



October 21, 2013

Eileen Fleck
Chief, Specialized Services Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: **State Health Plan for Facilities and Services: Specialized Cardiovascular Services COMAR 10.24.17**

Dear Ms. Fleck:

On behalf of MedStar Health, I am writing to provide the following comments regarding the proposed State Health Plan for Facilities and Services: Specialized Cardiovascular Services COMAR 10.24.17.

We are pleased to convey our support for many of the recommendations of the Technical Advisory Group (TAG) and provide these comments to strengthen the regulations and focus planning for cardiovascular services towards the triple aim of simultaneously improving population health, improving the patient experience of care, and reducing per capita cost.

At the outset, we believe it is important to note that the charge of the TAG was very limited in scope. While the clinical expertise of the individuals who participated was exceptional, the discussion was strictly limited, as appropriate for this group, to clinical issues. We appreciate the increased emphasis on quality in the draft plan, but the appropriate allocation of limited resources needed for specialized regional services goes beyond clinical factors. The cost effectiveness of delivering the services, the availability of specialized providers, utilization trends, prevention initiatives etc. are also important factors that must be part of the equation. Unfortunately, these key issues were not vetted or discussed as part of the development of the draft chapter.

Our specific comments are detailed below.

Key Environmental Changes Not Adequately Recognized

Other chapters of the State Health Plan for specialized services offer a comprehensive review of issues affecting the subject service culminating in a set of principles and policies that form the framework for planning and regulations. The proposed plan's issue and policy sections have been scaled down in content and do not sufficiently address the key environmental changes impacting the cardiovascular market. Specifically:

Reductions in Utilization

The plan does not address the dramatic declines in utilization occurring in the cardiovascular (CV) market that will affect procedure volumes and service capacity required in the future. Over the last 5

years in Maryland there has been a 16.2 percent reduction in cardiac surgery discharges and a 51.5 percent reduction in interventional cardiology discharges. The effects these trends have on access, quality, efficiency, and financial viability of existing programs must be considered in developing an appropriate plan for cardiac services for the future.

Further, the proposed plan seems to retreat from the core principles of specialization and regionalization which have been the hallmark of planning for specialized cardiovascular services for several decades. The issues section .03 should include specific policies related to cardiovascular utilization trends and the core principles of specialization and regionalization.

Hospital Payment Policy Changes

We appreciate the fact that the draft plan recognizes the significance of the pending changes to the hospital rate setting system. Moving from the current Medicare payment per admission, to a new model that focuses on overall hospital expenditures will be a seismic change for Maryland hospitals. The annual limit on the total increase in revenue based on the 10-year average growth in the state's economy and a guarantee of at least \$330 million in savings over five years to Medicare will mean a significantly increased focus on controlling costs. Cardiovascular expenditures, which represent a sizable share of total state health expenditures, will, by definition, be targets for utilization and cost control strategies.

It is critically important to understand the impact these changes will have on the financial condition of Maryland's hospitals before considering the addition of new cardiac and PCI programs. The changes will likely have an impact on the financial viability of sustaining a program with only 200 cases per year.

Prevention Initiatives

The plan should incorporate policies directed at controlling the utilization and cost of cardiovascular expenditures through care management and population health strategies. The proposed plan addresses prevention and outreach only marginally as a preference standard in competitive certificate of need reviews. We recommend stronger and more explicit policies be added to the chapter for promoting and incentivizing prevention and wellness. This approach would also facilitate and bolster the state's commitment to the federal Million Hearts campaign aimed at preventing 1 million heart attacks and strokes by 2017.

Certificate of Conformance vs. Certificate of Need

It is unclear how the requirement to establish a cardiac surgery program which requires a Certificate of Need differs from a Certificate of Conformance required to establish a PCI program. In both cases, applicants must address the certificate of need standards contained in COMAR 10.24.10 (A) and demonstrate that the proposed program is needed for its service area. However, there is a specific need methodology for identifying unmet need for Cardiac Surgery services but no specific need methodology for PCI programs. The plan should: 1) explicitly articulate the differences, if any, in the threshold standards for establishing need under a Certificate of Need review versus a Certificate of Conformance review; and, 2) contain a need methodology for elective PCI services as it has for Cardiac Surgery.

Minimum vs. Optimal Volume Standards

The proposed plan adopts *minimum* volume standards for establishing new programs rather than *optimal* volume standards that take into account efficiency and financial viability. The volume standards must strike the right balance between quality, cost and access objectives. Further, there is no compelling evidence of unmet need in Maryland to justify the gamble of increasing low volume /low quality cardiac programs. Cardiac surgery and elective PCI cases are rarely done on an emergency basis and virtually all Maryland residents are within reasonable drive times to a cardiac surgery or elective PCI program.

While we recognize that low volume programs can offer quality care, the evidence suggests that there is greater variability in quality in low volume programs than in high volume programs of between 600 -700 cases per year. And, there are a number of key variables that affect the quality of low volume programs. Maryland policy should be promoting optimal standards of care particularly in light of the changing hospital reimbursement system.

