

May 8, 2015

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

RE: Draft Amendments to State Health Plan for Facilities and Services:  
Specialized Health Care Services – Cardiac Surgery and  
Percutaneous Coronary Intervention Services; COMAR 10.24.17

Dear Ms. Fleck:

On behalf of MedStar Health, I am writing to respond to your request for comments on the draft amendments to the State Health Plan for cardiac surgery services dated April 17, 2015.

### **Achieving Quality Objectives**

Both Policy 2 and Policy 5 of the Plan, page 6, address the Commission's policies regarding quality for cardiac services.

Policy 2 states that quality will be promoted through the adoption of performance measures to evaluate programs *and through requirements for internal and external peer review of service delivery and outcomes.*

Policy 5 states that a hospital with cardiac surgery and/or PCI services will continuously and systematically work to improve the quality and safety of patient care. This includes planning, implementing and optimizing the use of electronic health record systems and electronic health information exchange that contributes to infection control, care coordination, patient safety and quality improvement.

While we absolutely endorse these policies, we also believe the regulations are more prescriptive and detailed than necessary to meet these objectives. The Commission is proposing standards for qualified external review organizations. These organizations have the expertise to conduct appropriate reviews, and will be able to meet the intent of the statute. A more simplistic, clear approach that does not add unnecessary regulatory hurdles would achieve the Commission's goals. The Commission's Cardiac Services Advisory Committee can provide expertise on any details for an appropriate framework.

## Clarifications – §.07C(4) and §.07D(5)

MedStar Health supports the staff's efforts to add clarifying language to the sections concerning the requirements of hospitals for certificates of ongoing performance and conducting performance reviews of individual interventionalists. We suggest that the regulations be organized and simplified to clarify what requirements apply to which entities and under what circumstances, who decides whether the interventionalists review are internal or external, annual, semi-annual or quarterly, and when the reports are due to the MHCC. More details about these and other concerns are described below.

Section .07C(4) – in the section referring to elective PCI programs, the existing Plan states that as part of the new certificate of ongoing performance process, a hospital's elective PCI program must annually submit a report to the Commission describing quality assurance activities. The clarifications add a requirement for hospitals to conduct staff meetings every other month for case review [paragraph (a)], and monthly for *primary* PCI system reviews [paragraph (b)], as well as specifying who must attend those staff meetings. It also adds a requirement for "at least semi-annual" external case review [paragraph (c)], and interventionalist reviews that are internal or external, annual, semi-annual or quarterly [paragraph (d)].

Section .07D(5) – The existing plan includes a requirement for hospitals with primary PCI programs to conduct at least semi-annual external case review and annual internal interventionalist review. The draft new language changes the interventionalists performance review to internal or external, annual, semi-annual or quarterly [paragraph (c)], and includes very prescriptive requirements for monthly and bi-monthly staff meetings.

Similar language is found in section .06A(5), certificate of conformance for primary PCI programs; however, this section, which apparently applies to proposals for new PCI programs (although not specifically stated at the beginning of the section) requires external *and* internal case review at least semi-annually, and annual internal review of interventionalists.

These sections all include requirements for monthly and semi-monthly staff meetings, dictating the frequency, composition and subject the for these meetings. It is not at all clear why the Commission would dictate how hospitals hold certain staff meetings. Internal processes, including internal peer review policies, are thoroughly detailed by The Joint Commission and internal bylaws, and thus do not require another layoff of regulatory requirements. These requirements should be deleted.

These sections [and others, such as §.07B(4)] also require an annual report, or upon request, to the Commission detailing quality assurance activities [paragraph (f)]. This appears to be intended as part of the certificate of ongoing performance process, to be conducted generally every five years. And, it is not at all clear what these annual reports are to include, other than documentation of the details of the hospital's quality assurance activities.

It is also not clear why these reports must be submitted every year, rather than only when the certificate of ongoing performance is renewed. Nor is it clear whether separate reports are to be submitted for the cardiac surgery program, the elective PCI program and the primary PCI program, since the requirement is repeated in three different places. These provisions should be simplified.

### **New Section §.08 – External Peer Review**

By setting standards for peer review organizations, as outlined in these draft amendments, the Commission will ensure that external peer review is done properly. As described above, these regulations could meet the intent of the legislation and be much improved if certain sections were less prescriptive. MedStar recommends that the Cardiac Services Advisory Committee, or a selected subcommittee, be consulted to create the necessary language for this section.

This section requires hospitals to review certain PCI cases either semi-annually or quarterly. It carries the ambiguity described above regarding the previous section .07 as to when, or under what circumstances, annual or semi-annual review is required.

