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August 25, 2015

VIA E-MAIL AND HAND DELIVERY

Mr. Paul E. Parker
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Anne Arundel Medical Center Response to Comments on Its Proposal to Change the
Type and Scope of Health Care Services Offered to Include Cardiac Surgery
Docket #15-02-2360

Dear Mr. Parker:

Enclosed please find six copies of Anne Arundel Medical Center, Inc.'s Response to Interested
Party Comments on AAMC's Certificate of Need Application.

A paper copy will follow.

Sincerely,



Jonathan Montgomery

Enclosures

cc: Mr. Ben Steffen
Mr. Kevin McDonald
Ms. Ruby Potter
Suellen Wideman, Esquire
Tom Dame, Esquire
Anne Arundel Medical Center (internal distribution)
Richard M. McAlee, Esquire (via email)
Joel Suldan, Esquire (via email)
Natalie McSherry, Esquire (via email)
Mr. Steven Schuh (via email)
Ella Aiken, Esquire (via email)
John T. Brennan, Jr., Esquire (via email)
Jinlene Chan, M.D. (via email)

Anne Arundel Medical Center
Response to Interested Party Comments

Table of Contents

	Page
I. Summary of Response	1
II. Need	4
III. Minimum Volume	5
IV. Access	12
V. Financial Feasibility	19
VI. Cost Effectiveness	21
VII. Impact on Prince George's Hospital Center	25
VIII. Quality	31
IX. Conclusion	35

ANNE ARUNDEL MEDICAL CENTER * MARYLAND
 PROPOSAL TO CHANGE THE * HEALTH CARE COMMISSION
 TYPE AND SCOPE OF *
 HEALTH CARE SERVICES OFFERED * DOCKET NO.: 15-02-2360
 TO INCLUDE CARDIAC SURGERY *
 * * * * *

**ANNE ARUNDEL MEDICAL CENTER
 RESPONSE TO INTERESTED PARTY COMMENTS**

I. Summary of Response

In this comparative review, the Commission should grant the certificate of need (“CON”) application of Anne Arundel Medical Center, Inc. (“AAMC”) to add cardiac surgery services (the “AAMC Application”). The AAMC Application demonstrates compliance with the general certificate of need standards¹ and with every applicable standard of the State Health Plan for Facilities and Services – Specialized Health Care Services: Cardiac Surgery and Percutaneous Coronary Intervention Services (the “SHP”).² Neither the comments of UM Baltimore Washington Medical Center (“BWMC”) nor those of MedStar³ or any other interested party detract from the following key facts:

First, AAMC has established need for its proposed cardiac surgery program. Contrary to MedStar’s Comment, the SHP does define need: there is “need” for a new program if the new program can generate at least 200 cardiac surgery cases per year. Need is not gross demand

¹ See COMAR 10.24.01.08(G)(3).

² See COMAR 10.24.17.00 *et seq.*

³ For ease of reference, this response refers to “Medstar” and the “MedStar Comment” when referencing the joint comments of MedStar Health hospitals MedStar Washington Hospital Center (“WHC”) and MedStar Union Memorial Hospital filed with the Commission on July 27, 2015.

minus existing capacity. Need is not a vague or esoteric state of affairs calling for a subjective judgment by the Commission. Need has a concrete definition, which AAMC has met.

Although MedStar, LifeBridge, and BWMC attempt to shave AAMC's volume projections at the margins, unlike the volume projections for BWMC's proposed program, AAMC's projections are robust and show that AAMC will meet the annual 200 case threshold with an ample cushion. AAMC will reach 237 cases by FY 2017 and 387 cases by FY 2019.

The most important basis for AAMC's projections is AAMC's pool of internally-generated cases. AAMC has built an effective and well-regarded cardiology program performing a steady volume of PCI cases under Maryland's CPORT program. As a result, many patients who eventually require cardiac surgery already choose AAMC for their care: AAMC currently transfers or otherwise refers approximately 234 patients for cardiac surgery per year. Although AAMC has cemented relationships with Johns Hopkins Medicine and with local cardiology practices to allow AAMC's cardiac surgery program to grow from this base, it is this base that ensures AAMC will exceed the minimum volume threshold, and it is this base that no interested party has undermined.

It is also these patients who can face unique access barriers to cardiac surgery care. For just 2014, AAMC has documented multiple incidents when AAMC patients have been refused transfer to existing programs on financial grounds (such as patient insurance status) or due to a lack of resources (such as lack of space in an intensive care unit). The affidavits and emails enclosed with this response show that, contrary to MedStar's denials, AAMC has raised these types of transfer problems to no avail. Moreover, transfers by their nature introduce clinical risks, in particular through the disruption to care coordination. AAMC patients and the residents

in AAMC's region need access to a community hospital performing the full continuum of cardiac services.

AAMC is well-positioned to meet this challenge. AAMC has excellent quality scores both for cardiology and for hospital services generally. To build on its award-winning cardiology program, AAMC has secured the collaboration of Johns Hopkins Medicine to provide access to renowned Hopkins surgeons for AAMC patients. The collaboration will also give AAMC access to Johns Hopkins Hospital staffing, protocols, and training. Contrary to MedStar's Comment, AAMC has established a full staffing plan that accounts for all incremental costs of creating a high-quality program at AAMC.

A cardiac surgery program at AAMC would not only improve patient quality of care and population health in AAMC's community, but it would also achieve lower health care costs for Marylanders. AAMC would be the lowest charge hospital for cardiac surgery in Maryland or the District of Columbia. A program at AAMC would save patients and payers ***\$7.7 million dollars per year***. By redirecting volume from high-cost D.C. hospitals, a program at AAMC would help lower Marylanders' Medicare expenditures, a crucial metric in Maryland's attempt to preserve the Medicare Waiver. In contrast, BWMC's inability to shift volume from D.C. hospitals means that BWMC will not deliver AAMC's meaningful change to Medicare expenditure or to the health system as a whole.

In summary, AAMC has met the SHP standards for granting a CON to add cardiac surgery services, notwithstanding the often self-serving comments of existing programs. The Commission should grant AAMC a CON to help Maryland's health care delivery system achieve its Triple Aim goals of improved care, improved population health, and lower per capita health care costs for Marylanders.

II. Need

AAMC has demonstrated need for the Proposed Program in accordance with the need methodology set forth in the SHP. MedStar's assertion that "the SHP does not establish a methodology for determining the need for a new program"⁴ is absolutely false.

The SHP clearly establishes that "need" for a new or relocated cardiac surgery program depends solely on whether the "program can generate at least 200 cardiac surgery cases per year."⁵ A hospital demonstrates that this criterion is met through projections from utilization trends in cardiac surgery cases in the hospital's reasonable expected service area⁶ and from the number of patients referred for cardiac surgery by the hospital.⁷

Contrary to MedStar's characterization, the SHP does not define, let alone turn on, any notion of "excess capacity"⁸ at existing cardiac surgery programs.⁹ The current SHP represents a definitive break from past methodologies. Past methodologies projected need based on a calculation of expected volumes against existing capacity (the approach implicitly relied upon by MedStar).¹⁰ The current SHP reflects the balance sought by the Commission between adequate access and adequate volumes at each program: SHP policy is to make "[c]ardiac surgery... geographically accessible consistent with efficiently meeting the health care needs of patients."¹¹

⁴ MedStar Comment at p. 5.

⁵ COMAR 10.24.17.05(A)(6)(a).

⁶ See generally COMAR 10.24.17.05(A)(6)(a),(b).

⁷ See COMAR 10.24.17.05(A)(6)(c).

⁸ MedStar Comment at p. 5.

⁹ Indeed, "closure of an existing program, in and of itself, is not sufficient to establish a new or replacement program." COMAR 10.24.17.05(A)(6)(d).

¹⁰ For example, the 2001 version of the SHP (excerpt enclosed as Exhibit 22) defined net need for each planning region by "subtracting the total existing capacity from the total projected number of cases" for that region.

¹¹ COMAR 10.24.17.03.

