

IN THE MATTER REGARDING
ANNE ARUNDEL MEDICAL CENTER

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BEFORE THE

MARYLAND HEALTH

CARE COMMISSION

Docket No. 15-02-2360

IN THE MATTER REGARDING
UNIVERSITY OF MARYLAND
BALTIMORE-WASHINGTON MEDICAL
CENTER

Docket No. 15-02-2361

**MEDSTAR HEALTH, INC.’S EXCEPTIONS TO THE REVIEWER’S
RECOMMENDED DECISION**

On behalf of MedStar Health, Inc., (“MedStar”), an interested party in this matter, we respectfully submit to the Maryland Health Care Commission (the “Commission”) the following exceptions (“Exceptions”) to the Reviewer’s Recommended Decision to approve of the cardiac surgery service proposal from Anne Arundel Medical Center (“AAMC” or “Applicant”).¹

I. SUMMARY OF ARGUMENT

MedStar submits that the Recommended Decision fails to meet the requirements for adoption by the Commission. First and foremost, the Recommended Decision overlooks the essential question of whether there is “unmet need” under COMAR 10.24.01.08G(3)(b) as a prerequisite to approving a new health care service. The general review criterion at COMAR 10.24.01.08G(3)(b) stands alone to require that the Applicant perform a “need analysis” that identifies an unmet public need. Furthermore, the Recommended Decision erroneously relies solely on the Applicant’s ability to meet the minimum volume standard as a proxy for determining that a need exists for a new cardiac surgery program in Maryland.

¹ Hereafter, the term “Applicants” shall refer to both AAMC and Baltimore Washington Medical Center (“BWMC”).

Next, in determining whether the Applicants met the minimum volume thresholds and analysis stated in COMAR 10.24.17.05A of the State Health Plan (“SHP”), the Recommended Decision improperly uses data not previously published in the Maryland Register – data not made available to the Applicants, to the interested parties, or to the public. Use of these data would exceed the scope of the Commission’s authority.

Finally, the Recommended Decision erroneously discounts other factors that seriously call into question any decision to grant AAMC’s proposal, including: (1) the adverse impact that AAMC’s proposal would have on the recently approved relocation and construction of the Prince George’s Hospital Center (the “PGRMC proposal”) and how the PGRMC proposal itself would affect AAMC’s volume projections; (2) the cost efficiency of approving a new cardiac surgery program in light of the recent PGRMC proposal approval and the capacity of existing providers to address volume increases in cardiac surgery; and (3) the SHP’s explicit statement that there are no “geographic access” barriers to cardiac surgery services in Maryland.

The Recommended Decision reflects serious legal and factual deficiencies. For the reasons set forth in these Exceptions, the Commission should reject the Recommended Decision before it. Alternatively, the Commission should postpone any decision on the approval of any new cardiac surgery programs in the Baltimore Upper Shore Region, pending a reasonable review of the operating performance of Prince George’s Regional Medical Center (“PGRMC”) after it reopens at its new location.

II. THE RECOMMENDED DECISION DOES NOT, AND CANNOT, CONCLUDE THAT THERE IS AN UNMET PUBLIC NEED.

As stated in the Recommended Decision, the primary justification for establishing a new program in the Baltimore Upper Shore Region is the conclusion that AAMC has the highest

potential for generating a lower charge cardiac surgery program. Nothing in the Recommended Decision links approval of the AAMC proposal to actual unmet needs of the Baltimore Upper Shore planning region population for a new program, as required by COMAR 10.24.01.08G(3)(b). Lower perceived charges is not an appropriate substitute for addressing the needs of the population through the addition of a new program.

A. Neither the Cardiac State Health Plan Nor Either Applicant Identify an “Unmet Need” for Cardiac Surgery Services.

The general review criterion on “Need” in COMAR 10.24.01.08G(3)(b) apply in all CON reviews of proposed health care projects. Where no SHP need analysis is applicable, “[t]he Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.” *Id.* MedStar contends that when examining the Cardiac SHP at COMAR 10.24.17.05A, its language does not establish an applicable analysis that defines how the Applicants can demonstrate unmet need. Rather, the SHP at COMAR 10.24.17.05A(6) sets forth a “minimum volume” analysis for Applicants to use to demonstrate that they will be able to generate 200 open heart cases procedures by the second year of operation to satisfy of the “Minimum Volume Standard” at COMAR 10.24.17.05A(1). The Recommended Decision incorrectly concludes that this minimum volume analysis is a substitute for the unmet need demonstration required in the second sentence of COMAR 10.24.01.08G(3)(b).

