



Report of the

Clinical Advisory Group on

Cardiac Surgery and PCI Services

Final Report
June 20, 2013

TABLE OF CONTENTS

	<u>Page</u>
Executive Summary	1
I. Introduction.....	3
II. Scope of Work	6
III. Issues Discussed and Recommendations.....	6
Regulatory Process.....	7
Oversight Structure	11
Requirements for New Program.....	13
Requirements for Existing PCI Programs.....	13
Discussion of Recommendations for Institutional Resources	16
Discussion of Recommendations for Patients Suitable for Primary PCI in Settings without On-Site Cardiac Surgery	18
Discussion of Recommendations for Physician Resources	20
Discussion of Recommendations for Volume Requirements	21
Discussion of Process and Outcome Measures	21
Other Issues for Future Discussion	22
 Figure 1: Members of the Clinical Advisory Group on Cardiac Surgery and PCI Services	 5
 Figure 2: Proposed Standards for Selection of Primary PCI Patients and Emergency Aortocoronary Bypass Surgery in Hospitals Without On-Site Cardiac Surgery	 19
 Appendices	
Appendix 1: House Bill 1141	
Appendix 2: CAG Meeting Summaries for September 2012 – April 2013	
Appendix 3: General Proposed Oversight Structure	

Executive Summary

Since 2006, Maryland has only allowed hospitals to perform percutaneous coronary intervention (PCI) services, a treatment for obstructed coronary arteries, at hospitals with cardiac surgery on-site, unless the hospital obtained a waiver and continued to meet certain standards. This approach was adopted because primary, or emergency, PCI is a lifesaving treatment for patients with acute ST-segment elevation myocardial infarction (STEMI), but emergency cardiac surgery may be required for a complication of, or inability to satisfactorily complete, PCI. As cardiologists gained experience with primary PCI and better techniques evolved, the risks of the procedure declined and results improved. Multiple well-structured multi-site clinical trials have validated the safety and efficacy of performing primary PCI for the treatment of STEMI in hospitals without on-site cardiac surgery. In 2012, a team led by Dr. Thomas Aversano of Johns Hopkins presented new research from a multi-site clinical trial (C-PORT E) that found elective (non-primary) PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. About ten Maryland hospitals participated in one or more of these research studies.

As a result of these new research findings, in 2012, the Maryland legislature passed a law directing the Commission to adopt new regulations for the oversight of PCI services at hospitals without on-site cardiac surgery. The law also specified that: a) the Commission establish a clinical advisory group (CAG) to advise the Commission on developing standards for cardiac surgery, emergency PCI services, and elective PCI services; b) a Certificate of Ongoing Performance (COP) review be established as the mechanism for an existing hospital providing specialized cardiovascular services to obtain approval for continuing these services; and c) a Certificate of Conformance (COC) review be developed as the mechanism for an acute general hospital to establish emergency or elective PCI services without obtaining a certificate of need.

The CAG was broadly representative of all perspectives on the delivery of cardiac services in the state and fully consistent with the requirements in the statute. National experts were sought from the standard setting committees at the American College of Cardiology and the Society of Thoracic Surgeons. Recognizing the chair of the CAG had to be both highly respected and independent, MHCC asked Dr. David O. Williams, a nationally known interventional cardiologist, and Loren F. Hiratzka, a highly respected cardiac surgeon, to co-chair the CAG. A list of CAG members is included in Figure 1.

The CAG met eight times between September 2012 and April 2013 to discuss: the regulatory process for issuing COCs; the issuing, renewing, and revoking of COPs; and proposed standards for existing and new PCI and cardiac surgery programs. The CAG relied on the current State Health Plan chapter on Cardiac Surgery and PCI Services, COMAR 10.24.17 (Chapter) as the starting point for the discussion of many of these issues and recommends maintaining some, but not all, of the current policies. The CAG had extensive discussions regarding the practice of PCI and cardiac surgery and the evaluation of institutional quality. The key recommendations are noted below.

The current Chapter emphasizes specific case volume requirements to show conformance with waivers to provide PCI services. Consistent with new documents from professional organizations, the CAG proposes that there be less emphasis on volume standards and greater

emphasis on the provision of high quality care. Specifically, the CAG recommends a target volume of 200 cases annually for both PCI and cardiac surgery programs, with a focused evaluation of program quality for PCI programs with an annual volume less than 200 cases. Similarly, the CAG recommends a focused evaluation of cardiac surgery programs that fall below 100 cases annually. In addition to these volume metrics, the CAG recommends that a focused evaluation of program quality be triggered if concerns are identified from an ongoing review of patient-level data collected and reported to MHCC. Hospitals with PCI services are already required to report such data to the Commission and participate in the CathPCI registry of the National Cardiovascular Data Registry (ACC-NCDR), and the CAG recommends that cardiac surgery programs be required to participate in a similar registry of the Society of Thoracic Surgeons (STS-ACSD). Although all Maryland cardiac surgery programs currently participate in the STS-ACSD registry, this data is not currently reported to MHCC.