III. Minimum Volume

AAMC will meet the standards for need and minimum volume set forth in the SHP. AAMC anticipates performing 387 cardiac surgery cases per year by FY 2019.¹² AAMC used four distinct but interlocking methods to project its volumes: internally-generated cases based on AAMC experience, cases generated by the affiliation with Johns Hopkins, surveys of local cardiology practices, and analogies to AAMC's market share in other surgical fields.

First, AAMC estimated its own internally-generated cases based on the experience of its existing cardiology program. This is not a bald projection. AAMC has forecasted volumes based on the actual number of patients already at AAMC, who have selected AAMC, and who require surgery.¹³ AAMC accounted for acuity and patient preference, estimating that AAMC will retain only 80% of those patients *who are already expected to choose AAMC for their care*.¹⁴

AAMC's unique base of internally-generated referrals is one reason why analogies by LifeBridge and MedStar between AAMC's volume projections and those of Suburban Hospital is inapt.¹⁵ Another reason is that AAMC has accounted for declining use rates in its projections, whereas need projections at the time of Suburban's application anticipated increasing use rates. Note also that Suburban was located within 11 miles of existing programs at MedStar Washington Hospital Center ("WHC"), Washington Adventist Hospital, and MedStar Georgetown University Hospital, whereas AAMC is located more than 20 miles from Prince

¹² See AAMC Application at pp. 77-78 – Chart 7.

¹³ BWMC accuses AAMC of a lack of transparency regarding this review process in its July 27, 2015 interested party comment on the certificate of need application of AAMC (the "**BWMC Comment**") at p. 12. However, AAMC set out specific categorizations of the cases AAMC evaluated. See AAMC's 3/30/15 Response to Completeness Questions ("**AAMC Completeness I**") at p. 20 – Chart 48.

¹⁴ AAMC Completeness I at p. 19.

¹⁵ This analogy appears in the July 23, 2015 interested party comment of LifeBridge on the certificate of need applications of BWMC and AAMC (the "**LifeBridge Comment**") at pp. 2-3. It also appears in the MedStar Comment at p. 25.

George's Hospital Center ("PGHC"), more than 30 miles from Johns Hopkins Hospital ("JHH") and Suburban Hospital, nearly 90 miles from Peninsula Regional Medical Center, and nearly 30 miles from WHC and University of Maryland Medical Center ("UMMC").

Contrary to BWMC's allegations, AAMC properly documented this projection. AAMC clinicians and administrators reviewed the records of all inpatient and outpatient transfers from AAMC to existing programs for cardiac surgery, involving a total of 303 patients.¹⁶ This review allowed AAMC to determine which patients were referred for surgery (and the type of surgery), as well as which patients were referred for mere evaluation for surgery.¹⁷ AAMC validly assumed that 50% of the patients referred for evaluation for cardiac surgery would ultimately receive that surgery – the 50% figure fit the experience of those AAMC cardiologists that make the majority of such referrals.¹⁸ The remaining 50% would be comprised not only by the patients who had no need for surgery, but also those patients who "will be too unstable for surgery, become deceased prior to surgery, or who are ultimately determined not to need surgery."¹⁹ No further discount on those grounds is warranted.

AAMC also validly assumed that 100% of the 95 patients specifically transferred for cardiac surgery received such surgery. AAMC cardiologists do not transfer patients from the hospital or the catheterization laboratory – and introduce the clinical risks associated with physical transfer and care coordination disruption²⁰ to such patients – without first determining that surgery is needed and appropriate. AAMC cardiologists first consult with a cardiac surgeon

¹⁶ AAMC Application at p. 80.

¹⁷ AAMC Application at p. 80.

¹⁸ AAMC Completeness I at p. 20.

¹⁹ BWMC Comment at p. 12.

²⁰ See ¶ 4 of Dr. Jerome Segal's affidavit (enclosed as Exhibit 23(a)).

to “reach a mutual decision about whether the patient needs cardiac surgery...and the appropriateness of a transfer” before initiating any transfer.²¹ In the context of those discussions, the surgeon may have access to relevant reports or other patient data such as cardiac catheterization films.²² But even if BWMC is correct that some discount of approximately 5% is appropriate for transferred patients who die prior to surgery (though AAMC records do not indicate this level of mortality)²³, even this 5% discount would only result in the loss of approximately 8 cases, as BWMC acknowledges in Chart 6 of its comment.

BWMC’s criticism that AAMC’s internally generated cases would only result in approximately 170-180 cases of 200 minimum cases by FY 2017 is hypocritical. BWMC *has documented far fewer internally generated cases*: in FY 2014, only about 97 BWMC cardiac catheterization patients needed surgery, whereas in the previous year, 234 patients of AAMC (inpatients, and outpatients requiring cardiac catheterization) required transfer to a hospital with a cardiac surgery program.²⁴ Additionally, these 170-180 cases are not the only source of expected cases, as BWMC knows. BWMC itself anticipates that adding a cardiac surgery program will attract patients who currently bypass it altogether and receive cardiac care from hospitals with existing programs.²⁵

²¹ *Id* at ¶ 3(d).

²² *Id* at ¶ 3(c).

²³ And it is this discount that AAMC applied in AAMC Completeness I at p.20 – Chart 48 to outpatient referrals. Again, because referring cardiologists often consult with surgeons to reach a mutual decision about the need for surgery *prior* to the referral by the cardiologist, AAMC validly assumed that 95% of its patients referred specifically for *surgery* underwent surgery, while perhaps only 50% of its patient referred for *evaluation* for surgery ended up undergoing surgery. MedStar’s criticism on this point (MedStar Comment at p. 28) should be rejected.

²⁴ AAMC Completeness I at p.20 – Chart 48.

²⁵ On page 10 of BWMC’s 3/30/15 completeness response, for example, BWMC states that “[a]s the program becomes established to cardiologists and patients, UM BWMC also expects to experience increased market share due to insurance provider and patient preference for lower cost of care settings.”

Second, AAMC projected volume based on its unique relationship with Johns Hopkins Medicine.²⁶ AAMC and Johns Hopkins have entered into a cardiac surgery affiliation agreement, a redacted version of which is enclosed as Exhibit 24 (the “**Cardiac Affiliation Agreement**”).²⁷ Under the Cardiac Affiliation Agreement, Johns Hopkins Medicine has committed a Chief of Cardiac Surgery – Dr. John Conte²⁸ –to a new cardiac surgery program at AAMC. Johns Hopkins has also committed to supplying expertise and assistance to AAMC in AAMC’s oversight of the program.²⁹ As a result, Johns Hopkins surgeons who would otherwise perform surgery at Johns Hopkins Hospital will perform surgery at AAMC, in accordance with patient preference and acuity.

The Cardiac Affiliation Agreement is a durable foundation for projections. The Cardiac Affiliation Agreement has a twenty-year term, renewing for additional ten-year terms.³⁰

Based on these commitments, AAMC estimated that approximately 50% of the cases Johns Hopkins Hospital would otherwise perform for patients in AAMC’s proposed cardiac surgery service area would instead be performed at AAMC.³¹ The remaining cases would continue to be performed at JHH due to acuity or patient preference. The 50% figure is conservative in that regard. Many of the patients who end up receiving surgery at JHH already choose AAMC for their cardiac care. In CY 2013, JHH had 162 cardiac surgery cases involving

²⁶ AAMC Application at pp. 80-81.

²⁷ The context of the Cardiac Affiliation Agreement is outlined in the affidavits of Ms. Victoria Bayless (enclosed as Exhibit 25(a)). Mr. Ronald Peterson (enclosed as Exhibit 25(b)).

²⁸ Please see the enclosed Exhibit 26 for more information about Dr. Conte.

²⁹ See ¶ 2(A) of the Cardiac Affiliation Agreement.

³⁰ See ¶ 5 of the Cardiac Affiliation Agreement.

