

October 21, 2013

Eileen Fleck
Chief, Acute Care Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215Re: Draft Regulations For Information Comment; State Health Plan for Facilities and Services:
Specialized Cardiovascular Services COMAR 10.24.17

Dear Ms. Fleck:

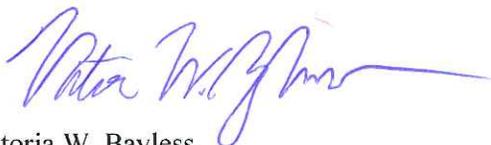
Attached are the comments of Anne Arundel Medical Center (“AAMC”) on the draft State Health Plan for Facilities and Services: Specialized Cardiovascular Services, COMAR 10.24.17 (the “Draft Chapter”).

At the outset, I would like to express our appreciation for the leadership and efforts of the Maryland Health Care Commission (“MHCC”) and its staff in convening and facilitating the deliberations of the Clinical Advisory Group (CAG) under the legislation enacted in the 2012 legislative session (Chapter 418). We also appreciate the MHCC’s efforts since the CAG completed its work to update and revise the existing State Health Plan chapter on cardiac surgery and PCI services. AAMC believes that the existing chapter is ill-suited to be the framework for cardiac surgery and PCI services in this transformational time of health care reform and emphasis on patient-centered care and access and provider accountability for cost efficiency and enhanced quality outcomes.

While the Draft Chapter contains certain improvements over the existing Chapter, for the reasons set forth in the attached comments, AAMC believes that the Draft Chapter also falls short of being such a framework. The Draft Chapter purports to open the door to consideration of new cardiac surgery programs, but it imposes what amounts to a moratorium on applying for a new program for an indefinite, potentially years-long period. Further, when applications for a new program are accepted, the Draft Chapter imposes review standards regarding impact on existing programs that are unjustified, unreasonable and unworkable, and which far exceed the standards to which applicants under the current Chapter have been subject and applicants for other projects are subject. It also imposes a minimum volume requirement on new cardiac surgery programs that is inconsistent with the CAG’s recommendations. In short, the Draft Chapter adopts review standards that far exceed what is necessary and appropriate to preserving the viability and quality of existing programs and fails to provide a meaningful opportunity for the consideration of new cardiac surgery programs in the State.

Thank you for your consideration of our comments.

Very truly yours,

Victoria W. Bayless
President & Chief Executive Officer

Enclosure

**COMMENTS OF ANNE ARUNDEL MEDICAL CENTER
ON DRAFT REGULATIONS FOR INFORMAL COMMENT – STATE HEALTH PLAN
FOR SPECIALIZED CARDIOVASCULAR SERVICES (COMAR 10.24.17)**

The following are the comments of Anne Arundel Medical Center (“AAMC”) on the draft State Health Plan for Facilities and Services: Specialized Cardiovascular Services, COMAR 10.24.17 (the “Draft Chapter”).

Issues and Policies (.03)

Like the existing State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17) (the “Existing Chapter”), the Draft Chapter recognizes a policy that cardiac surgery should be financially and geographically accessible, consistent with efficiently meeting the health care needs of patients. Unlike the Existing Chapter, however, the Draft Chapter contains no acknowledgment or discussion of equity of access and the issues created by geographic access being achieved by requiring Maryland residents travel out of state for cardiac surgery. Maryland lacks any regulatory authority over cost, quality, or any other matter at out of State programs. The CAG explicitly recognized this fact, which led it to recommend restricting the impact standard applicable to a new program to other cardiac surgery providers in Maryland. The CAG report states (at 10):

In evaluating the potential impact of a new cardiac surgery or PCI program on existing providers, the CAG recommends that only the impact on Maryland providers be considered. In part, the rationale for this recommendation is that hospitals in the District of Columbia and surrounding states are not subject to the same quality parameters that the CAG recommended for Maryland hospitals. Hospitals in the District of Columbia and surrounding states are also not subject to other Maryland regulations and cannot be controlled in any way the MHCC.

