accurate if one uses the Alternative Model proposed by the Reviewer to actually perform a quantitative analysis. Rather, these tables show, using that Alternative Method, that the result of the "healthy competition" endorsed by the Reviewer would be that PGHC would not achieve or sustain a level of 200 cardiac surgery cases per year, even under the "best case" assumption of a 25% market share.

Not only do these calculations show a negative impact on PGHC in its current location, but they indicate a negative effect on PGHC's ability to obtain a Certificate of Ongoing Performance after it relocates to the newly approved PGRMC. COMAR 10.24.17.07A(1)(b). These projections indicate that PGHC would be in jeopardy of being able to meet the requirements of COMAR 10.24.17.07B(6) to maintain an annual volume of 200 or more cases. If it fails to reach 200 cases per year, it will be subject to possible

closure, thereby putting in jeopardy any local access to cardiac surgery care for Prince George's County residents who have already endured years of disparity in health care.

H. The Reviewer misconstrued the financial feasibility requirements of COMAR 10.24.17.05A(7), and his finding that the AAMC application met this standard for a cardiac surgery services should be rejected.

Part of the financial feasibility requirement is that an applicant demonstrate, among other things, that the proposed program "will generate excess revenues over total expenses for cardiac surgery, if utilization forecasts are achieved for cardiac surgery services." COMAR 10.24.17.05A(7)b(iv). AAMC has not demonstrated that its proposed cardiac surgery program meets this standard. Rather, the projections AAMC has submitted demonstrate that its proposed cardiac surgery program would have negative net revenue for three years. It would not meet the standard, yet the Revised Recommended Decision finds that it does. This finding is based on misinterpretation of the standard and should be rejected.

In its initial application, AAMC assumed that its GBR would be adjusted for incremental volume related to the project at an 85% variable cost factor for the first three years of the project. Revised Recommended Decision p. 82. This assumption was shown to be in error when the Reviewer requested and received a review of the projections by HSCRC that indicated that HSCRC policy allowed for only a 50% retention of revenue associated with increased volumes taken from other Maryland hospitals. DI #68GF. The Reviewer then requested that AAMC provide revised versions of all the financial

schedules in conformance with the HSCRC policy with respect to revenue generated from projected shifts from hospitals with existing cardiac surgery programs. DI #69GF.

This recalculation, of course, would have to include any shift from PGHC. The Reviewer struck AAMC's initial response to his request, and allowed AAMC to submit a Modified Application to address this issue. DI #22AA. Although the Modification was filed November 7, 2016 - almost five months after PGHC's Motion to Supplement its Comments to reflect its current volume and quality (DI# 62GF) - still no analysis was provided of the impact on PGHC.

The projections in AAMC's modified application demonstrated that AAMC's proposed cardiac surgery service program would not generate excess revenues over expenses for cardiac surgery within three years, instead operating at losses of \$3.7, \$3.3, and \$3.0 million in FY 2017, FY 2018, and FY 2019 respectively. DI #22AA, Table J-2. Thus, the proposed program should not have been recommended for approval because it did not meet the financial feasibility standard for cardiac surgery services.

The Reviewer acknowledged this in finding that, "AAMC has projected, however, that based on HSCRC policy with respect to recognizing additional revenue deriving from shifts in service volume from one hospital to another, the revenue AAMC would add as a direct effect of providing cardiac surgery will be less than the expense of providing this new service. This creates a problem with respect to finding this application in compliance with this standard, based on the documentation requirement in subparagraph (b)(iv)[.]" Revised Recommended Decision, p. 95. However, the

Reviewer nonetheless recommended approval based on his misinterpretation and misapplication of the standard.

The standard expressly requires that the proposed program, **on its own**, will generate excess revenues over total expenses "for cardiac surgery." Notwithstanding the express language of the regulatory standard, and despite finding that assessment at the program level, as provided in the standard, was a "reasonable and conventional interpretation of the standard's requirement" (Revised Recommended Decision p. 97), the Reviewer speculated about what the Commission would have adopted as a standard, had it known what payment model the HSCRC would adopt. Revised Recommended Decision p. 98. Ignoring the specific language of the regulatory standard, the Reviewer found that the standard allowed for "flexibility" in assessing financial feasibility if a proposed new program meets all other standards and criteria and does not jeopardize the overall financial viability of the hospital. Revised Recommended Decision, p. 99.

The Reviewer's interpretation is contrary to the plain words of the standard and is inconsistent with the language and intent of the standard in its entirety. The standard includes evaluation of both the program feasibility and the hospital's financial viability: "[a] proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital." COMAR 10.24.17.05A(7). The plain language of the standard is clear and unambiguous. It requires that a proposed program meet both aspects of financial feasibility.

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Indeed, such an "interpretation" of the standard is essentially the adoption of an entirely different regulatory standard, and this can only be done through the agency's rulemaking function, not in the context of a comparative CON application review.

I. The Reviewer Erred by Denying the Motion for Recusal and to Strike the Recommended Decision.

For the reasons stated in the Motion for Recusal and to Strike the Recommended Decision, the Reviewer should have recused himself from this comparative review or, at a minimum, disclosed to the parties at the outset what appeared to be a conflict of interest. PGHC excepts to the Reviewer's decision denying that motion.

IV. CONCLUSION

Based on the failure of AAMC or the Reviewer to recognize and analyze the adverse impact of the proposed program at AAMC on PGHC's existing program, and the consequent effect of that impact on its calculation of the overall effect on costs of the health care system, together with the erroneous interpretation and application of the financial feasibility standard, PGHC requests that the Commission reject the findings and analysis of the Reviewer and deny the application of AAMC, or at the least, require that AAMC meet its regulatory burden of proof by presenting evidence of an impact analysis showing that its proposed program would meet the requirements of both COMAR 10.24.17.05A(2) and 10.24.01.08G(3)(f).

Dated: March 10, 2017

Respectfully submitted,

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George's Hospital Center

IN THE MATTER OF * BEFORE THE

ANNE ARUNDEL MEDICAL * MARYLAND HEALTH

CENTER, INC. * CARE COMMISSION

* Docket No.: 15-02-2360

* * * * * * * * * * *

INTERESTED PARTY DIMENSIONS HEALTH CORPORATION D/B/A PRINCE GEORGE'S HOSPITAL CENTER'S EXCEPTIONS TO RECOMMENDED DECISION

ATTESTATION BY JEFFREY L. JOHNSON

Affirmation: I hereby declare and affirm under the penalties of perjury that the facts stated in the Exceptions to Revised Recommended Decision are true and correct to the best of my knowledge, information, and belief.

Jeffrey L. Johnson, MBA, FACHE

March 10, 2017

Date

Senior Vice President, Strategic Planning & Business Development

Dimensions Healthcare System

CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of March, 2017, a copy of the foregoing

Exceptions to Revised Recommended Decision was sent via email and first-class mail to:

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