³¹ See AAMC Application at pp. 80-81.

patients in AAMC's proposed cardiac surgery service area.³² Those cases included 37 direct transfers from AAMC, or approximately 22% of the total.³³

Third, AAMC projected volume based on surveys of cardiologists in six local cardiology practices. The six practices represent a total of 26 cardiologists, 4 of whom hold clinical leadership positions at AAMC. Each of these cardiology practice groups has expressed support for a cardiac surgery program at AAMC, and clinicians in each practice have indicated their desire to use the new program at AAMC. Clinicians have acknowledged the benefits of a local service site, the continuity of care it will afford, and the added value of the JHM affiliation. Projecting cases from these six practices, AAMC can anticipate approximately 274 cases originating from these practices by FY 2017, rising to 319 cases by FY 2019.³⁴

BWMC's Comment does not accurately represent the number of cases AAMC documented with respect to local cardiologists.³⁵ Table 1 of that comment counts only those cases referenced by physician letters in the Exhibit 17(a) attached to AAMC's 3/30/15 response to completeness questions. But that Exhibit 17(a) mistakenly excluded two letters, one from Dr. Jennifer Brady and one from Dr. Elizabeth Reineck, both AAMC Cardiology Specialists physicians. The two letters were included with AAMC original application as pages 57 and 58 of Appendix 3(i).³⁶ Dr. Brady's letter documents 15 cases, and Dr. Reineck's letter documents 40-50 cases. These two letters account for the "gap" Table 1 purports to identify between the 105 cases AAMC documented from AAMC Cardiology Specialists physicians, and the 50 cases from

³² AAMC Application at p. 81.

³³ AAMC Application at p. 81.

³⁴ AAMC Completeness I at p. 15 – Chart 8(a).

³⁵ BWMC Comment at p. 7 – Table 1.

³⁶ Exhibit 17(a) included with AAMC's Completeness I as an excerpt of Appendix 3(i), for the convenience of the Commission staff.

such physicians referenced in letters included in Exhibit 17(a). Finally, the Cardiology Associates cases included in AAMC's Chart 8(a) - but excluded by BWMC's Table 1 - should be counted by the Commission for the reasons attested to by Dr. Segal in AAMC's response to Question 3 of AAMC's second round of completeness questions.³⁷

When projecting volume based on these representations from local cardiologists, AAMC adequately accounted for patient preference and acuity. (AAMC also accounted for the decline in cases called for by the Commission's overall volume projections; in contrast, BWMC failed to account for patient preference or use rate decline, at least for those cases originating with the UM Division of Cardiovascular Medicine).³⁸ AAMC did not estimate that it would perform cardiac surgery on all patients referred for such surgery by these cardiologists; rather, the cardiologists themselves estimated what proportion of such patients would actually receive referrals to AAMC for cardiac surgery. Some cardiologists estimated that all or nearly all of their patients requiring cardiac surgery would receive a referral to AAMC. But others – such as Dr. Juan M. Cordero and Dr. George Panas of Chestertown Cardiology – instead estimated that a majority or a significant number of such patients would receive a referral to AAMC. These cardiologists understand the typical acuity of their own cases and presumably have a sense of patient preference; the Commission should not layer another level of discount upon these estimates.³⁹ And an appropriate discount for preference and acuity is what the projection across practices reflects. In total, AAMC estimated that it would perform 67% of these cardiologists' cases in FY 2017 and 80% of such cases after FY 2017. Even if assuming that AAMC's share of these cardiologists'

³⁷ See AAMC's 5/6/15 Response to Second Set of Completeness Questions ("AAMC Completeness Response II") at pp. 5-6.

³⁸ See AAMC Completeness II at pp. 14-15 - Chart 8(b).

³⁹ See AAMC's Comment at p. 6 - n. 14.

approximately 400 cases would remain at 67% after FY 2017, AAMC could still expect to perform approximately 270 cases.⁴⁰

AAMC understands that surveys of cardiology practices regarding referral intentions are not ironclad guarantees of volume.⁴¹ But a patient's cardiologist has substantial say in where their referred patients will receive cardiac surgery, contrary to MedStar's Comment.⁴² As noted in Dr. Segal's affidavit⁴³ and in a recent article in *Hospitalist News* (enclosed as Exhibit 27), a patient's cardiologist typically chooses the surgeon who will receive the referral. For example, if a referring cardiologist selects a WHC surgeon, the referring cardiologist can be confident that the surgery will be performed at WHC and not UMMC. Here, Johns Hopkins's cardiac surgeons intend to perform cardiac surgery at AAMC for patients in AAMC's service area.⁴⁴ Finally, the leadership of Cardiology Associates has confirmed to Dr. Jerome Segal, the medical director of AAMC's Heart Institute, that Cardiology Associates physicians intend to refer patients to a high quality program at AAMC.⁴⁵ In any event, it should be stressed again that AAMC is not solely reliant on surveys of local cardiologists and cardiology practices.

Finally, AAMC projects volume based on reasonable market share assumptions. AAMC currently has a large share of Anne Arundel County's cardiology market,⁴⁶ even though AAMC's lack of a cardiac surgery program is a deterrent for some patients and physicians. This

⁴⁰ See AAMC Completeness II at pp. 14-15 - Chart 8(a).

⁴¹ See AAMC Completeness II at p. 5.

⁴² See MedStar Comment at p. 26.

⁴³ See ¶ 3(b) of Dr. Jerome Segal's affidavit (enclosed as Exhibit 23(a)).

⁴⁴ ¶ 1(E)(i) of the Cardiac Affiliation Agreement.

⁴⁵ See AAMC Completeness II at p. 4. Dr. Segal also attested to a statement in AAMC Completeness II (at p. 4) that Chart 8(a) "denotes the referral data AAMC collected from the six local cardiology practices" listed in that chart.

⁴⁶ AAMC Application at p. 139

is especially true for Eastern Shore residents, many of whom live an hour or more away from hospitals in Baltimore or Washington. Indeed, AAMC has a substantial market share in various surgical fields that region, despite BWMC's claims to the contrary.⁴⁷ Based on its decade-long relationship with Johns Hopkins, AAMC expects that relationship to increase AAMC's market share. And AAMC has reached a comparable share in other surgical fields with more competition and a greater number of providers. For example, AAMC has reached a 40% share and a 32% share respectively for joint replacement surgery and bariatric surgery – highly competitive surgical fields which are not subject to certificate of need.⁴⁸

Each of the four methods AAMC used to project volume is valid individually, as each is based on sound assumptions, data, and analysis. Together, they establish that AAMC will substantially exceed the 200 annual case threshold of the need and minimum volume standards of the SHP.

IV. Access

AAMC has established that cardiac surgery services at AAMC would address significant barriers to necessary cardiac care for its patients and its community.

A. Access for Patients at the Hospital

AAMC patients face barriers to receiving timely cardiac surgery care. AAMC has documented in this review five cases within the previous calendar year when AAMC patients required cardiac surgery or complex PCI with surgical back-up, but have been refused transfer or delayed transfer to existing cardiac surgery programs.⁴⁹ In response to MedStar's claim of

⁴⁷ See enclosed Exhibit 28.

⁴⁸ AAMC Application at p. 82.

⁴⁹ Four case studies were enclosed with AAMC's Application as Exhibit 7(i). Patient 1's case, discussed below, is a fifth case.

ignorance regarding any difficulties faced by AAMC patients in securing transfer to WHC, AAMC here offers a more detailed account of three of these cases, verified by the clinicians involved.

1. Patient 1

The affidavit of Julia Blackburn, the nurse director of AAMC's cardiac catheterization laboratory, documents the case of Patient 1.⁵⁰ That case involved a patient requiring urgent transfer to Washington Hospital Center. Although a WHC surgeon initially agreed to accept the patient, the WHC admissions office canceled the transfer until Ms. Blackburn protested that the transfer agreement between AAMC and WHC mandated that WHC accept the patient.⁵¹ Even then, the admissions office informed AAMC "that financial issues needed to be addressed prior to transfer."⁵² Ultimately, 94 minutes elapsed between the time the WHC surgeon was contacted for transfer and the time the MedStar Transport team arrived.⁵³

AAMC immediately identified this transfer problem to WHC. That same day, Ms. Blackburn reported the incident to Dr. Jonathan Altschuler, the medical director of AAMC's cardiac catheterization laboratory.⁵⁴ Dr. Altschuler then forwarded the report to Dr. Stuart F. Seides, who is the physician chief executive of MedStar Heart & Vascular Institute.⁵⁵ MedStar's statement that the AAMC Application was "the first time"⁵⁶ AAMC identified the problem

⁵⁰ Ms. Blackburn's affidavit is enclosed as Exhibit 23(e).