Even if we assume that the Recommended Decision intended to substitute COMAR 10.24.17.05A(6), entitled “Need,” for the need analysis required by the first sentence of COMAR 10.24.01.08G(3)(b), the Recommended Decision erroneously concludes that such an analysis

supersedes the requirement in the second sentence of the same regulation.² Recommended Decision at 74 and 100-101. If it were “correctly” identified as the required need analysis, then it would supersede 3(b) and, using the Recommended Decision’s logic, any applicant that can project over 200 procedures by year two would merit approval. This conflation of “public need” and “minimum volume” disregards whether factors such as actual utilization, capacity at existing providers, access barriers, and referral trends would also support a new health care service’s approval. Because the SHP considers only minimum volume, it does not incorporate these other factors critical to a population-focused need analysis.

Therefore, despite being named “Need,” COMAR 10.24.17.05A(6) merely identifies how the Applicants can reasonably demonstrate that they are able to meet the Minimum Volume Standard. This section does not and cannot independently demonstrate “unmet needs of the population to be served” as required in COMAR 10.24.01.08G(3)(b) because the analysis only defines volume at the institutional level. As a result, the Recommended Decision fails its first and most crucial objective – to determine whether or not Maryland, and specifically the Baltimore Upper Shore planning region, actually needs additional cardiac surgery services. MedStar submits that there is no need for additional providers: existing service providers have capacity to take on additional volume and there are no significant access problems. The Applicants must fulfill the SHP’s other need criterion in COMAR 10.24.01.08G(3)(b) to establish unmet needs of the population.

² Had the Commission intended that COMAR 10.24.17.05A(6) serve as a substitute for the COMAR criterion on the unmet need of the population, it should have written the standard to reflect that intent, and allowed stakeholders to provide input through the public comment process before putting it into effect. This was not the case; therefore, we must conclude that this was not the intent.

B. The Recommended Decision Incorrectly Applies the “Need Analysis” Standard As Stated in the SHP By Relying Upon Unpublished Utilization Data to Justify Applicants’ Minimum Volume Projections.

The standard in the SHP titled “Need” requires an applicant’s minimum volume analysis “to account for the utilization trends in the most recent published utilization projections of open heart surgery cases in Regulation .10.”³ COMAR 10.24.17.05A(1)(d). Otherwise, the Applicant must “demonstrate why the methods and assumptions employed in the Regulation .10 utilization projections are not reasonable as a basis for forecasting case volume.” *Id.* The Recommended Decision improperly uses unpublished cardiac surgery case volume data to decide, without appropriate notice to the interested parties or the public, that “updating the demand forecast for a target year of 2021 would be based on an increasing use rate trend.” Recommended Decision at 11-12. Moreover, the Recommended Decision also ignores all the published data available that demonstrates, unequivocally, that existing providers have the ability to absorb additional cardiac surgery volume, and that there is no shortage of cardiac surgery services. Docket No. 34GF at 2-6; *see also* COMAR 10.24.17.05A(1)(d) and 2015 Notice. As stated by the Commission itself, “[t]hese updated utilization projections [in the 2015 Notice] will apply in the review of [CON] applications acted on by MHCC during the period during which these projections are in effect . . . and remain in effect until [the Commission] publishes updated projections.” 2015 Notice. The Recommended Decision’s reliance on data not published in the Maryland Register is impermissible under the regulations and violates due process. It is *ultra vires* for the Recommended Decision to incorporate the new data into the CON review record where the

³ Maryland Register, Vol. 42, Issue 3, (Feb. 6, 2015) (the “2015 Notice”).

Applicants, the interested parties, and the public have not had the opportunity to consider the data and respond thereto.

C. Even Where Consideration of the Currently Unpublished Data Would be Warranted, This Data Shows That the Current Supply of Cardiac Surgery Providers Can Accommodate Increasing Volume.

The Recommended Decision notes that “cardiac surgery case volume at Maryland hospitals increased strongly in the 1990s, a 74% increase between 1990 and the peak case volume year of 2000,” and thereafter, “[c]ase volumes declined approximately [30% between 2000 and 2011.]” *Id.* at 8 (emphasis added). As shown below in Table 1, current cardiac surgery volume in the Baltimore Upper Shore region is still less than 2009 levels.