In addition to ongoing review of patient-level data, the CAG recommends that hospitals be required to conduct an internal review of randomly selected PCI cases representing at least 10 percent of their total annual case volume and an external review of randomly selected PCI cases representing at least five percent of their total annual case volume. These reviews must include an evaluation of the appropriateness of care through reviewing angiograms and clinical records. Hospitals are accountable for addressing quality concerns raised through these reviews by reporting the results of external reviews to MHCC with the hospitals' proposed corrective actions.

Another way the CAG proposes promotion of high quality care is through the evaluation of specific outcome measures, such as risk-adjusted mortality, and process measures, such as door-to-balloon (DTB) time for primary PCI services. DTB time is currently used to evaluate hospitals' compliance with waivers to provide primary PCI services. However, the CAG recommends modification of the DTB time currently used by the Commission staff to be consistent with the DTB time used by the ACC-NCDR. The ACC-NCDR DTB time excludes transfer cases and cases with delays due to factors generally regarded as outside a hospital's control.

The CAG recognizes that development of outcome measures to evaluate the quality of programs would require an ongoing effort based on audited data. Consequently, the CAG recommends that a standing committee or subcommittee oversee this responsibility. The CAG also recognizes that the regulations and standards may need further modification, and thus Commission staff will likely need ongoing technical or clinical advice as the implementation process unfolds. To meet this need, the CAG recommends the creation of a standing advisory committee with representatives from Maryland providers of PCI services, cardiac surgery services, and other appropriate provider and patient organizations.

I. Introduction

Percutaneous coronary intervention (PCI) is a treatment for obstructed coronary arteries through the use of catheter-based techniques. For patients with acute ST-segment elevation myocardial infarction (STEMI), primary PCI can be a lifesaving treatment. When PCI is performed electively on appropriate patients, it reduces symptoms and improves an individual's quality of life.¹ When PCI first was introduced, it was performed only at hospitals with cardiac surgery on-site because the occurrence of complications and urgent cardiac surgery were high compared with today's patient outcomes.² Over time, the need for emergency surgery has significantly declined³, and well-conducted research has verified the safety and efficacy of performing PCI at hospitals without cardiac surgery.

Beginning in the 1990's there was a clear indication that primary PCI was superior to thrombolytic therapy for the treatment of STEMI. To provide primary PCI rapidly to as many patients as possible, there was interest in performing primary PCI at facilities without on-site cardiac surgery. Early studies suggested this was safe, and a landmark trial called C-PORT demonstrated that primary PCI could be provided safely at hospitals without cardiac surgery on-site and provided superior outcomes compared with thrombolytic therapy.⁴ As a result of this and other research, clinical practice guidelines from professional organizations changed and, in 2006, the MHCC started providing waivers to hospitals who met required standards allowing primary PCI without on-site surgery. Waivers were necessary because Maryland's regulations required the co-location of PCI services and cardiac surgery. There are currently 13 hospitals in Maryland that provide primary PCI services through such a waiver. As PCI continued to evolve, additional research and experience showed the safety of non-primary (elective) PCI at hospitals without on-site surgery. Between 2009 and 2011, several hospitals in Maryland obtained waivers to perform elective PCI without on-site cardiac surgery as part of a large research project known as C-PORT E⁵. This was an investigation to determine whether elective PCI performed at hospitals without cardiac surgery on-site was as safe and efficacious as elective PCI performed at hospitals with cardiac surgery on-site. Eight of 13 hospitals providing primary PCI without on-site surgery were granted waivers for elective PCI services as part of their participation in that research study. There are 10 hospitals in Maryland that provide both cardiac surgery and PCI services.

The results of C-PORT E showed it was safe to provide elective PCI services at hospitals without cardiac surgery on-site under carefully controlled circumstances. The mortality rate six weeks after elective PCI and the occurrence of major adverse cardiac events over the next nine months were not statistically different between hospitals with and without on-site cardiac

¹ American Heart Association. "Percutaneous Coronary Intervention (PCI) without Surgical Back-up Policy Guidance." March 7, 2012. <http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_437472.pdf>

² Ibid.

³ Ibid.

⁴ Aversano, T, Aversano, L, Passamani, E, Knatterud, G., Terrin, M., Williams, D., Forman, S. "Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery." *New England Journal of Medicine*. 2002 April 17; 287(15):1943-51.