⁵¹ *Id* at ¶ 5.

⁵² *Id* at ¶ 5.

⁵³ *Id* at ¶ 6.

⁵⁴ *Id* at ¶ 8(a).

⁵⁵ *Id* at ¶ 8(b). The email chain is enclosed as Exhibit 23(f).

⁵⁶ MedStar Comment at p. 13.

transfer to MedStar is false, as confirmed by Ms. Blackburn's affidavit and the accompanying email chain between Dr. Seides, Dr. Altschuler, and Ms. Blackburn.

2. Patient 2

The affidavits of Ms. Blackburn and of Dr. Stafford Warren, the Vice Chair for the Commission's Cardiac Surgery Advisory Committee, document the case of Patient 2.⁵⁷ Following Patient 2's emergent catheterization, Dr. Warren contacted a WHC surgeon to arrange for the transfer of the patient to WHC. Shortly after the WHC surgeon accepted the patient, "WHC called to revoke acceptance of the transfer, citing the patient's insurance status."⁵⁸ AAMC immediately had to find another transfer option for the patient, and "ultimately two hours elapsed between [the WHC surgeon's] acceptance of the patient on behalf of WHC, and the time transport left [AAMC's] Cath Lab to transfer the patient to UMMC."⁵⁹

Finally, Patient 2's case shows the problem inherent in using MedStar Transport's records to determine whether transfer difficulties exist.⁶⁰ MedStar Transport would *of course* have no record associated with Patient 2 because *WHC refused the patient altogether*. Per the understanding of the director of AAMC's Heart Institute, "MedStar Transport is not even contacted until after the referring physician and the Receiving Physician have determined the appropriateness of a transfer and determined that a transfer may take place."⁶¹ Why would MedStar Transport have a record of a patient they were never asked to transport?

⁵⁷ Dr. Warren's affidavit is enclosed as Exhibit 23(b).

⁵⁸ ¶ 10(d) of Ms. Blackburn's affidavit (enclosed as Exhibit 23(e)).

⁵⁹ *Id* at ¶ 10(f).

⁶⁰ MedStar Comment at p. 13.

⁶¹ ¶ 4 of Dr. Jerome Segal's affidavit (enclosed as Exhibit 23(a)).

In any event, AAMC identified the transfer problem in this case to WHC as well. The day after the incident, Ms. Blackburn called and emailed an administrative manager at MedStar Heart & Vascular Institute.⁶² She explained that WHC had an obligation to accept the transfer of AAMC patients for cardiac surgery regardless of the patient's insurance status, specifically mentioning the transfer agreement between AAMC and WHC.⁶³ The manager's reply email thanks Ms. Blackburn for the information and states that the manager "will most definitely escalate this and find out how to proceed hopefully rectifying his moving forward so we are all on the same page. Will most certainly keep in touch."⁶⁴ Ms. Blackburn has not received any follow-up communication from the manager on this issue. Again, MedStar's statement that the AAMC Application was "the first time"⁶⁵ AAMC identified a transfer problem to MedStar is false, as confirmed by Ms. Blackburn's affidavit and the accompanying email chain.

3. *Patient 3*

In their affidavits, Dr. Salvatore Lauria and Dr. Jennifer Brady, both Anne Arundel Medical Group cardiologists, describe how an AAMC inpatient (Patient 3) waited two days for a transfer to Washington Hospital Center.⁶⁶ WHC initially refused the transfer on the grounds that "WHC lacked an intensive care unit (ICU) bed for the patient, and that WHC could not accept transfer of Patient 3 until an ICU bed became available."⁶⁷ WHC did not contact AAMC before

⁶² ¶ 11(a) of Ms. Blackburn's affidavit (enclosed as Exhibit 23(e)).

⁶³ *Id* at ¶ 11(a).

⁶⁴ The email chain is enclosed as Exhibit 23(g).

⁶⁵ MedStar Comment at p. 13.

⁶⁶ ¶¶ 4, 5 of Dr. Lauria's affidavit (enclosed as Exhibit 23(c)).

⁶⁷ *Id* at ¶ 4.

Patient 3's cardiologists were forced to request transfer on an emergent basis two days later.⁶⁸

MedStar is correct that the patient did not die en-route; in fact, the patient died after transfer.⁶⁹

These cases show why MedStar's insistence on "excess capacity" is misdirected.⁷⁰ When WHC denies a patient's transfer for insurance reasons, or a lack of bed space or ICU space, all the operating room capacity in the world will not give the patient access to cardiac surgery services at WHC.

In sum, "the lack of cardiac surgery services at AAMC is a significant barrier to timely access to cardiac surgery and high-risk PCI requiring cardiac surgical back-up."⁷¹

B. Geographic Proximity

Cardiac surgery patients in AAMC's proposed cardiac surgery service area must extensively travel to receive necessary pre-operative care and post-operative care, as well as surgical care. The Commission should consider geographic proximity relevant to access for the following reasons.

First, the State Health Plan has not shut the door on this issue entirely. It is true that the SHP's discussion of cardiac services issues and policies includes the following sentence: "Geographic access to cardiac surgery services and elective PCI is not a problem in Maryland, with respect to patient travel time or survival."⁷² But this general statement about cardiac surgery in Maryland as a whole does not preclude AAMC from "justify[ing] establishment of cardiac surgery services...based on inadequate access to cardiac surgery services in *a health planning*

⁶⁸ *Id* at ¶ 6.

⁶⁹ *See Id* at ¶ 8.

⁷⁰ *See, e.g.*, MedStar Comment at p. 2.

⁷¹ The final paragraphs of the affidavits of Drs. Brady, Segal, and Lauria all contain this statement. Dr. Warren's affidavit contains a similar affirmation in the final paragraph. Dr. Brady's affidavit is enclosed as Exhibit 23(d).

⁷² COMAR 10.24.17.03.

*region...*⁷³ Rather, the policy statement of the Commission simply shifts the burden on AAMC to “[d]emonstrate that access barriers exist...”⁷⁴ in a particular region, notwithstanding the lack of a geographic access problem generally in Maryland. A contrary interpretation would render the SHP’s access standard entirely superfluous or nugatory, in violation of the bedrock principles Maryland applies in interpreting statutes and regulations.⁷⁵

Second, AAMC’s case on travel times is essentially uncontested, though interested parties do attempt to downplay its importance. In CY 2013, the majority of cardiac surgery patients from AAMC’s proposed cardiac surgery service area travelled 35-95 minutes to receive their surgery from Baltimore City or Washington, D.C. hospitals.⁷⁶ Moreover, the elderly comprise a significantly higher percentage of the population in Anne Arundel County and the four Eastern Shore Counties than in Maryland generally: by CY 2019, the elderly will comprise 17.1% of Marylanders in this sub-region.⁷⁷

Third, AAMC has offered unrebutted evidence that patient travel distance for pre-operative care and post-operative care correlates with patient mortality. This is not a matter of “convenience for residents” of AAMC’s service area, contrary to LifeBridge’s Comment.⁷⁸ The article “Travel Distance and Health Outcomes for Scheduled Surgery” (the “**Chou Study**”)

⁷³ COMAR 10.24.17.05(A)(5)(a) (emphasis added).

⁷⁴ COMAR 10.24.17.05(A)(5)(a)(i).

⁷⁵ Maryland courts “construe statutes and rules as a whole so that no word, clause, sentence, or phrase is rendered surplusage, superfluous, meaningless, or nugatory.” *Black v. State*, 426 Md. 328, 338-39 (2012) (internal quotation omitted).

⁷⁶ AAMC Application at p. 138.

⁷⁷ AAMC Application at p. 133.

