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CARDIOVASCULAR INSTITUTE

July, 5th, 2015

Eileen Fleck,
Chief, Acute Care Policy and Planning,
Maryland Health Care Commission,
4160 Patterson Ave.,
Baltimore, MD 21215

Re: June 18, 2015 Draft Amendment to State Health Plan for Cardiac Services

Dear Ms. Fleck:

I would like to thank you and the Maryland Healthcare Commission for providing the opportunity to comment on the June 18, 2015 Draft Amendment to State Health Plan for Cardiac Services.
First of all, I would like to commend the Maryland Healthcare Commission for the thorough work that has been done so far in developing new policies and a quality assurance process, which I believe will result in optimization of care for patients undergoing cardiac services in Maryland.

Regarding the Draft Amendment my comments are as follows:

1) **Page 20, section (3), quality**. The document states that an applicant should establish a program to educate patients about treatment options and monitor the effectiveness of the program. I am in full agreement with the importance of having appropriate programs to educate patients about treatment options, and such programs should be implemented in any cardiac program, either new or previously existing. The challenge is how to measure the effectiveness of such programs outside a well-designed clinical study. Perhaps the commission might want to consider promoting and supporting the development of new standards and change the language to "monitor the effectiveness of the program according to specific standards as developed by the Advisory Committee". Those standards should be applied also to already existing cardiac programs.
2) **Page 28, section (c), internal or external review**. The issue of internal or external review remains confusing through the document. My question is whether programs can choose either an external review or just an internal review. This issue applies both to primary PCI (STEMI) cases as well as elective PCI cases. My suggestion is to consider internal review for primary PCI (STEMI) cases, as part of the multidisciplinary process for STEMI care well outlined in the document, and to support external reviews for all other cases. In my opinion, when assessing

quality and appropriateness of elective or urgent cases other than STEMI, external reviews can provide safeguards for the program and might prevent potential internal bias within the review process.

Regarding the total number of cases to be reviewed, significant differences apply when considering primary PCI (STEMI) cases versus non-Primary PCI cases. Given the relatively low number of primary PCI (STEMI) cases within a given institution, and the additional complexity of patient care in this setting, in my opinion all primary PCI cases should be reviewed within the multidisciplinary program outlined in the standards. Regarding non STEMI cases (elective or Urgent PCI cases) the review process could be simplified by stating in each section that each interventionalist should have at least 5 cases or 10% of cases, whichever number is greater, reviewed on a semi-annual basis. If the total number of cases for the 6-month time period is less than 5, all cases should be reviewed. At the end of the year, if the total number of cases reviewed for an individual interventionalist is less than 10, additional cases should be added from the prior 6-month period if available. In this way, there will be also assurance that at least 10% of total institutional cases will be reviewed on a semiannual basis, thus fulfilling the entire review requirements for the institution. Low volume interventionalists will have all cases reviewed if the total number for the year is less than 10, while higher volume interventionalists will have 10 cases or 10% of cases reviewed, whichever number is greater, on an annual basis.

3) **Page 40, data collection**. The document states that each PCI program shall participate in uniform data collection and reporting. Programs are requested to participate in the ACC-NCDR registry with submission of duplicate information to the Maryland Health Care Commission. I assume that institutions will be requested to submit individual patient records also to the Maryland healthcare commission in addition to the ACC-NCDR registry. Duplicate data reporting is in general onerous for organizations. I wonder whether the Maryland Health Care Commission will be able to develop a direct interface with the ACC-NCDR registry or it will be able to accept electronic data submission. It will be critical to avoid any unnecessary duplication of efforts and data submission.
4) **Page 41.Annual review, section c and d**. The document states *"(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08. (d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows: (i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases at the hospital during the relevant period, as provided in Regulation .08; or (iii) A quarterly review or other review period conducted in a manner approved by Commission's Executive Director that*

assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraph .07C(4)(d)(i).". I found this section somewhat confusing, and potentially suggesting separate reviews for the hospital and for each individual interventionalist. In addition, section "c" states "external review" while section "d" states "external or internal review". As stated above, my suggestion is to simplify the process and to clarify whether an internal review can be used in lieu of an external review.

5) **Page 44, section c, risk adjusted mortality for PCI**. The primary outcome measurement that will be assessed is the 30-day risk adjusted mortality. As of now, while institutions participating to the STS registry are requested to provide also 30-day mortality for patients undergoing CABG, and thus the information is available through the STS program, there is currently no requirement to provide 30-day mortality data for PCI to the ACC-NCDR. In addition, there have been only few studies evaluating 30-day mortality rates following PCI. The analysis available have been performed on claim data, by linking through a special process clinical data and claim data, or by linking clinical data including patients' identifiers with the national death registry. New York State has pioneered the assessment of 30-day mortality rates for CABG and PCI by linking the state registry with data from the Department of Health and its Bureau of Vital Statistics, the New York City Department of Health and Mental Hygiene, and the Social Security Administration. In Massachusetts, Mass-DAC participating PCI programs must collect 30-day follow-up information for all Massachusetts and non-Massachusetts residents receiving a PCI. The goal of assessing 30-day mortality rates in Maryland is ambitious and should be pursued, though it will require developing the same process that has been developed in New York State or in Massachusetts, and develop an appropriate data analysis program. For the short term, my suggestion is to focus on in hospital mortality rates, for which available risk adjustment models have been able to provide very robust data, and to add additional outcome variables such as for example contrast nephropathy, bleeding, and the composite endpoint including death, emergency CABG, stroke and repeat target vessel revascularization, which are important markers of quality within a PCI program. These data are already available in the report that each program receives from the ACC Cath PCI registry, and using them will avoid duplicate efforts.
6) **Page 51**. **Annual review of PCI cases**. I have the same comments as in section 2 and section 4.
7) **Page 60**. **Procedure success**. My suggestion is to follow the definition of angiographic and procedure success according to the most recent ACC/AHA PCI guidelines "*A successful PCI produces sufficient enlargement of the lumen at the target site to improve coronary artery blood flow. A successful balloon angioplasty is defined as the reduction of a minimum stenosis diameter to 50% with a final TIMI flow grade 3 (visually assessed by angiography) without side branch loss, flow-limiting dissection, or angiographic thrombus. For coronary stents, a minimum stenosis diameter of 20% (as visually assessed by angiography) has previously been the clinical benchmark of an optimal angiographic result. Given improvements in technology and techniques, as well as recognition of the importance of an adequately deployed stent to decrease the risks of stent restenosis and thrombosis, the writing committee concluded that a minimum diameter stenosis of 10% (with an optimal goal of as close to 0% as possible) should be the new benchmark for lesions treated with coronary stenting. As with balloon angioplasty, there should*

be final TIMI flow grade 3, without occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus". Procedure success is then defined as angiographic success in the absence of any major complications.

8) **Page 62. Board certification**. Most interventional cardiologists who have been in practice > 20 years are also board-certified in interventional cardiology. Despite the ongoing controversy regarding board certification, I believe that active board certification is still a reasonable indirect marker of "up to date" knowledge and competence, and that any reviewer should be Board Certified in Cardiology and Interventional Cardiology regardless when he or she completed the fellowship training.

I would like to thank you for the opportunity to comment on the June 18th draft Amendments to State Health Plan for Cardiac Services. Once again, I commend the effort of the Maryland Healthcare Commission and I look forward to future opportunities to provide any assistance with this ambitious project.

Sincerely,

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Medical Director, LifeBridge Health Cardiovascular Institute
Member, MHCC Cardiac Services Advisory Committee