At a minimum, the Draft Chapter should recognize that equity of access and quality of service cannot be assured when Marylanders must travel out of state for service. AAMC believes that the MHCC should also proactively address this inequity by recognizing a policy seeking to maximize the availability and utilization of in-state cardiac surgery programs through the certificate of need process. Doing so will better position Maryland to live within the parameters of the new waiver proposal, under which the Maryland system will be accountable for cost and quality of cardiac surgery provided at hospitals outside of the State.

Additionally, the Draft Chapter contains a policy (Policy 4) that cardiac surgery and PCI services will be financially and geographically accessible, but the discussion of access (pp. 9-10) is limited to PCI services. The Draft Chapter should also include a discussion of the importance of geographic accessibility to cardiac surgery services. This discussion should recognize access not just in terms of travel time, but also proximity to home and family. These are themes of the Rural Area Health Delivery and Planning Workgroup (“Rural Workgroup”) looking at issues of

access in rural areas. These considerations are particularly relevant to the indigent. The Draft Chapter provides a preference for an established record of outreach to the indigent.

Health Planning Regions (.03)

The Draft Chapter retains cardiac surgery as a regionalized service and the concept of health planning regions (HPRs) for this service. At the same time, however, it would impose review standards that blur the distinction between HPRs altogether. As will be discussed further below, the review standards in the Draft Chapter would impose new and unprecedented burdens on an applicant to address impact and utilization not only in the HPR in which the new program would be located, but in adjacent HPRs as well. This is particularly unreasonable for the new Baltimore Upper Shore HPR as proposed in the Draft Chapter, which is adjacent to the other three HPRs, such that the applicant would be required to address impact and utilization across the entire State of Maryland. That the division between HPRs has so little meaning or effect in the context of the review standards calls into question why they are being retained at all.

The Draft Chapter would significantly expand the current Metropolitan Baltimore Region to include five Upper Shore counties (to be known as the Baltimore Upper Shore region). While the Draft Chapter states that regions are configured based on utilization patterns, geographic proximity, capacity and the volume of cardiac surgeries for the population, no information is provided as to the basis for the change. AAMC does not take issue with including these additional counties with Anne Arundel based on these and other factors, but AAMC does have concerns with the resulting size of the HPR, as well as whether it continues to be appropriate to attach Anne Arundel County and these Upper Shore counties to the Baltimore region to create a mega, far-flung-HPR. Notably, in the CAG process, Dr. Aversano specifically expressed concerns that the existing HPRs are “very large.” With the exception of the organ transplant chapter (under which there are only two regions to correspond to the OPO designations), the geographic reach of the Baltimore Upper Shore HPR significantly exceeds any other regional service area that the MHCC has recognized to date.

The same factors that led to putting the Upper Shore counties together in the same region as Anne Arundel County (utilization patterns, geographic proximity, capacity and volume) would support the creation of a fifth HPR combining these counties and Anne Arundel County. Doing so would ensure that the HPRs are an appropriate size and that disparate jurisdictions with no common utilization patterns are not in the same HPR. It would also be consistent with the principles of regionalization, in particular, the principle that specialized services should be located in areas possessing a large concentration of population. Anne Arundel County’s population is in excess of 500,000, the largest county by far without a cardiac surgery program located within its borders. Creating this new HPR would also promote geographic access within rural areas, consistent with the goals of the Rural Workgroup.

Finally, AAMC questions the retention of the District of Columbia in Maryland’s health planning regions given the recommendations of the CAG discussed above. Maryland lacks any regulatory control over out-of-State hospitals, including in particular cost and quality. The fact that Maryland residents travel to the District of Columbia for cardiac surgery is not a reason to

include the District in a Maryland HPR; if it were, then other states would need to be included as well.

Conditions for Consideration of New Cardiac Surgery Programs (.04A(1))

While the Draft Chapter creates an opportunity to apply for a new cardiac surgery program, the conditions that must be met in order for a review schedule to be published are unreasonable and create a delay of at least 2-3 years, potentially much longer. First, the Draft Chapter prohibits consideration of any new cardiac surgery programs until there is a finding that the hospital rate setting system is “adequately stable” to allow an evaluation of the future costs and benefits of a new program. This amounts to a moratorium on the consideration of a new program, the duration of which is dependent on a determination as to which no standards are provided and without any process by which the determination must be made. The Commission already has authority to look at the financial viability of all projects for which a CON is sought. The stability of the rate setting system as it may affect an individual project (which may or may not entail significant capital costs) can be considered as part of the CON process.