⁷⁸ LifeBridge Comment at p. 2.

shows that increasing a patient's travel distance for one-time, scheduled cardiac surgery – even by a few miles – can increase mortality by about 15%.⁷⁹

MedStar incorrectly interprets the Chou Study as finding this 15% increase of mortality for every additional 100 miles of travel,⁸⁰ when in fact the Chou Study found the 15% increase in mortality for patients traveling an average of only **15 miles** farther. Line 3 of Table 2 of the Chou Study shows that “near” patients (with lower mortality) were located 8.8 miles from the nearest graded hospital performing coronary artery bypass graft (CABG), while “far” patients (with higher mortality) were located 23.3 miles from the nearest graded CABG hospital. Although “near” patients and “far” patients had the same risk levels, the 15 miles difference in travel translates to a 15% change in the mortality rate.⁸¹

MedStar is correct that the Chou Study calls for more research on why travel distance affects health outcomes.⁸² But whatever the underlying explanation, the Chou Study shows that travel distance *does* affect outcomes: the study had an enormous scope of ten years and over 100,000 CABG patients, and found the effect even when exclusively focusing on *elective* surgery for residents of non-rural areas.⁸³

Finally, MedStar notes that the Chou Study's conclusion states that regionalization and quality improvement *may* be more important policy considerations than minimizing travel distance.⁸⁴ Note the context, however: the Chou Study focused on cases performed in a

⁷⁹ The Chou Study is an exhibit to the AAMC Application.

⁸⁰ MedStar Comment at p. 12.

⁸¹ Chou Study at p.253.

⁸² MedStar Comment at p. 12. Of course, one might ask whether any research paper in history has not called for more research.

⁸³ Chou Study at pp.251-252.

⁸⁴ MedStar Comment at p. 12.

jurisdiction that had abandoned certificate of need requirements, and that many of the hospitals evaluated by the Chou Study performed under 100 cardiac surgery cases per year.⁸⁵ AAMC has not asked the Commission to minimize travel distances at all costs, or to abolish the certificate of need process. Rather, AAMC has asked the Commission to take travel distances into account in evaluating AAMC's Application. MedStar and LifeBridge, on the other hand, want the Commission to ignore geographic proximity completely – a position the Commission cannot and should not adopt.

V. Financial Feasibility

A. AAMC's Revenue Estimates are Valid

AAMC can reasonably expect to retain 85% of the revenue generated by the AAMC's proposed program, even as an asymmetrical 50% revenue reduction is imposed for cases lost to AAMC.

First, the HSCRC has indicated that, for new services, it has the flexibility to provide targeted funding through the annual update process for individual hospital budgets.⁸⁶ The HSCRC has shown such flexibility in funding Holy Cross Germantown Hospital. That same flexibility is appropriate here. AAMC is similarly attempting to establish a new hospital service, not grow an existing one.⁸⁷ Additionally, the HSCRC has recognized the opportunity to appropriately fund new programs which have the potential to achieve significant healthcare savings.

⁸⁵ Chou Study at 252.

⁸⁶ Enclosed as Exhibit 29 is the HSCRC staff's May 2015 presentation entitled "Global Budget Revenue Contracts Market Shift Adjustments Draft Technical Report."

⁸⁷ Which distinguishes AAMC from PGRMC, contra BWMC Comment at p. 27, n. 9.

Second, the HSCRC has written a letter to AAMC expressing its intention to work with AAMC specifically to fund a new cardiac surgery program at AAMC.⁸⁸

Third, Maryland's Waiver Agreement with CMS anticipates that Maryland hospital costs per capita may rise in connection with the establishment of a new facility, allowing that the cap on Maryland hospital revenue may be adjusted as a result.⁸⁹

B. AAMC Reasonably Projects Staffing Costs

AAMC has set forth an effective staffing plan for its proposed cardiac surgery program, and has fully accounted for the cost of its plan. Contrary to MedStar's objections, AAMC's staffing plan is complete, and does not omit perfusionists, cardiac surgeons, or intensivists. AAMC's general staffing plan is set forth in its Application;⁹⁰ a more detailed breakdown is enclosed as Exhibit 31.

As AAMC explained in its Application,⁹¹ AAMC has contracted for the services of Hopkins' perfusionists and cardiac surgeons under the AAMC-JHH Cardiac Agreement. This contract saves AAMC from the cost and uncertainty of recruitment, and guarantees the availability of proven, skilled practitioners. AAMC's financial projections take the cost of these non-employee professionals into account via Line 2j of AAMC's Tables J and K (Revenues & Expenses, Inflated – New Facility or Service).⁹²

⁸⁸ The letter is enclosed as Exhibit 30.

⁸⁹ Page 9 of the All-Payer Model Agreement states: "Per capita cost increases may occur due to factors unrelated to the Model (e.g....the construction of the new hospital facility in Prince George's County). The State may submit in writing to CMS feedback on the impact of any such factors on the Model, including a suggestion on how to adjust the Model on the basis of such factors."

⁹⁰ See AAMC Application at p. 63 – Chart 3.

⁹¹ See AAMC Application at p. 63.

⁹² See AAMC Application at Appendix 1.

AAMC also has contracted for the services of anesthesiologists and intensivists through existing contracts with physicians groups. AAMC contracts with Anesthesia Company, LLC for anesthesia services. This large physician group practice provides anesthesia services in a variety of settings and disciplines at AAMC and in the local community. The group has committed, in contract, to supply anesthesiologists for future service lines at AAMC (such as cardiac services) without a subsidy. Payer mix and other local economic factors enable this group to rely on professional fees. This advantage allows AAMC to secure anesthesia services for the cardiac program without incremental increases in personnel cost. Similarly, AAMC's contract for intensivist services also calls for AAMC's intensivist group to supply additional intensivists to support future service lines. The costs of AAMC's anesthesiologist and intensivist contracts are accounted for through AAMC's Table H (Revenues & Expenses, Inflated – Entire Facility).⁹³

In summary, and contrary to MedStar's Comment,⁹⁴ AAMC has based its financial projections on a complete staffing plan. AAMC has secured perfusionists and surgeons through the AAMC-JHH Cardiac Agreement, and accounted for the cost. AAMC has similarly secured intensivists and anesthesiologists through favorable existing subcontracts, enabling AAMC to provide these services as new clinical programs are added.

VI. Cost Effectiveness

A. An AAMC Program Would Reduce Costs to Patients and Payers

AAMC's Application demonstrates that a cardiac surgery program at AAMC would generate significant cost savings for patients and payers. AAMC will generate a **\$7.75 million**

⁹³ See AAMC Application at Appendix 1.

⁹⁴ MedStar Comment at pp. 18-20.

annual reduction in spending, even though other Maryland hospitals will only lose 50% of the revenue associated with cardiac surgery cases lost to AAMC.⁹⁵

BWMC and interested parties have not dented AAMC's case. AAMC's superior cost per case mix adjusted discharge (CMAD), both compared to BWMC and to hospitals with cardiac surgery, is entirely legitimate and derives from AAMC's efficiency and commitment to cost-effectiveness. It is not derived from spreading overhead costs to overused rate-regulated outpatient services, contrary to BWMC's claims.⁹⁶ The ratio of inpatient to outpatient hospital revenue is irrelevant. For more than 15 years, the HSCRC has adjusted the relative charge per CMAD of Maryland hospitals to account for relevant differences between hospitals (such as payer mix and medical education costs). Medicare uses similar metrics to derive a hospital's "Standard Rate" under the Inpatient Prospective Payment System. Neither the HSCRC nor Medicare use the level of a hospital's outpatient services as a metric for adjustments, and to do so here would be inappropriate. Finally, AAMC's efficiency relative to BWMC is confirmed by a measure independent of the ratio of inpatient to outpatient revenue: overhead expense per licensed bed. BWMC has overhead costs per bed that are 12.5% above those of AAMC.⁹⁷

This legitimate cost savings to patients and payers will help Maryland satisfy the terms of the All-Payer Model Agreement (the "Medicare Waiver") by helping Maryland meet the Medicare Waiver Test, as AAMC has explained.⁹⁸ More recent data has confirmed that the Medicare Waiver Test will remain more difficult for Maryland to meet than the All-Payer Test. The HSCRC staff has estimated that through FY 2016 there is a \$635,200,000 difference

⁹⁵ AAMC Application at p. 174 – Chart 40.