⁵ Aversano, T., Lemmon, C.C., Liu, L. "Outcomes of PCI at Hospitals with or without On-site Cardiac Surgery." *New England Journal of Medicine*. 2012 May 10; 366(19):1792-802.

surgery.⁶ As a result of these findings, legislation was enacted in 2012 (HB 1141)(enrolled as Chapter 418 in the 2012 Laws of Maryland) directing the Commission to adopt new regulations for the ongoing provision of PCI services at hospitals without on-site cardiac surgery. A copy of the statute is included in Appendix 1. The law also directed MHCC to establish a clinical advisory group (CAG) that would advise the Commission and recommend standards for cardiac surgery services, emergency PCI services, and elective PCI services for inclusion in regulations.

The statute specifically provided that the CAG shall be composed of experts in cardiac surgery and PCI services, including:

1. Clinicians and representatives from hospitals in the State with and without on-site cardiac surgery services and with and without PCI services;
2. At least one representative of an acute general hospital that is not part of a merged asset system and provides only emergency PCI services; and
3. Other persons with needed expertise from inside and outside the State.

A list of the members of the CAG is included in Figure 1.

⁶ Ibid.

Figure 1: Members of the Clinical Advisory Group on Cardiac Surgery and PCI Services

Co-Chairs:

Loren Hiratzka, M.D.
Bethesda North Hospital;
Good Samaritan Hospital

David Williams, M.D.
Memorial Hospital of Rhode Island;
Harvard Medical School, Division of Brigham
and Women's

Members

Thomas Aversano, M.D.
Greater Baltimore Medical Center
Hopkins Heart Center

Charles Chambers, M.D.
Hershey Medical Center of Penn State
University

Sridhar Chatrathi, M.D.
Doctor's Community Hospital

Gregory Dehmer, M.D.
Texas A&M Health Science Center;
Scott and White Clinic

Yuri Deychak, M.D.
Johns Hopkins Community Physicians Heart
Care;
Suburban Hospital

James Gammie, M.D.
University of Maryland, School of Medicine
and Center for Heart Valve Disease

George Groman, M.D.
Cardiovascular Specialist of Central Maryland;
Howard County General Hospital

Chris Haas, D.O.
Western Maryland Health System

Deborah Harper, R.N.
Heart Center, Sinai Hospital (Baltimore)

Lori Hollowell, R.N.
Mission Lifeline and ACTION-Registry GWTG

Peter Horneffer, M.D.
St. Joseph Medical Center

Keith Horvath, M.D.
NIH Heart Center, Suburban Hospital;
National Heart Lung and Blood Institute

Paul Massimiano, M.D.
Washington Adventist Hospital

Lisa Myers, R.N.
Maryland Institute for Emergency Medical
Services Systems

Michael Peskin, M.D.
Maryland Department of Health and
Mental Hygiene

Richard Pomerantz, M.D.
Saint Agnes Hospital

Jeffrey Quartner, M.D.
MedStar Union Memorial Hospital

Shahid Saeed, M.D.
Medstar Franklin Square Medical Center

Sharon Sanders, R.N.
Carroll Hospital Center

Mitchell Schwartz, M.D.
Anne Arundel Medical Center

Timothy Shanahan, D.O.
Memorial Hospital at Easton

John Shuck, M.D.
Delaware Chapter, American College of
Cardiology;
Bayhealth Medical Center

Gary Walford, M.D.
Johns Hopkins University, School of Medicine;
Johns Hopkins Medicine

Stafford Warren, M.D.
Chesapeake Cardiology

David Zimrin, M.D.
University of Maryland Medical Center

II. Scope of Work

The CAG was charged with making recommendations to MHCC on appropriate systems of oversight for cardiac surgery and PCI services and to identify appropriate quality measures for those services. The specific charge given to the CAG is shown below:

1. Identify key findings from research and key guidelines that are relevant to requirements for the establishment of cardiac surgery and/or PCI services, as well as standards of ongoing performance that should be required for the continuation of such services.
2. Rank factors that the Commission should use in considering the establishment of cardiac surgery and/or PCI services and ongoing review of existing programs (including: *who reviews; what data are reviewed; the frequency of reviews; and “red flags” that will trigger elevated oversight*).
3. Determine points in the regulatory process where institutional accountability can inform the Commission in decision-making.
4. Evaluate appropriate data sources to support program monitoring.
5. Identify key considerations for the Commission, beyond the demonstration of clinical capabilities, in determining circumstances under which it should accept applications to create a cardiac surgery service, or initiate primary PCI or non-primary PCI services at hospital without cardiac surgery on-site. Issues include a balancing of access to services and impact on existing providers.
6. Suggest appropriate duration for certificates.

These topics were addressed at eight meetings held between September 2012 and April 2013. A copy of the meeting summary for each meeting is attached in Appendix 2.