Another condition that must be met is “at least” a full year of reporting on the quality measures recommended by the Cardiac Services Advisory Committee (CSAC). This is likely to delay the consideration of new programs for two to three years, assuming the Commission does not require additional time for reporting beyond the one full year as the standard as drafted would reserve discretion to require. It is likely to take at least this long to complete the adoption of the new Chapter, appoint the CSAC, allow the CSAC to complete its deliberations and make recommendations as to standards, allow for Commission adoption of the standards, and then reporting under the standards for at least a full year.

There is no basis for this substantial delay in the consideration of new programs. First, an applicant for a new program should not be required to await reporting by existing programs under quality standards. Quality reporting by existing programs is not relevant to whether a new program meets the applicable standards for approval. Further, the CAG already made recommendations about quality outcome measures and process measures for cardiac surgery, which are described on page 2 of the CAG’s final report. This was an explicit part of the charge to the CAG – to “identify key findings from research and key guidelines that are relevant to requirements for the establishment of cardiac surgery and/or PCI services, as well as standards of ongoing performance that should be required for the continuation of such services.”

The CAG did not recommend a committee be convened to repeat the work it had already completed. Rather, as set forth on page 11 of the final CAG report, the role of the committee that the CAG recommended is “provide advice on the implementation of regulations pertaining to PCI services and cardiac surgery [and to] provide advice on a hospital’s plan of correction, when a hospital fails to meet ongoing regulatory requirements.” (emphasis supplied). It also called for a committee to assist in the analysis of data from hospitals to evaluate program quality. Thus, the CAG envisioned a committee to advise the staff on the implementation of the Chapter and analysis of data to evaluate program quality. The CAG did not call for a committee to establish quality standards, let alone call for delaying consideration of new programs pending existing programs’ reporting of quality data.

Relocation of Cardiac Surgery Programs (.04C(1))

The Draft Chapter includes new rules governing relocations of cardiac surgery programs, including a requirement that the program be operating in compliance with the standards for a Certificate of Ongoing Performance. As drafted, however, these rules only apply to letters of intent and applications filed after the new chapter becomes effective (.02E). Accordingly, they would not apply to two pending CON applications to relocate cardiac surgery programs. Given that the legislation calling for these standards was in effect long before these applications were filed, it is appropriate to apply these standards to those applications.

Review Standards (.05A)

Minimum Volume for New Programs (.05A(1))

The Draft Chapter requires an applicant to “demonstrate the ability” to perform a volume of 250 cases, and to actually perform 200 cases by the end of the second year of operation. The volume requirement for cardiac surgery programs was the subject of extensive discussion by the CAG. The CAG recommended (CAG Final Report at p. 9) approving a new program “only if an applicant demonstrates that the proposed program can attain sufficient patients to meet the minimum start-up volume of 200 cases annually within two years.” The CAG did not recommend requiring applicants to demonstrate the ability to achieve greater volumes. To the contrary, as set forth in the CAG report (at 10), the recommendation of 200 cases was based on literature that indicates “a volume-outcome relationship and that suggests programs may be providing quality services at volumes below 200 cases.” (emphasis supplied).¹ Accordingly, it did not recommend that programs with lower volume (between 100 and 200 cases) be closed; rather, it recommended that such a program should be subject to a focused review in order to ensure the quality of the program. For the same reason, the CAG recommended lowering the impact standard for a new program (minimum number of cases that existing programs must be allowed to retain) from 350 to 200 cases.

In requiring applicants to demonstrate the ability to provide more than 200 cases, the Draft Chapter is contrary to the CAG’s recommendation. This standard should be changed to require the applicant to demonstrate the ability to perform 200 cases, and to actually perform 200 cases by the end of the second year.

This standard also requires the applicant, in demonstrating compliance with the minimum volume requirement, to address the most recently published utilization projections in the HPR in which the program will be located, but also in any other HPR from which it projects to draw 20% or more of its patients. This requirement is the first of several requirements on applicants in the Draft Chapter to address HPRs other than the one in which the program will be located. The requirement to address the utilization projections should be limited to the HPR in which the project will be located. The Existing Chapter does not impose any obligation on the applicant to address the projections in other HPRs.