⁹⁶ BWMC Comment at p. 31.

⁹⁷ See enclosed Exhibit 32.

⁹⁸ See AAMC Completeness I at pp. 32-37.

between the current experience and the maximum allowable under the All-Payer Test.⁹⁹ Therefore, the impact of AAMC's program on the All-Payer Test is irrelevant. On the other hand, the Medicare Waiver Test remains unpredictable, as the HSCRC cannot control Medicare expenditures on Maryland residents outside of Maryland, let alone nationwide Medicare expenditures.

Rather than engage AAMC on the *specifics* of this analysis, MedStar retreats into a meritless comparison between high-volume hospitals *in general* and low-volume hospitals *in general*. MedStar cites Auerbach, *et al.*, "Case Volume, Quality of Care, and Care Efficiency in Coronary Artery Bypass Surgery," for the proposition that "health care costs could be reduced by \$171 million annually if all patients who under CABG at low volume providers had instead chosen higher volume hospitals."¹⁰⁰ While that study found that savings would be achieved by directing patients from the lowest volume hospitals (112 cases per year on average) to higher volume hospitals, little savings would result from a shift of patients from the third highest or second highest volume hospitals to the highest volume hospitals (644 cases on average). In other words, at the volumes AAMC will achieve, the Auerbach study is irrelevant.

Indeed, MedStar's failure to compare WHC's cardiac surgery charges to AAMC's proposed charges suggests that AAMC is correct that a shift in volume from WHC to AAMC would generate substantial savings for patients and payers. MedStar attempts to obscure this conclusion by arguing that since two programs require more resources than one program, adding a program at AAMC will merely "duplicate existing services" when contrasted with more

⁹⁹ The HSCRC staff has estimated that the maximum growth rate of hospital revenues under the All Payer Test was 9.21% and that the actual growth rate was 5.24%. With aggregate annual hospital revenues of approximately \$16 billion, these projections imply that Maryland would be 3.97% (9.21 – 5.24%) below the All Payer Test caps, or \$635,200,000 in dollar terms ($\$635,200,000 = .0397 \times \$16,000,000,000$). An increase in Maryland hospital revenue of \$2.4 million per year over two years is simply irrelevant to Maryland's performance under this test.

¹⁰⁰ MedStar Comment at 15.

intensive utilization of existing providers¹⁰¹ On this logic, *a new competitor could never generate cost savings*. This is false: a new program can use resources more efficiently and pass along the savings. But what matters ultimately is the cost to the patients and payers who finance the health care delivery system. And AAMC has established that, as the lowest-charge program in the region, it will save those patients and payers millions of dollars.

B. An AAMC Program Would Not Drive Up Costs Elsewhere

Contrary to BWMC's Comment, the Commission should accept the 50% revenue retention permitted by the HSCRC as a fair rebalancing of revenue for hospitals that would lose volume to a new program at AAMC. AAMC has presented evidence that a 50% revenue reduction approximates the variable cost savings to hospitals, on balance.¹⁰² Moreover, the GBR system allows these hospitals to retain 100% of revenue for volume reductions caused by other factors, such as declining utilization rates (a significant windfall). In any event, the 50% revenue figure represents the HSCRC's considered judgment, which should be respected.

Moreover, BWMC's criticism contradicts the assumptions that underpin its own application. In its response to completeness questions, BWMC estimated variable costs as **55%** of total cardiac surgery costs for hospitals other than academic medical centers, and **49.5%** of total cardiac surgery costs for UMMC and JHH.¹⁰³ BWMC made these estimates based on UMMC experience and BWMC's projections regarding its own program. AAMC estimates that the *incremental* variable costs of AAMC's own program may be relatively lower, due in part to favorable contracts for professional clinical services (as explained above). Ultimately, what

¹⁰¹ MedStar Comment at 14.

¹⁰² A report by the Medicare Payment Advisory Commission – AAMC Exhibit 18(e) – estimates that less than 50% of hospital costs are truly fixed.

¹⁰³ BWMC Completeness I at p. 11 (Table 21, note 3).

BWMC has actually shown is (a) that each hospital's ratio of fixed and variable costs will turn on factors unique to that hospital, (b) that 50/50 is a fair estimate of that ratio for the average hospital, and (c) that the Commission has no alternative but to accept that 50/50 assumption in the absence of detailed financial data on the impacted hospitals.

Finally, BWMC's criticism that "hospital experience has proven the difficulty of controlling expenses during periods of declining volume"¹⁰⁴ is highly hypocritical. In its modified application, BWMC imposes a greater reduction of revenue upon UMMC – over **\$5,000,000 per year** every year starting FY 2017 – than AAMC will impose on any single Maryland hospital.¹⁰⁵ Yet BWMC anticipates that UMMC's operating margin will only decline by \$300,000-\$400,000 in those years.¹⁰⁶

BWMC's attempt to downplay AAMC's superiority on costs and charges simply fails and should be rejected.

VII. Impact on Prince George's Hospital Center (PGHC)

A. AAMC Met the Impact Standard

AAMC used a valid methodology to estimate the volume loss and associated financial impact upon other hospitals entailed by AAMC's proposed cardiac surgery program. AAMC assumed that AAMC would shift the same proportion of its cases from other hospitals as are currently transferred from AAMC to those hospitals.¹⁰⁷ This assumption is sensible because it reflects the preferences of those patients and physicians whom AAMC will seek to serve as

¹⁰⁴ BWMC Comment at p. 19.

¹⁰⁵ BWMC Modified Application, Table 30.

¹⁰⁶ *Id.*

¹⁰⁷ *See* AAMC Application at 91.

AAMC's cardiac surgery program grows.¹⁰⁸ For example, if, in the absence of a cardiac surgery program at AAMC, a physician currently transfers half her patients from AAMC to Washington Hospital Center, it makes sense to assume that she would continue to do so in the absence of an AAMC program.

AAMC then applied the transfer ratio described above, as adjusted for its relationship with Hopkins,¹⁰⁹ to the aggregate number of cases performed by each hospital in CY 2013. The volume shift projection in Chart 11 of AAMC's Application reflects the final analysis of the impact of an AAMC cardiac surgery program on each hospital's volume.¹¹⁰

The above steps showed no impact to PGHC from the AAMC program. Since no AAMC inpatient or cardiac outpatient is transferred to PGHC from AAMC, and since PGHC only performed five cardiac surgery cases in CY 2013, AAMC assumed that PGHC would lose no cases from AAMC retaining such patients.¹¹¹

B. AAMC's Impact Analysis was Legitimate

AAMC's impact analysis followed the requirements of the State Health Plan, despite Dimensions' assertions to the contrary.

First, the use of CY 2013 data follows the utilization projection methodology set forth in the SHP. That methodology uses as its base year "the most recent calendar year for which data is

¹⁰⁸ BWMC, in contrast, simply assumes that other hospitals will lose cases to BWMC in proportion to such hospitals' existing market share.

¹⁰⁹ AAMC specially accounted for AAMC's collaborative relationship with Johns Hopkins Hospital and Johns Hopkins Medicine cardiologists. See the discussion of volume (above) as well as AAMC Application at p. 91.

¹¹⁰ AAMC Application at p. 92.

¹¹¹ The AAMC Application stated that its analysis "did not address the impact of a new program on Prince George's Hospital Center, which has served fewer than 20 cases per year in CY 2012 and CY 2013." In context, AAMC meant that the analysis it did perform did not show impact upon PGHC; AAMC did not mean to suggest that it had not considered whether PGHC would be impacted. In fact, Chart 11 of AAMC's Application (p. 92), which lists the hospitals from which AAMC expects to shift cases, listed PGHC with an expected case shift of zero. Similarly, Chart 19 of AAMC's Application (p. 139) set forth PGHC's market share in the segment of Prince George's County encompassed in AAMC's service area.

available from both the Commission's uniform hospital discharge abstract data set and the District of Columbia discharge abstract data set."¹¹² CY 2013 was the base year the Commission used in its February 2015 projection under this methodology – the projection issued in the same month AAMC and BWMC filed their applications. The use of CY 2013 data is not illegitimate simply because it reflects unfavorably upon PGHC, which only performed five cases in CY 2013.