Last, we would note the volume standards for Cardiac Surgery programs are institutional standards. There are no physician operator minimum volume standards as is the case for PCI programs. We recommend that the cardiac surgery programs have both institutional and physician volume standards.

Remedies for Poor Performance Untested

The draft plan attempts to compensate for the use of minimum volume standards through enhanced oversight and performance standards with the potential to close underperforming programs. We believe it is far easier to control entry on the front end than to close an underperforming program on the back end. Once opened it will be difficult if not impossible to close a program. Under its current authority via CON conditions the Commission has never closed a program that failed to meet its volume standards. Under the proposed rules and the broad latitude given to the Commission to interpret the performance standards, closing a program would come only after protracted delays during which patients would be subject to less than optimal care.

Diminished Impact on Existing Programs Problematic

The proposed plan also changes the impact standard for establishing new surgical programs. In the current plan, a proposed new program can not cause the volume of an existing program to drop below 350 heart surgery cases per year. The proposed plan would allow a new program to cause an existing program's volume to drop to 200 cases annually, thus making it easier to approve a new program. We question the wisdom of this policy particularly given the significant changes to the hospital rate-setting system as discussed above and the lack of evidence that there is unmet need.

Expansion of PCI May Not Improve Access

A team of researchers from the RAND Corporation, Tufts Medical Center and Tufts University School of Medicine reported in the July 9th *Circulation: Cardiovascular Quality and Outcomes*¹ the results of a study that analyzed the specific hospitals and locations where new programs were set up between 2004

¹ <http://www.cardiovascularbusiness.com/topics/coronary-intervention-surgery/expansion-pci-does-not-improve-access>

and 2008. The study found that 251 new programs emerged nationwide over the four-year period and the number of hospitals able to offer services grew by 16.5 percent. The estimated cost of operating these new programs was between \$2 billion and \$4 billion. Despite the vast growth and expenditures, the number of patients able to receive timely PCI increased by only 1.8 percent. According to Thomas Concannon, PhD, the lead author of the study over a 10 year period, the number of patients who get access to this procedure in an emergency has not moved. It has stayed below 50 percent of patients with heart attack. In an accompanying editorial, Isuru Ranasinghe, MD of the Yale University School of Medicine added there isn't great demand for PCI as there once was. Incident acute myocardial infarction, and particularly STEMI rates have declined over the last 15 years. Ranasinghe stated as with PCI it is not clear whether the expenditures and treatment have led to better patient outcomes.

In light of these data, it will be important to collect and analyze the data over time as the draft plan envisions before approving additional PCI program.

Rationale Needed for Changes in the Planning Regions

The regional health planning regions for cardiovascular services have been significantly redefined in this plan. What was historically the Metropolitan Baltimore Region has been expanded to include five counties previously in the Eastern Shore region to create a new 11 county Baltimore Upper Shore Region. The Metropolitan Washington Region is expanded by adding Frederick County from the Western Maryland Region. The rationale for these changes is not provided in the plan and should be explained. We also suggest projections of unmet need and capacity of the revised regions for both cardiac surgery and PCI services be included in an appendix to the plan. The geographic coverage and diversity of the new eleven-county Baltimore Upper Shore region may have significant implications for redistributing programs and geographic access that are difficult to assess without explicit need projections.

Also missing from the planning region discussion is acknowledgement of the availability and use of cardiac centers by Maryland residents in border jurisdictions such in Washington DC and Delaware. Facilities in these jurisdictions provide vital resources for Maryland residents, particularly those residents in rural areas where access to Maryland programs is problematic. The plan recognizes these resources in its cardiac surgery need projections, and the Maryland Institute for Emergency Medical Services (MIEMSS) has designated cardiac intervention centers in these border jurisdictions for the purpose of EMS transports for STEMI patients. This plan should also explicitly recognize the availability of these facilities that serve significant numbers of Maryland residents.

MIEMSS Policy and Data Coordination

We would like to suggest that the plan include policies that promote better coordination and sharing of performance data between MIEMSS and MHCC. There will be duplicative reporting requirements if these regulations are adopted. We also take note that MIEMSS designation policies have a significant impact on allocating volume among cardiac programs; consequently MIEMSS designation and transport policies need to be in sync with the proposed regulations. There should be a formal mechanism to ensure consistency and coordination of regulations and policies between the Commission and MIEMSS.

Again, MedStar Health thanks you for the opportunity to comment on the proposed regulation. We look forward to working with you and others to ensure the successful adoption of a plan that ensure access to quality and cost effectiveness of cardiovascular services for the residents of Maryland.

Sincerely,

A handwritten signature in blue ink that reads "Pegeen Townsend". The signature is fluid and cursive, with a large loop at the end of the last name.

Pegeen Townsend
Vice President
Government Affairs
MedStar Health