TABLE 1: Cardiac Surgery Cases by Health Planning Region and Hospital, CY 2009–2015

Hospitals	Year						
	2009	2010	2011	2012	2013	2014	2015
Baltimore Upper Shore Region							
Johns Hopkins Hospital	969	946	969	1,026	1,142	1,182	1,262
St. Joseph Medical Center	717	534	339	285	296	448	454
Sinai Hospital	465	408	296	317	345	382	409
MedStar Union Memorial Hospital	953	677	688	575	585	636	626
University of Maryland Med. Center	733	714	817	851	923	984	1,000
Region Totals	3,837	3,279	3,109	3,054	3,291	3,632	3,751
Washington Metropolitan Region							
Prince George’s Hospital Center	27	44	15	18	8	29	105
Suburban Hospital	231	240	205	279	205	244	212
Washington Adventist Hospital	463	370	398	463	374	301	285
MedStar Washington Hospital Center	1,562	1,414	1,399	1,216	1,447	1,694	*
George Washington University Hospital	182	116	122	108	96	193	*
Howard University Hospital	7	10	18	20	16	19	*
Region Totals	2,465	2,184	2,139	2,084	2,130	2,461	*
Eastern Shore Region							
Peninsula Regional Medical Center	437	442	420	366	425	431	433
Western Maryland Region							
Western Maryland Regional Medical Center	250	250	224	215	169	170	174
State Totals							
(excludes D.C. located hospitals)	5,245	4,625	4,371	4,395	4,472	4,807	4,960

Source: 2015 Notice and Recommended Decision at 9, 11.

In the interim, the Commission approved: (1) the establishment of Suburban's low-volume cardiac surgery program in 2004, which has been unable to increase its volume above 250 cases per year since inception and (2) the transfer of a reemergent cardiac surgery program to a new PGRMC facility. The approval of yet another low-volume cardiac surgery program cannot be justified based on a small recent uptick in volume that merely backfills previously lost surgery counts in 2010-2011. Given the previous downward trend in adult cardiac surgery cases between 2008-2013, the current uptick through 2015 merely demonstrates that volumes are normalizing – there is no growth overall when reviewing cardiac surgery trends since 2009.

III. THE RECOMMENDED DECISION PREMISES THE APPROVAL OF AAMC'S PROPOSAL ON OTHER CONCLUSIONS THAT CONTRADICT THE COMMISSION'S STATED POLICIES IN THE STATE HEALTH PLAN.

The Recommended Decision improperly focuses the need for cardiac surgery services on the Applicants' minimum volume projections, while overlooking the factors related to: the potential impact that a new program would have on existing facilities; projected demand and the capacity of existing facilities to accommodate that future demand; and geographic access. The Recommended Decision neglects these factors when it arbitrarily and capriciously recommended approval of AAMC's proposal.

A. The Recommended Decision Improperly Ignores the Recent Certificate of Need Approval of Prince George's Regional Medical Center and the Negative Impact Both Programs Will Have on Each Facility's Cardiac Surgery Utilization.

The Recommended Decision ignores perhaps the most important single fact in this case – the Commission's recent grant of a CON for the new PGRMC on October 20, 2016. Of note, the Commission approved a \$543 million modified proposal for this project, of which \$400 million is directly state- and county-funded to relocate the Prince George's Hospital Center ("PGHC")

and its revived cardiac surgery program. A new competitor cardiac surgery program only half an hour away at AAMC would threaten even these low volume levels, likely crippling the PGRMC proposal and threatening its viability. Despite the Applicant's statements to the contrary, the success of PGRMC proposal, once complete, will rely on cardiac surgery patients from much of the same service area as AAMC – yet its existence was ignored in the Recommended Decision's failure to apply a full assessment of "need" and in assessing AAMC's market share and minimum utilization projections. This constitutes gross error and is arbitrary and capricious.

The Recommended Decision states instead that "AAMC cannot be faulted for not quantifying a case shift from PGHC to AAMC in its CON application, given that PGHC's case volume was so negligible during the time frame in which AAMC was preparing its application." Recommended Decision at 41. This directly ignores the negative impact the AAMC proposal will have on an important CON project recently approved by the full Commission and discredits the Commission's explicit decision to approve the PGRMC proposal based on its own merits. By dismissing the concerns related to PGRMC as merely "shelter[ing] existing providers from healthy competition," the Recommended Decision reflects a significant error in the assessment of "need" and the "impact on existing facilities" in this case. *Id.* at 118. To avoid (1) reversing its own endorsement of the PGRMC proposal; (2) to ensure that the state's investment is fully supported; and (3) not putting taxpayer funds at unnecessary risk, the Commission must delay the approval of any other cardiac surgery program until the PGRMC relocation project is complete and the cardiac surgery program is operational at the new location, as a matter of good public policy.