Second, the SHP's impact standard calls on AAMC to analyze its impact on other cardiac surgery programs *as they currently exist*, not against the (heavily redacted) business plans of those programs. AAMC must demonstrate that its program would not "[r]esult in an existing cardiac surgery program *with an annual volume of 200 or more* cardiac surgery cases...*dropping* below an annual volume of 200 cardiac surgery cases" if the program has "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..."¹¹³ Similarly, AAMC must demonstrate that its program would not "[r]esult in an existing cardiac surgery program *with an annual volume of 100 to 199 cardiac surgery cases or more...dropping* below an annual volume of 100 cardiac surgery cases" if the program has "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..."¹¹⁴ These standards plainly protect programs with *current* volume from *dropping* below a certain threshold. They do not protect programs with *projected* volume from *failing to rise* above the

¹¹² COMAR 10.24.17.08(A)(1).

¹¹³ COMAR 10.24.17.05(A)(2)(b)(ii) (emphasis added).

¹¹⁴ COMAR 10.24.17.05(A)(2)(b)(iii) (emphasis added).

volume thresholds.¹¹⁵ In that regard, Dimensions admits that PGHC’s program: (1) “does not currently have over 200 cardiac surgery cases per year...”¹¹⁶; (2) does not project reaching the 200 case minimum volume threshold until **FY 2022**¹¹⁷; and (3) has not received an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles.¹¹⁸

In contrast, it is not legitimate to require AAMC to compare the impact of its own proposed program against theoretical volume at other programs.

For these reasons, AAMC’s initial impact analysis was legitimate under (a) and (b)(i) of the SHP’s impact standard, and PGHC’s program simply does not qualify for protection under sections (b)(ii) and (b)(iii) of that standard.¹¹⁹

C. AAMC Would Not Compromise PGHC’s Volumes

AAMC’s proposed program would not prevent PGHC from reaching 200 cases, even if the Commission were, contrary to the SHP, to use Dimensions’ projections of volume as the benchmark for analyzing AAMC’s impact. AAMC’s proposed program would take few enough cases from Prince George’s County that PGHC could reach 200 cases on County volume alone, while still leaving cases for other hospitals which currently draw cases from the County.

¹¹⁵ The SHP protects new programs seeking to grow in another way. “A new cardiac surgery program will only be considered in a health planning region if the most recently approved program in the health planning region has been in operating for at least three years.” COMAR 10.24.17.04(A)(1)(d). PGHC had a cardiac surgery program long before 2012. PGHC has had decades to grow its program.

¹¹⁶ Dimensions’ Comment at 18.

¹¹⁷ Dimensions’ Comment at 18.

¹¹⁸ Dimensions’ Comment at 15.

¹¹⁹ Similarly, a cardiac surgery program at AAMC would not cause Suburban Hospital’s program to decline below the 200 case threshold, contrary to LifeBridge’s Comment (at pp. 3-4). At Suburban’s current market share levels, and in light of the Commission’s use rate projections for CY 2018, Suburban will fall to under 190 cases per year by CY 2018 even in the absence of a cardiac surgery program at AAMC. See AAMC Application at p. 156 – Charts 30 and 31. LifeBridge itself all but admits that declining use rates, by themselves, will cause a decline in cases See LifeBridge Comment at p. 4.

AAMC only expects to take 14% of the cardiac surgery cases originating from Prince George's County in CY 2019.¹²⁰ Although AAMC has projected an overall market share of 40% across its entire cardiac surgery service area, the bulk of AAMC's cases will come from its primary service area in Anne Arundel County. That is, AAMC anticipates a 40-50% projected market share in Anne Arundel County, but only a 25-35% share in the small segment of Prince George's County that is part of AAMC's service area.¹²¹ Since AAMC's projected cardiac surgery service area does not extend to Prince George's County in general, only about 14% of the entire County's total volume would be absorbed by AAMC.

D. AAMC Would Not Compromise the Financial Feasibility of PGHC's Program

Dimensions cannot show that any impact of AAMC upon the PGHC program would threaten the viability of Dimensions' program.¹²² PGHC has already shown that its program can survive through periods of lower than expected volumes. PGHC has maintained its cardiac surgery program through two recent calendar years in which 20 or fewer cases were performed at the hospital. And PGHC does not appear to anticipate reaching 200 or more cases on an annualized basis until FY 2022. Most importantly, Dimensions has not produced any financial information to controvert AAMC's Application other than the statement that PGHC needs to "offset \$4.8M of program fixed costs...."¹²³ Dimensions' bare assertion that "AAMC's proposed

¹²⁰ See enclosed Exhibit 33 for a graphical representation. AAMC projected Prince George's County cardiac surgery volume in the target year (CY 2019) by applying the SHP's use rate decline against the CY 2013 base year. Under the Commission's utilization projections, total adult cardiac surgery cases in CY 2019 are expected to be 355.

¹²¹ See AAMC Application at p. 139 – Chart 17 (comparing AAMC's share of cardiology services and transfers in primary service area vs. secondary service area).

¹²² AAMC must demonstrate only that its program would not "[c]ompromise the financial viability of cardiac surgery services at an affected hospital." COMAR 10.24.17.05(A)(2)(b)(i). AAMC need not show that other programs would be held harmless financially by the approval of a program at AAMC.

¹²³ Dimensions' Comment at p. 14

program would compromise the financial viability of PGHC's cardiac surgery program"¹²⁴ should not be credited.

E. Public Policy

It would be bad public policy to allow a theoretical impact on PGHC to prevent the creation of a needed cardiac surgery program in Anne Arundel County.

First, PGHC ranks as one of the most expensive hospitals in the State of Maryland on a charge per case basis. In contrast, AAMC's charge per case for cardiac surgery is projected to be one the lowest in the State of Maryland. With pressure to reduce Medicare cost per capita, the State should be focused intensely on concentrating volume at lower-cost hospitals. This imperative is current and real, and AAMC's program will lower health spending as it shifts volume to its lower cost hospital. This fact should bear far more weight than a theoretical threat to PGHC's future volumes.

Second, Dimensions and UMMS have still not explained how the programs at PGHC and BWMC will co-exist, let alone how the proposed program at PGRMC and BWMC will co-exist. As noted above, Dimensions' Comment affirms that PGHC's cardiac surgery program will continue to rely on UM Division of Cardiac Surgery physicians. Until an explanation is offered, the Commission should not assume that the programs at UMMC, BWMC, and PGHC would be impenetrable to each other based on the geographic location of the patient. Patient preference and physician referral decisions do not always neatly follow jurisdictional boundaries. The Commission should instead require Dimensions and UMMS to explain how the three programs would interact.

¹²⁴ Dimensions' Comment at p. 14

Third, it would be bad public policy to deny a needed program to hundreds of thousands of Anne Arundel County and Eastern Shore residents to protect the theoretical volume of a program that performed as few as five cases in a recent calendar year. PGHC had a cardiac surgery program long before 2012. PGHC has had decades to grow its program. PGHC should not stand in the way of a program at AAMC.

VIII. Quality

A. Quality and Volume

The Commission should reject MedStar's attempt to overrule the determination of the Commission's Clinical Advisory Group on Cardiac Surgery and PCI Services that "regulation of cardiac surgery services should place greater emphasis on quality rather than volume."¹²⁵ The Commission has cemented this determination into the SHP not only in that policy statement but also in the need and minimum volume standards, as explained above. These twin SHP standards reflect the fact that a program that can generate at least 200 cardiac surgery cases a year is a quality program, and AAMC expects to be performing well above that number – i.e., 387 cases a year – by FY 2019. Notwithstanding the clarity of the SHP, MedStar argues that AAMC's application should be denied because high-volume hospitals provide better quality of care than low-volume hospitals and, if additional need for cardiac surgery exists, that need should be handled by existing high-volume hospitals.¹²⁶

MedStar's "volume as surrogate for quality" theory has been widely debunked in the more recent and more statistically robust studies of the sort relied upon by the Commission's Clinical Advisory Group.

