

October 21, 2013

Eileen Fleck
Chief, Acute Care Policy & Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Comments on the Informal Draft State Health Plan For Facilities And Services:
Specialized Cardiovascular Services COMAR 10.24.17

Dear Ms. Fleck:

Thank you for the opportunity to comment on the informal draft of the Specialized Cardiovascular Services Chapter of the State Health Plan ("Draft Chapter"). We appreciate the great deal of work that went into the development of this Draft Chapter. We also endorse the part of the process that solicits input to improve the draft, consistent with the goals and objectives of the State Health Plan.

Cardiac surgery and percutaneous coronary intervention ("PCI") programs are among the services the Maryland Health Care Commission ("MHCC") regulates. Just as the MHCC seeks to ensure the regulatory process within its purview is fairly applied to ensure the availability of quality services, hospitals with such programs share this commitment. Adventist HealthCare's hospitals have committed substantial resources to meeting community needs for quality cardiac surgery and primary and elective PCI through capital investment, building effective clinical teams, developing ancillary services and through cardiac disease prevention and wellness programs.

Adventist HealthCare's commitment to cardiac surgery services commenced some 50 years ago when Washington Adventist Hospital became one of the first community hospitals in Maryland to provide this surgical procedure. Washington Adventist Hospital was also an early provider of PCI, and Shady Grove Adventist Hospital was an early leader in participating in the research programs that have made this service available on a primary and then elective basis. These comments are based on the decades of experience and commitment that Adventist HealthCare's cardiac surgery and PCI teams have demonstrated, fully supporting the MHCC's health planning process.

Our comments relate to four areas:

1. The Cardiac Service Advisory Committee
2. The Impact Standards
3. Relocation of Programs – Cardiac Surgery
4. The Adoption of Enforcement Standards

The Cardiac Service Advisory Committee (“CSAC”) should be a diverse, broadly representative group.

The Draft Chapter provides that the CSAC selected by the MHCC will include

representatives of providers of cardiac surgery, providers of PCI services, a representative of the Maryland Institute for Emergency Medical Services System, and representatives of the Maryland Chapter of the American College of Cardiology and the Maryland Chapter of the Society of Thoracic Surgeons, and others as appropriate. Representatives of providers of cardiac surgery and PCI services will be selected to cover a wide geographic range and multiple health care systems.

We agree with this approach and urge that the representation of programs offering cardiac surgery and PCI be broad and diverse. The Draft Chapter shrinks two of the health planning Regions, i.e. the Eastern and Western Region, so that most of Maryland’s jurisdictions are in the Metropolitan Washington and Baltimore Upper Shore Regions. The composition of the CSAC should include broad representation even though the cardiac surgery and PCI programs are to be mainly grouped in two large Regions. This is especially important given the ongoing oversight that will result from the Certificate of Ongoing Performance standards and process.

The Draft Chapter reflects an internal inconsistency that needs to be addressed. On the one hand, the Draft Chapter maintained a longstanding MHCC policy based on the benefits of a limited number of hospitals offering cardiac surgery and PCI specialized services. Yet, on the other hand, the Chapter appears to make other, inconsistent changes that are contrary to this principle.

On page 5, the Chapter recognizes:

Cardiac surgery and PCI services are specialized hospital services. For specialized services, the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base. This pattern promotes both high quality care and an efficient scale of operation. The Chapter outlines standards intended to influence the geographic distribution, capacity, and scope of services for providers of cardiac surgery and PCI services based on considerations of cost-effectiveness, efficiency, access and quality.

However, the Draft Chapter incorporated the following major elements:

- Eliminates a longstanding standard that only one new cardiac surgery program at a time will be approved and that there will be a three-year period after a new program is operational before another new program is approved.

- Omits the following language that appears in the current State Health Plan from the Draft Chapter:

The Commission will approve the establishment of a new cardiac surgery program in a Regional Service Area projected to have stable or declining open heart surgery utilization only if the Commission determines that the establishment of the new program will demonstrably benefit the service area population in access, quality and/or cost-effectiveness, and the value of that benefit is greater than any increased cost that may result from distributing the projected open heart surgery cases over a larger number of programs in the Region.