¹ The Draft Chapter (at 7) even recognizes that contemporary studies show a weaker relationship between volume and quality than earlier studies had suggested.

Impact (.05A(2))

Like the minimum volume standard, this standard also imposes unprecedented requirements on the applicant to address HPRs other than the HPR in which the program will be located. Under this standard, the burden is now on the applicant to affirmatively demonstrate that the new program will not negatively impact programs in other HPRs. Specifically, the applicant has the burden to make three showings related to an adjacent HPR. The most unreasonable of the three showings is in (c), under which the applicant must demonstrate that the new program will not result in any loss of volume at a program in an adjacent HPR that is operating at less than 200 cases per year and that has an “overlapping service area.” This is an unreasonable and unfair burden to put on the applicant, essentially holding it accountable for a program that is already underperforming. There is nothing in the CAG recommendations that supports such a requirement.

In the Existing Chapter, the only basis upon which the Commission will consider a new program in an HPR is if there is an underperforming program in that HPR. The Draft Chapter would reverse course without any explanation for doing so, making the existence of an underperforming program an insurmountable hurdle for an applicant seeking a new program in an adjacent HPR. The requirement in .05A(2)(c) should be stricken altogether, or limited to an underperforming program in the same HPR.

Additionally, .05A(2)(a) and (b) should also be limited to the HPR in which the new program would be located. Under .05A(2)(a), the applicant is required to demonstrate that the financial viability of any “affected” hospital in the HPR where the program will be located and in any adjacent HPR will not be compromised. This requirement is circular and imposes an unfair burden given that the Baltimore Upper Shore region is adjacent to all of the other HPRs. If a program in an adjacent HPR believes that its financial viability will be negatively impacted, it can seek to become an interested party in the review for that purpose. For the same reason, the burden under .05A(2)(b) should be limited to the HPR in which the new program would be located. The Existing Chapter does not put any burden on the applicant with respect to other HPRs and there is no suggestion that the viability of existing programs has not been adequately protected up to now.

Further, .05A(2) should be revised to restrict considerations of impact to programs located in the State of Maryland. The CAG recommended that consideration of impact on existing programs should in all cases be limited to Maryland programs. By including out-of-state hospitals in the impact standard, the Draft Chapter is inconsistent with the CAG’s findings and recommendations.

Finally, as will be explained further below, the definition of “overlapping service area” is unreasonable and unworkable. Accordingly, it should not be utilized in .05A(2) for any purpose. Consideration of impact on existing programs should be limited to programs within: (1) the same HPR, and (2) the State of Maryland.

Quality (.05A(3)) and Cost Effectiveness (.05A(4))

In both of these standards, the Draft Chapter puts a new burden on the applicant to demonstrate the lack of impact on programs in an HPR outside of the HPR in which the program will be located. The standard in §A(3) requires the applicant to demonstrate that quality of care at an existing program in an adjacent HPR is unlikely to be negatively impacted. The standard in §A(4) requires an applicant that projects any shift in volume from existing programs to quantify the shift in volume and the estimated financial impact on the program of each such hospital.² This requirement is not limited to the HPR in which the new program would be located, or even the adjacent HPR; it would apply throughout the State.

Both standards impose an unfair and unreasonable requirement on the applicant because the applicant would not have information necessary to quantify financial impact at another program. Nor is there any way an applicant can “demonstrate” that quality of care at another program will not be impacted other than simply to assert it, making this standard either impossible to satisfy or, alternatively, meaningless. If a program in an adjacent HPR believes that the quality of its program will be negatively impacted or the financial viability of its program threatened, it may seek to become an interested party in the review for that purpose. The Existing Chapter does not put any burden on the applicant with respect to other HPRs and there is no suggestion that the quality or financial viability of existing programs has not been adequately protected up to now. Further, as discussed above, this is an unfair burden given that the Baltimore Upper Shore region is adjacent to all of the other HPRs.

Need (.05A(6))

The requirement to demonstrate need requires the applicant to account for need not only in the HPR in which it will be located, but also in any other HPR from which it projects drawing 20 percent or more of its cases. The Draft Chapter states (at 5) that it defines HPRs “for the purpose of planning and regulating cardiac and PCI services.” Requiring the applicant to demonstrate need in other HPRs is unprecedented in the State Health Plan and inconsistent with the purpose of defining planning regions.