¹²⁵ COMAR 10.24.17.05A(3)

¹²⁶ MedStar Comment at 15-16.

For example, a study by Dr. Welke and his colleagues found little connection between volume alone and mortality. The authors conducted a retrospective cohort analysis of 948,093 Medicare patients undergoing CABG in 870 hospitals nationwide from 1996 to 2001 and categorized the hospitals into quintiles based on CABG volume.¹²⁷ They also classified the hospitals by the volume criterion proposed by the Leapfrog Group and used logistic regression to adjust hospital mortality rates for patient characteristics. The range in risk-adjusted mortality rates for hospitals within the quintiles was substantial: 1% to 17% at very low-volume hospitals (<125 cases annually), 2% to 12% at low-volume hospitals (125 to 204 cases), 2% to 10% at medium-volume hospitals (205 to 299 cases), 2% to 9% at high-volume hospitals (300 to 449 cases), and 3% to 11% at very high-volume hospitals (>449 cases). Moreover, volume alone was a poor discriminator of mortality (*c* statistic = .52). Similar variation in adjusted mortality rates was seen within the Leapfrog categories: 1% to 17% at low-volume hospitals (<256 cases) and 2% to 11% in high-volume hospitals (>256 cases), and the Leapfrog criterion was a poor discriminator of mortality (*c* statistic = .51). Of the 660 low-volume Leapfrog hospitals, 253 (or 38%) had risk-adjusted mortality rates that were similar to or lower than the overall risk-adjusted mortality of the high-volume hospitals (5.2%). The authors concluded that volume alone as a discriminator of mortality is only slightly better than a coin flip (*c* statistic = .50).

More recently, Dr. Shahian and his colleagues reached a similar conclusion. Their study examined 144,526 CABG patients from 733 hospitals nationwide.¹²⁸ Of the 733 hospitals, 87.4% performed fewer than 450 CABG procedures annually, meaning only 12.6% performed more

¹²⁷ Welke, et al., "Limitations of Hospital Volume as a Measure of Quality of Care for Coronary Artery Bypass Graft Surgery," *Annals of Thoracic Surgery* 80.6 (2005):2114-9.

¹²⁸ Shahian, David M., et al., "Association of hospital coronary artery bypass volume with processes of care, mortality, morbidity, and the Society of Thoracic Surgeons composite quality score," *Journal of Thoracic and Cardiovascular Surgery*, 139:2 (2010):273-82.

than 450 cases a year. The difference in the mortality rate between the lowest volume group (<100 cases a year) and the highest volume group (>450 cases a year) was only .9%. There was little to no difference in the STS-composite score for the group performing 300-499 cases a year and the group performing more than 450 cases a year. Given the wide residual variability in outcomes at all hospital volumes, the authors concluded that volume alone is a poor predictor of an individual hospital's true risk-adjusted mortality rate.

A study published by Dr. Kurlansky and his colleagues in 2012 found community hospital programs with meaningful university affiliations – the exact sort of program AAMC wishes to establish – demonstrated stronger program quality.¹²⁹ The authors looked at 2218 consecutive patients undergoing CABG in five cardiac surgery programs affiliated with the Columbia University HeartSource program from 2007 to 2009. The endpoints included operative mortality, major morbidity, and National Quality Forum-endorsed process measures as defined by the Society of Thoracic Surgeons. They found that, when comparing low volume centers (< 200 cases a year) and high-volume centers (> 200 cases a year), there was no difference in the mortality, morbidity, or any of the medication process measures. After adjusting for both the Society of Thoracic Surgeons risk score and the propensity score, no association was found for either hospital or surgeon volume with mortality or morbidity. However, a lack of compliance with National Quality Forum measures was highly predictive of morbidity, regardless of volume, even after adjustment for predicted risk. The study suggests that meaningful university affiliation might represent a new quality paradigm for cardiac surgery in the community hospital setting. Through its affiliation with Johns Hopkins, this is precisely what AAMC hopes to accomplish here.

¹²⁹ Kurlansky, Paul A., *et al.*, "Quality, not volume, determines outcome of coronary artery bypass surgery in a university-based community hospital network," *Journal of Thoracic and Cardiovascular Surgery* 143.2 (2012): 287-92.

B. Quality Improvement

AAMC has adequately documented its quality improvement processes as a hospital. In response to COMAR 10.20.10.04(A)(3)(b), AAMC described its **excellent** performance under CMS' Hospital Compare metrics, and identified its action plan for the sole unfavorable metric in Hospital Compare (relating to emergency department turnaround times).¹³⁰

BWMC's criticizes AAMC for using Hospital Compare rather than the Maryland Performance Evaluation Guide¹³¹, although BWMC has acknowledged that the new version of the Guide does not make relative quartile performance of Maryland hospitals "readily apparent."¹³² Nevertheless, AAMC has a quality plan that accounts for the Maryland Performance Evaluation Guide measures for which AAMC falls in the bottom quartile.¹³³ The quality plan is enclosed as Exhibit 34.

Also, the Guide relies heavily on the Hospital Compare data itself.¹³⁴ The Guide simply presents that data at a substantial lag time. AAMC's Application used Hospital Compare data updated through January 2014, while BWMC's Application used a version of the Guide that referenced data from the period between October 1, 2012 and September 30, 2013.¹³⁵ AAMC

¹³⁰ AAMC Application at p. 36.

¹³¹ BWMC Comment at p. 32.

¹³² BWMC Application at p.42.

¹³³ Note that AAMC ranks in the bottom quartile in only six metrics used by the Guide, while BWMC ranks in the bottom quartile on 18 metrics.

¹³⁴ Per the Guide website, quality measures are not independently analysed, but are derived from AHRQ Quality Indicators, CMS Hospital Compare ratings, and HCAHPS patient experience ratings. See: <https://www.marylandqmdc.org/MarylandHospitalCompare/index.html#/resources/Methods> (last accessed 8/24/15).

¹³⁵ Compare AAMC Application at p. 36 with BWMC Application at p.42.

presented the timeliest data to the Commission. Moreover, AAMC continues to outperform its Maryland peers on HCAHPS metrics, metrics which are also referenced in the Guide.¹³⁶

Finally, the Commission staff was apparently satisfied with AAMC's response, as staff did not ask a completeness questions related to this standard.

IX. Conclusion

In this comparative review, the Commission should approve the certificate of need application of Anne Arundel Medical Center, Inc. to add cardiac surgery services.¹³⁷

Respectfully submitted,



Dated: August 25, 2015

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¹³⁶ See enclosed Exhibit 35.

¹³⁷ Attestations for this response are enclosed as Exhibit 36.

Anne Arundel Medical Center
Response to Interested Party Comments

List of Exhibits

1. Exhibit 22 SHP Cardiac Surgery and Therapeutic Catheterization
2. Exhibit 23(a) Affidavit of Jerome Segal, M.D.
3. Exhibit 23(b) Affidavit of Stafford Warren, M.D.
4. Exhibit 23(c) Affidavit of Salvatore S. Lauria, M.D.
5. Exhibit 23(d) Affidavit of Jennifer Brady, M.D.
6. Exhibit 23(e) Affidavit of Julia Blackburn, R.N.
7. Exhibit 23(f) Email Timeline of Events
8. Exhibit 23(g) Email Patient Transfer
9. Exhibit 24 AAMC JH Licensing and Program Agreement
10. Exhibit 25(a) Affidavit of Victoria Bayless
11. Exhibit 25(b) Affidavit of Ronald Peterson
12. Exhibit 26 Biography of Dr. John Conte
13. Exhibit 27 Article of Heart Terms
14. Exhibit 28 AAMC Eastern Shore Market Share
15. Exhibit 29 HSCRC Draft Technical Report
16. Exhibit 30 HSCRC Letter to AAMC
17. Exhibit 31 AAMC Staffing Breakdown
18. Exhibit 32 Costs Per Licensed Bed
19. Exhibit 33 AAMC Market Share for Prince George's County
20. Exhibit 34 AAMC Quality Action Plan
21. Exhibit 35 HCAHPS Data Analysis Report to Maryland Hospital Association
22. Exhibit 36 Attestations