- Without explanation, no longer includes in the Draft Chapter current State Health Plan language requiring a hospital seeking a cardiac surgery program to have an average daily census based on total acute care service other than newborns of at least 100 patients in each of the two most recent calendar years.
- Shrinks the size and population in two of the four Regions, i.e. the Eastern and Western Regions, without addressing how existing cardiac surgery and PCI programs serve their historical regions. Even though the Maryland Institute for Emergency Medical Services Systems (“MIEMSS”) has its own regions and specialized hospital designations, the Chapter does not discuss the health planning effect of the difference between the MIEMSS regions used by ambulance crews for emergency transport to designated cardiac interventional hospitals and the MHCC’s definition of Regions for planning purposes.
- Does not explain why the District of Columbia is considered for Metropolitan Washington planning purposes but not adjoining States near other parts of Maryland where the population travels for care, such as parts of Delaware, Pennsylvania and West Virginia.
- Under .05A(1)(d), the requirement to comply with the “Minimum Volume” and “Impact” standards shall address “the most recent published utilization projection” under .08. However, .08 permits applicants to demonstrate why the methods and assumptions in the .08 projections are not reasonable for forecasting volume. This means that instead of the Chapter establishing a common set of uniformly applied health planning standards based on published regulations, the CON process can result in an application-specific health planning process in which standards are applied to some applicants instead of established, regional planning.
- Section .08 includes other important changes to the methodology for cardiac surgery with no explanation of the basis, why this is more accurate and the effect of projections of use and need, particularly when spread over the larger populations in the two newly expanded planning Regions for this service. Attachment A details a number of significant changes to the methodology under .08 without explaining how these changes are consistent or inconsistent with

the draft Chapter's stated goal and longstanding MHCC precedent, of making cardiac and PCI services in a limited number of specialized hospitals.

The Chapter's standards on impact should be augmented to feature more emphasis on the impact of quality at an existing program. Further, the Health Services Cost Review Commission should also assess the impact of new cardiac surgery and PCI programs on the overall finances of affected hospitals.

The Draft Chapter's Impact standard should be strengthened. While the Draft Chapter otherwise stresses the importance of quality standards as more relevant than volume, quality is not mentioned at all in the Impact standard. Also, the financial impact element does not take into account the upcoming major changes in the HSCRC waiver and rate-setting process and the broader impact on hospital finances.

The Draft Chapter relies on quality as a more important metric than volumes. On page 8, the Draft Chapter states:

The Commission's clinical advisory group (CAG) considered * * * this study as well as others [footnote omitted], in addition to the 2011 ACCF/AHA Guide for Coronary Artery Bypass Graft Surgery, in making its recommendation that the Commission's regulation of cardiac surgery services should place a greater emphasis on quality rather than on volume.

However, the Impact standard is silent on impact on quality. Rather, under .05A, the Draft Chapter states:

(2) Impact

An applicant must demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:

- (a) Compromise the financial viability of the cardiac surgery services at an affected hospital; or
- (b) Result in an existing cardiac surgery program with an overlapping service area dropping below an annual volume of 200 cardiac surgery cases; or
- (c) Result in the loss of additional volume at an existing cardiac surgery program that has an annual volume of less than 200 cardiac surgery cases and that has an overlapping service area.

First, the Draft Chapter's Impact standard refers to losses of volumes in existing cardiac surgery programs based on how an applicant for a new program defines its service area, not based on regional planning or Impact to the spectrum of existing programs that could be affected. In this way, the applicant can seek to limit the impact analysis the MHCC would conduct. Note that, while the lead-in language states that the Impact standard has to take into account "other providers of cardiac surgery in

the health planning region or an adjacent health planning region” the actual volume standards under .05A(2)(b) and (c) undermine this by referring in a more limiting way to an evaluation of programs with an “*overlapping service area.*” The MHCC is planning for Regions and the draft Chapter allows applicants to rely on volumes from adjoining regions. Thus, the loss of volumes should, as the Chapter states, take into account a loss of volumes among other cardiac surgery programs in the same or adjacent Region not simply those in an applicant-defined service area.

Second, we also question the degree of the drop from the current SHP standard stating that a new program will not cause an existing cardiac surgery program to drop below 350 cases. This is particularly the case when the draft Chapter states that the applicant for a new program must forecast that it will reach 250 cases. Thus, if this volume standard will drop, it should use 250 cases instead of 200 cases under .05A(2)(b) and (c).

Third, under .05A(3), concerning Quality, but not under Impact, the Draft Chapter states:

(b) An applicant must demonstrate that the quality of care for cardiac surgery patients at an existing cardiac surgery hospital in its health planning region or an adjacent health planning region is unlikely to be negatively affected by the addition of the proposed new program.

Cardiac surgery programs are only one component of a broader system of cardiac services at hospitals offering integrated surgical and PCI services, the quality of which suffer a negative impact due to close proximity. This is harmful competition for limited physicians and staff.