Preferences (.05A(7))

The Draft Chapter eliminates the preference that exists in the Existing Chapter for applicants whose program includes a research, education and training component on cardiovascular diseases. No explanation is provided for the elimination of this preference. It should be retained in the new Chapter.

Additionally, due to the lack of regulatory authority over out-of-State hospitals (including application of quality standards), a preference should be provided to the program that would mitigate outmigration to the greatest extent. This is consistent with the CAG’s recommendation that impact on out-of-state programs should not be a consideration in an application for a new program.

² Any new program would, of course, involve a shift in volumes from existing programs so this requirement will always be applicable.

Utilization Projection Methodology (.08)

The utilization projection methodology projects utilization in the target year (six years from the base year) by looking at utilization in the base year and the preceding five years. AAMC agrees that making the target year six years out from the base year is appropriate, but that six years is too long of a look-back period from which to project forward. Utilization six years ago is even less predictive of what utilization will be in the target year than utilization three years ago (the look-back period under the Existing Chapter). If six years back is to be used, then the methodology should be changed to be more sensitive to trends in the latter part of the long period. The utilization projection methodology in the Draft Chapter utilizes a simple average of the percent change in utilization in each of the five years preceding the base year in order to project utilization in the target year. This methodology ignores trends that are important to projecting future utilization. For example, if utilization was steady or even declined in the early years but increased in each of the later years, the methodology would not account for this upward trend leading into the projection period. The methodology should provide for a regression of the percent changes, which would take those same five values and, instead of averaging them, take a simple linear regression of them and then apply this trend forward.

Definitions (.09)

The Draft Chapter retains the definition of “cardiac surgery” as including both “open heart surgery” and “closed heart surgery.” However, the Draft Chapter eliminates the definitions of “open heart surgery” and “closed heart surgery,” along with the references to specific ICD-9 codes incorporated in those definitions in the Existing Chapter. While AAMC recognizes that ICD-9 is shortly changing to ICD-10, it continues to be important to provide certainty around what is considered “cardiac surgery” for purposes of (among others) applying the utilization projection methodology. This could be accomplished in the same manner as the definition of PCI, which refers to specific ICD-9 codes and incorporates by reference the “corresponding” ICD-10 codes.

Additionally, the Chapter should be flexible enough to take into account new practice patterns and procedures coming into clinical use that are blurring the lines between cardiac surgery and interventional procedures. This includes transcatheter aortic valve replacements (TAVR). TAVR is performed by cardiac surgeons and can only be performed in settings with cardiac surgery backup. TAVR will be increasingly utilized in an aging population. It is an interventional procedure that provides an alternative to surgery for some patients, and also an option for patients for whom cardiac surgery is not an option, thus representing new cases. The ICD-9 codes associated with TAVR as well as other new surgical and interventional procedures were added in 2011 and include 35.05, 35.06, 35.08, 35.09, 35.97 and 37.37.

The Draft Chapter defines “service area” for the first time, a term that is used in the impact standard discussed above. It is defined to mean where the top 85% of patients who received diagnostic catheterization at the hospital that resulted in a referral for cardiac surgery reside. The definition of this term is unreasonable and unworkable. The number of patients who receive diagnostic catheterizations at a hospital without cardiac surgery onsite is small because doctors generally do not refer patients to such hospitals for diagnostic catheterization if they are

likely candidates for cardiac surgery. The definition results in a service area that is not at all representative of a hospital's actual service area and, indeed, may not even be contiguous.

The definition as to existing programs refers to where 85% of the patients who received cardiac surgery reside. As applied to underperforming programs with very low volumes (.05A(2)(c)), this definition is unlikely to generate a representative service area. It is also unreasonable as applied to programs that exceed the volume requirements because it results in unreasonably large service areas. For example, the application of the standard to the large programs based at academic medical centers results in a statewide service area for those institutions. Likewise, high volume programs will have virtually identical service areas under this definition. There is no definition or use of "service area" in the Existing Chapter. The definition of "service area" should be stricken, along with the two standards in .05A(2) in which this term is used.