B. The Recommended Decision Ignores SHP Policy Statements That There Is No Lack of Geographic Access to Existing Cardiac Services in the State of Maryland.

The Recommended Decision categorically and independently found that the AAMC proposal will solve issues related to “travel distance and travel time or delays.” Recommended Decision at 68-69. In fact, the SHP states there is no “geographic access” problem in the state: “[g]eographic access to cardiac surgery services . . . is not a problem in Maryland, with respect to patient travel time or survival.” *Id.* at 11 (emphasis added); Docket No. 34GF at 2, 10-11, 21. Further, as the SHP states, “the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base.” *Id.* at 67; Docket No. #34GF at 14-15. Even the Recommended Decision acknowledges that “[w]hile many residents of Anne Arundel and the Eastern Shore counties in the Baltimore/Upper Shore region are required to travel longer to a hospital with cardiac surgery services than most residents of the health planning region, the consequences and costs for most of these cases are not sufficiently burdensome that they require preeminent consideration in a decision to approve this project.” Recommended Decision at 69 (emphasis added).

While both the SHP and the Recommended Decision properly conclude that there is no geographic access problem in Maryland, the Recommended Decision then disregards those conclusions when it states, “that travel distance and travel time can serve, in part, as a secondary justification for the proposed AAMC project.” *Id.* This conclusion should also be rejected, and the Commission should determine that AAMC’s proposal is inconsistent with the SHP standard at COMAR 10.24.17.05A(5) titled “Access.”

C. The Recommended Decision Makes Unreasonable Conclusions On Other Key SHP Standards, Such as Minimum Volume, Financial Feasibility, and Cost-Effectiveness.

The Recommended Decision reaches arbitrary conclusions concerning other key SHP standards, which result in an erroneous recommendation to approve AAMC's proposal, such as:

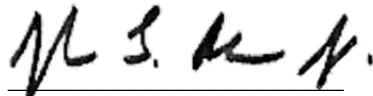
1. Concluding that AAMC will achieve a "best case scenario" market share projection of 25% by the second year of operation in order to allow AAMC to barely meet by the 200 procedure minimum volume threshold. Recommended Decision at 26-32. Without these inflated scenarios, the AAMC proposal would fail to meet the "Minimum Volume Standard" and the "Need" standard in the SHP. COMAR 10.24.17.05A(1) and (6).
2. Determining, without authority in the SHP, "that the Commission would not have adopted a [financial feasibility] standard that required a [cardiac surgery] program to generate revenue over expenses." Recommended Decision at 94. "Assessment at the program level . . . is a reasonable and conventional interpretation of the standard's requirements." *Id.* at 93. Therefore, instead of assuming the cost-controlling role of the Health Services Cost Review Commission, the Commission should find no compelling unmet need to approve a new cardiac surgery service at this time.
3. Assessing the cost-effectiveness of AAMC's program without fully evaluating the option of maintaining the status quo number of cardiac surgery programs. This ignores the requirement to "compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities" under COMAR 10.24.01.08G. Recommended Decision at 59-62. The Recommended Decision should have focused on whether Applicants will have lower charges than existing

providers for lower intensity cases, rather than on whether Applicants could best achieve minimum surgery volume as a sufficient measure for basic quality of cost-effectiveness.

IV. REQUESTED ACTIONS

The Commission ought not accept the Recommended Decision, which is inconsistent with law and the CON review processes provided by the COMAR CON regulations, exceeds the scope of the Commission's authority, and is arbitrary and capricious. Both CON applications submitted in this review cycle should be denied in the absence of additional need for cardiac surgery services. In the alternative, the Commission should postpone any further review of any cardiac surgery services until the PGRMC replacement hospital has been opened with an established track record of no less than two years for its cardiac surgery program.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of January 2017, a copy of MedStar Health, Inc.'s Exceptions to the Reviewer's Recommended Decision was sent via email and first-class mail to:

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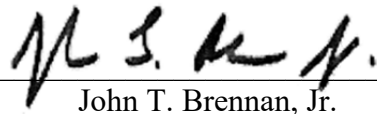
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