Section D(1)(a)(v), requirements for external peer review organizations, states that a Commission approved peer review organization, if the organization includes a reviewer that that is part of a Maryland hospital system, must include at least four hospitals from at least two health care systems. MedStar recommends this be changed to require representation from at least three health care systems in order to assure a more equitable representation. MedStar's Heart and Vascular Institute is the biggest provider of cardiac surgery and PCI services in the Baltimore-Washington area, with four facilities in the Baltimore Upper Shore and Metropolitan Washington regions. The depth and breadth of the services we provide suggests that MedStar could play a critical role in a Maryland-based external peer review organization as envisioned by this section.

Section D(1) has a part (a), but no part (b).

### **Internal Review of Interventionalists - §.09**

Requirements for internal performance review of interventionalists (§.09) also state that the reviews are to be done annually or semi-annually. Again, it is unclear when annual or semi-annual review is required, or under what circumstances. This requirement should be clarified.

### **Definitions**

MedStar has concerns about the definition of cardiac surgery and several other definitions.

Regarding the definition of "cardiac surgery", the ICD-9-CM procedure codes 35.05, 35.06, 35.07, 35.08 and 35.09 were added to the SHP in 2014. These procedures, which are an endovascular approach to a heart valve repair, were approved by the FDA in 2011 at specific

hospital sites in the US for those patients that were otherwise non-operable. The procedures are now approved for high risk patients. Union Memorial performed approximately 100 of these cases last year, and trials are will soon be underway using these same procedures on moderate risk patients. Two other new procedure codes were also added to the definition of cardiac surgery in the 2014 Plan update: 35.97, percutaneous mitral valve repair and 37.37, excision/destruction of other lesion or tissue of heart, thoracoscopic approach.

These procedures are sometimes performed by the cardiac surgeon or the interventional cardiologist, or both, in the room at the same time, usually in the cardiac cath lab or in a hybrid room. further, reimbursement policies do not consider them cardiac surgery. Because the approach for all these procedures is percutaneously, they are found in the APR-DRGs as PCI procedures. For these reasons, these seven codes should not have been included in the definition of cardiac surgery. The Cardiac Services Advisory Committee should determine whether the Commission’s definitions are up to date.

MedStar Health recommends that these definitions be deleted from the definition of cardiac surgery unless and until either reimbursement policies change to consider them cardiac surgery, and/or the Commission’s own advisory committee provides advice on which current ICD-9<sup>1</sup> codes are cardiac surgery, and which are PCI.

The definition of “percutaneous coronary intervention” continues to include five ICD-9 codes. However, three of those codes do not exist on the CMS list of ICD-9 codes and have not existed since 2005, when they became casualties of bundling. Codes 36.06 and 36.07 are correct codes for PCI procedures.

Other definitions also need revision. The definition of “emergency PCI” incorrectly directly equates emergency with primary PCI. While all primary PCIs are emergencies, not all emergency PCIs are primary PCI. We suggest you refer to the ACC definitions for revisions.

The new definition of “plain balloon angioplasty” should be revised. When no stent is placed, the procedure is a balloon angioplasty as reflected in this definition in the draft amendments. There is no recognized category for a “plain” balloon angioplasty, thus the word “plain” should be deleted.

Finally, the definition of “primary PCI operator” needs to be revised. The primary PCI operator is a case-specific term. The primary operator is generally recognized as the physician that performed that specific case. In addition to this discrepancy, there are complexities in how this term is used. In a case where two physicians were involved, the second physician, often a fellow doing certain parts of the procedure, is not necessarily the primary operator. If improperly used, the term could result in case count errors. Therefore MedStar recommends that the cardiac services advisory committee be consulted to provide guidance to the MHCC on the definition and its uses throughout the Plan chapter.

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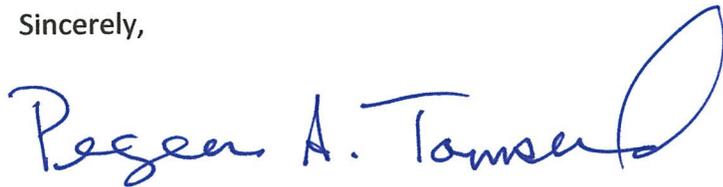
<sup>1</sup> Or ICD-10 codes

This all suggests that all definitions, ICD-9 based or otherwise, should be re-examined for consistency with current practice as defined by professional organizations such as the American College of Cardiology. Again, we believe that using the cardiac services advisory committee, or a subcommittee, would be the best way to address this issue.

### Summary

MedStar greatly appreciates the Commission staff's continued work to clarify and strengthen this Plan chapter. We look forward to continued dialogue and discussion, and would be happy to discuss these comments with you in more detail. Please feel free to call.

Sincerely,

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

Pegeen A. Townsend  
Vice President, Government Affairs  
MedStar Health