We suggest this provision be moved to .05A(2) and that the language be edited to require the applicant to demonstrate that there will not be a negative impact related to quality. It should read:

An applicant for a new cardiac surgery program must demonstrate that the quality of care for cardiac surgery and PCI patients at an existing cardiac surgery hospital in its health planning region or an adjacent health planning region will not cause a negative impact affect by the addition of the proposed new program. This includes, for example, causing an existing cardiac surgery program to be at risk for not meeting the MHCC’s quality standards and Certificate of Ongoing Performance for cardiac surgery or PCI.

Fourth, we suggest an amendment to the above standard requiring the applicant not to “Compromise the financial viability of the cardiac surgery services at an affected hospital.” Cardiac surgery is only one important part of an integrated cardiac service at hospitals offering these specialized services including PCI, medical cardiology, ancillary services and cardiac disease prevention and wellness programs. Cardiac surgery impact has hospital-wide financial implications. Financial viability impact is not a meaningful metric if it is limited to the cardiac surgery services only.

- The above standard should state that the new program will not “Have a significant negative impact on the financial viability of the program of cardiac services at an affected hospital including cardiac surgery, PCI and other related cardiac services.”
- In addition, given the importance and financial integration of cardiac services at hospitals with a full spectrum of cardiac services including cardiac surgery, PCI and related services, we urge the standard be amended to state that the HSCRC will be asked to comment on both the financial feasibility of the new cardiac surgery program and the financial impact on affected hospitals in the health planning region or adjoining region (not limited to cardiac surgery only).

Fifth, the MHCC should restore a concept that has for many years been a part of the cardiac surgery Chapter in the SHP, which the draft Chapter removes. Under the current SHP:

A hospital that applies for a new cardiac surgery program will be required to enter into an agreement with the HSCRC outlining how the open heart surgery and percutaneous coronary intervention cases will be incorporated into the hospital's Charge per Case (CPC) or Total Patient Revenue agreement with HSCRC. The agreement will outline the number of cases that are projected by the hospital in each of the open heart surgery and percutaneous coronary intervention Diagnostic Related Groups (DRGs), the case mix weights and the average CPC for each open heart surgery and percutaneous coronary intervention DRO, the projected total open heart surgery and percutaneous coronary intervention revenue based on the case mix weights, the average CPC for the open heart surgery and percutaneous coronary intervention cases, and the projected open heart surgery and percutaneous coronary intervention revenue the hospital is willing to give up in its overall HSCRC Charge per Case or Total Patient Revenue standard.

A hospital that applies for a new cardiac surgery program will be required to give up a minimum amount of revenue, as defined by the HSCRC, based on its projected volumes and costs for the new service as set forth in its Certificate of Need application.

Certainly, the HSCRC waiver and rate-setting process is changing. This language referring to the Charge per Case or Total Patient Revenue standard would need to change, but the draft Chapter does not explain why the MHCC is abandoning the longstanding concept of a negotiation with the HSCRC by an applicant seeking a new cardiac surgery program.

The Draft Chapter's standard on the relocation of programs should be amended.

First, under proposed .04, the Draft Chapter states:

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

(a) If a hospital with cardiac surgery seeks to relocate, in addition to meeting all CON review criteria and applicable standards in COMAR 10.24.10 and other SHP chapters, the hospital must demonstrate compliance with all standards for a Certificate of Ongoing Performance for both cardiac surgery and PCI services.

There should not be a discriminatory standard applied to a hospital with a cardiac surgery program simply because it seeks to relocate within its existing service area. A hospital with a Certificate of Ongoing Performance will need to meet those standards irrespective of whether it seeks to relocate. Other hospitals with cardiac surgery programs may be engaged in other, major projects. Yet, they are not subject to this special requirement. There should be one standard, uniformly applied. We recommend that this standard not be limited to “relocations” and instead state:

(a) If a hospital with a cardiac surgery program or PCI program applies for a CON that relates to the delivery of such services, the hospital must hold a Certificate of Ongoing Performance for such services based on current compliance or an approved plan of correction.

Second, we request a change to .04(b). The state’s health care delivery system is entering into a new phase under a new HSCRC waiver that requires hospital systems to be able to plan effectively for the services they offer. This needs to take into account that cardiac surgery and PCI services are important services but they are only one part of an entire hospital for which health systems need to plan. The draft Chapter states:

(b) A merged hospital system may not relocate its existing cardiac surgery capacity and emergency and elective PCI services to another hospital within its system without obtaining a Certificate of Need.

We urge that this language be revised to state:

(b) A merged hospital system may not relocate its existing cardiac surgery capacity and emergency and elective PCI services to another hospital within its system without obtaining a Certificate of Need, unless the Commission approves an alternate plan that is determined (i) not to increase the number of programs or program locations, (ii) to be consistent with the Commission’s merger and consolidation process and (iii) is between hospitals in the same jurisdiction and within that merged hospital system.

