October 21, 2013

To: Acute Care Policy & Planning, Maryland Health Care Commission

From: The Maryland Cardiac Surgery Quality Initiative

Subject: Comment on Proposed State Health Plan for Specialized Cardiovascular Services

The Maryland Cardiac Surgery Quality Initiative (MCSQI) is a voluntary statewide non-profit organization established by members of the cardiac surgery practices in Maryland. Our group consists of a consortium of surgeons, cardiologists, database managers, hospital administrators and other healthcare professionals associated with the practice of cardiac surgery. MCSQI's Statement of Purpose document is attached for your reference. Our group strongly supports efforts to ensure quality and appropriateness for all procedures performed by cardiologists and cardiac surgeons. At a recent Board of Directors meeting, the group extensively reviewed the proposed regulations on cardiac surgery. This correspondence constitutes our response to the proposed regulations of the MHCC's State Health Plan.

MCSQI was formed independent of the recent MHCC activity with a goal of reviewing individual program data and identifying and sharing best practices in an effort to improve the quality and reduce the cost of cardiac surgery throughout the State of Maryland. MCSQI is well positioned to conduct both internal and external review of cardiac surgery services, delivery, and outcomes. The group is prepared to report annually on the results of this review process. MCSQI has a formal governance structure, a Quality Committee, and is patterned after successful analogous organizations in other states for process measures and quality improvement. It is supported by the administration of cardiac surgery programs across the state.

On a consensus-basis, the group is addressing the Maryland Health Care Commission's reporting requirements on focused reviews, data collection, quality of care, and volume standards. We are in alignment with most of the proposed

requirements, but would like to express some concerns and request further clarification on the following issues:

- Disclosure of Source Data: Sharing identifiable patient information as part of the internal and external review processes described in Quality section 4(e) could involve the submission of a data file containing patient names or identifiers as well as clinical data relevant to the review criteria. Details of this process need further delineation. In the interest of patient confidentiality and HIPAA compliance, we urge that patient-level data not be disclosed and remain internal to the MHCC if review is deemed necessary.

- Risk-Adjustment: The risk-adjusted mortality rates described in section 5 on Performance Standards are reliant upon ratios of observed mortalities to the number expected by the Society of Thoracic Surgeons (STS) risk prediction algorithm. Better definitions of what constitutes "exceeding the statewide average beyond an acceptable margin" and "a risk-adjusted mortality rate that is consistent with high quality patient care" are necessary. We also feel that comparison of programs to the state average may not be sufficient. Additional benchmarking against the entire network of local peers, including highest and lowest performers, can provide a better context for quality dialogue. One of MCSQI's aims is to create an aggregate database of the hospitals' STS patient data, which would provide a more comprehensive basis for this analysis.

- Appropriateness and Quality: Differences in referral, patient screening and the variety of procedures performed between interventional cardiology and cardiac surgery require nuanced evaluations of these specialties. In cardiology, PCI procedures address one disease, so analyzing the clinical films and guidelines such as the American College of Cardiology's reports are suitable to assess appropriateness of care. Patients may not be evaluated by more than one physician prior to PCI and the screening may therefore be

deemed less rigorous than cardiac surgery. In the case of PCI, post hoc reviews may assess appropriateness of therapy.

Cardiac surgeons perform a wide variety of procedures to treat a wide variety of diseases. Patients are screened 100% of the time before they are referred for cardiac surgery, often multiple times, and the appropriateness of therapy has already been assessed. Measuring the overall quality of care is a much more relevant way of evaluating surgical programs.

Therefore, MCSQI recommends against the review process via random selection of five to ten percent of cases as described in Quality sections 4(b) and (c) for cardiac surgery. A random sample of only five or ten percent will leave a large margin for error, and will not necessarily pinpoint a program's higher risk cases. While defensible for PCI review, this process will yield low results for surgery cases and drive up overall costs. If the goal of the review process is focused on coronary artery bypass grafting (CABG) cases then this needs to be explicitly stated and reviews tailored for that purpose. However to account for the entire range of procedure types performed by cardiac surgeons, the review of summary level data will provide a better assessment of performance. The STS quarterly reports and National Quality Forum (NQF) National Voluntary Consensus Standards for Cardiac Surgery are two examples of systems that address the overall quality of hospital care. To augment these reports, similar measures could be recommended to the MHCC's Clinical Advisory Group and provided via the MCSQI database.

We support the development of the multidisciplinary "heart team" approach to discuss all treatment options available for diseases for which several therapies are available, before elective application to ensure appropriateness.

- Procedure Volume: In Volume Requirements section 6, please clarify what occurs when a hospital performs between 100 and 200 cases, and amend the

wording in 6(a) to: "a cardiac surgery program shall *strive to* maintain an annual volume of 200 or more cases."

- Flexibility for Future Procedures: The methodology ultimately chosen needs to be flexible enough to ensure that appropriate evaluations occur for all current and future therapies. The use of pacemaker and automated internal cardioverter defibrillator (AICD) technologies in particular are subject to the same quality and appropriateness concerns and do not appear to be addressed by recent MHCC deliberations. Transcatheter Aortic Valve Replacement (TAVR)—with multiple different devices involved—and mitral valve interventions with devices such as the Mitra clip are in clinical trials and will likely be approved for use in the near future. Like PCI, there will be the opportunity with these therapies for self-referral and inappropriate use of expensive technologies.

MCSQI is an organization dedicated to ensuring the quality, appropriateness, and cost effectiveness of cardiac therapies in the State of Maryland. We request that the MHCC consider our comments to help ensure the optimal care of patients with heart disease now as well as in the future.

Regards and thank you for your consideration,

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