Mergers and consolidations are still subject to MHCC oversight. This amendment ensures that a health system’s cardiac surgery and PCI program would remain in the same jurisdiction and enable effective planning for entire hospitals within health systems in a way that is responsive. A long, uncertain and expensive CON process for only one particular service is counter to the imperative for effective planning that favors a shift to outpatient and community based services.

The current SHP explains that the basis for requiring a CON for the relocation of a cardiac surgery program within a merged asset system is that:

The potential relocation or dividing cardiac surgery programs may result in the proliferation of programs in the absence of need, and defeat the principles of regional planning.

Our suggested revision is fully consistent with this principle that resulted in the establishment of the current standard, and still ensures there is no proliferation or division of programs. It is consistent with regional planning and the effective consolidation of services and health system movement toward community based services.

The MHCC's process for adopting and enforcement standards for ongoing oversight should be the subject of further discussion and rulemaking to ensure compliance with due process requirements.

Adventist HealthCare fully supports efforts to ensure that the quality of cardiac surgery and PCI programs is maintained and improved. Adventist HealthCare has participated, and seeks to continue to participate, in the MHCC's standard setting process. We have some suggestions that we believe improve this process. Some of these may not be fully capable of resolution before the draft Chapter is adopted. Rather than slow the adoption process, we recommend that the Draft Chapter provide for a process wherein there can be full resolution of matters relating to due process and administrative and other applicable law. This guidance should be clear to affected hospitals and the MHCC at the same time that new quality standards are developed and put in place.

There are various provisions that describe how the MHCC will take on the mantle of an oversight agency more akin to the Office of Health Care Quality. Cardiac surgery and PCI programs will need to obtain and maintain compliance with Certificates of Ongoing Performance and are at risk for closure of these services. See, e.g., .04B(1) and (2). This includes "focused reviews" under .07 that would involve MHCC, or MHCC contractor, review of clinical records according to regulatory standards to be adopted. This should include a discussion of the process by which a Certificate of Ongoing Performance could be removed or relinquished, when there might be disagreement on the basis for such agency action. If the MHCC is to function akin to a licensing agency with authority to review records, require an approval to operate a service and take actions to remove that authority, there should be a full discussion about legal due process standards akin to other agencies performing such functions.

These need not be established for the Draft Chapter to be adopted, but they should be in place, through regulatory rulemaking, before they are imposed. These include, for example:

- The credentials, training and oversight of staff conducting chart reviews, just as such standards and training is required for Office of Health Care Quality (OHCQ) surveyors.
- Confirming whether it is the MHCC's intention to bear the cost of the review just as other agencies hire their own survey teams.

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- Confirming the availability of appeal procedures both at the administrative and ultimately through judicial appeal, just as there are for comparable reviews by OHCQ. It strikes us as inequitable to remove a program without appropriate due process.
- Confirmation that the chart review process does not interfere with or expect a deviation from confidentiality protections afforded to hospital quality assurance processes. These are not violated by the hospital licensing and certification process and any MHCC chart review should be subject to the same protections.
- A better understanding of the process for the approval of a hospital's plan of correction and how that relates to timing for compliance.

Thank you for considering our views on these aspects of the Draft Chapter.

Sincerely,



Paula S. Widerlite
Vice President, System Strategy

Significant Changes to the Health Planning Methodology in .08

- Under A(2) the target year is changed from the current State Health Plan from a three year planning horizon to a planning horizon that is six years after the base year. This is a long time under typical health planning approaches. It means that a cardiac surgery program might be approved and be in operation several years before the need forecasted under the Draft Chapter ever exists. This may be very harmful to existing programs in the intervening years.
- Under .08D(b) there is a shift from three years under the current State Health Plan to six years of data for cardiac surgery use rates. This is done without any discussion of whether use rates are flat, increasing or decreasing over this new, six-year period. If use rates are declining, there should be an explanation of why looking back six years is appropriate. This is particularly the case given the use of a six year target year. This means there will be a *12 year gap* between the earliest use rate data and the target year used to project need. This may mean that older higher use rates, that may since have declined, affect the need projection well into the future. There should be a discussion of why this new approach more accurately projects need than the historical approaches to use rates and target years.
- Similarly, there is no discussion of the rationale for the change under the use rate calculations from relying on percentage changes between each of the years for each age group to, instead, summing the percentage changes in use rates. Given the use of six years of use rate data, the effect of this revision should be explained.
- The use rate for the population 65+ is in one age cohort. Given the longevity of the aging population there should be a discussion of whether use rates in a more senior age cohort should be considered separately as well as a discussion of the effect of not doing so and instead considering use rates among the entire population age 65+ in one group.