III. Issues Discussed and Recommendations

The first two areas addressed in this report are the CAG’s discussion and recommendations regarding the regulatory process and oversight structure. This information provides a useful framework for understanding the recommendations for standards that were developed by the CAG. This is followed by a discussion of the requirements for new and existing programs. The last section describes issues relating to pediatric cardiac surgery services that were deferred for future discussion because the CAG agreed it did not have the expertise necessary to adequately address the topics. At the beginning of each section, a summary of recommendations is provided, followed by descriptive information on the deliberations of the CAG.

Regulatory Process

Prior to the passage of HB 1141, Maryland hospitals had to obtain a certificate of need to perform cardiac surgery, and hospitals without on-site cardiac surgery that wanted to provide PCI services had to obtain waivers from the requirement for co-location of PCI services and cardiac surgery. HB 1141 established a Certificate of Ongoing Performance as the mechanism for an existing hospital providing primary PCI services, both primary and elective PCI services, or the three services of cardiac surgery, primary PCI and elective PCI to obtain approval to continue providing those services. HB 1141 also established Certificates of Conformance as the mechanism for an acute general hospital to establish emergency (primary) PCI services or elective PCI services without a certificate of need. The recommendations in this section pertain to the new regulatory review process that the MHCC must establish for the issuance of COCs and for the issuance, renewal, and revocation of COPs.

Due to the large number of recommendations for this section, recommendations are listed under subheadings. In addition, recommendations that are new policies or standards are indicated by ****new**; policies and standards that are modifications of existing standards are indicated by ***modified**; recommendations to keep a current policy or standard are unmarked.

Summary of Recommendations

Timing of Renewals and New Approval of Certificates of Ongoing Performance

- *There should be a focus on monitoring programs through data collection that allows for longer than a two year interval between renewals of Certificates of Ongoing Performance. ****new***
- *After obtaining a Certificate of Conformance a program should be required to obtain a Certificate of Ongoing Performance a year later. ****new***

Ongoing Review

- *Focused reviews of programs should be conducted based on triggers recommended by the CAG. These triggers include data reported in the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) and Society of Thoracic Surgeons Adult Cardiac Surgery Data (STS-ACSD) reported to MHCC that raise concerns about the quality of patient care or accuracy of reporting. ****new***

Evaluation of Need

- *Utilization projections should continue to be part of the Chapter to identify patterns of potential over- or under-utilization and to provide context for evaluating the need for new cardiac surgery programs, and a utilization projection should be developed for PCI programs. ***modified***

Impact

- *A proposed new program should not be rejected based solely on the case volume drop at another program with an overlapping service area, as long as each affected program is expected to maintain an annual volume of at least 200 PCI and, if applicable, 200 cardiac surgery cases. *modified*
- *A new primary PCI, elective PCI, or cardiac surgery program will only be considered when the volume of PCI services or cardiac surgery services at other providers in the health planning region or an adjacent planning region will not be negatively affected to a degree that will compromise the financial viability of PCI or cardiac surgery services at the affected Maryland hospitals.⁷ **new*

Approval Policies for new Cardiac Surgery Services

- *Existing PCI Providers. In a comparative review of applications in which all applicants have met all policies and standards, the Commission will give preference to an applicant already providing primary and elective PCI services over a hospital that is not providing any PCI services. **new*
- *Number of New Programs Allowed. The Commission will approve only one new adult or pediatric cardiac surgery program at a time in each Regional Service Area. After a new program has been approved, the Commission will not consider an additional program in that Regional Service Area until the new program has been in operation for at least three years.*

⁷Following publication of this report in June 2013, Mitchell Schwartz, M.D., a member of the CAG contacted Commission staff to request that this recommendation be removed from the report or changed to reflect the recommendation included in the draft report circulated for comment because he believes the draft report circulated for comment reflects the consensus of the CAG, and the final language does not. Specifically, he indicated that hospitals should be referenced rather than programs. Staff reviewed the recordings of the two CAG meetings where recommendations regarding the acceptable level of impact were discussed (December 2012 and April 2013). The use of the term hospital versus program was not discussed at either CAG meeting or in comments received on the draft report circulated for comment. At the December CAG meeting, there was consensus that a proposed new cardiac surgery program should “maintain current level of 200 surgical cases projected annually without adverse impact on other Maryland state programs.” At the April CAG meeting, Staff proposed for discussion a recommendation that “[a] new primary PCI, elective PCI, or cardiac surgery program will only be considered when the volume of PCI services at other providers in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will compromise the financial viability of other hospital providers.” Dr. Schwartz commented that only Maryland providers should be referenced, as the CAG had agreed at the December CAG meeting, and the CAG agreed with this point. When the draft report was circulated, the recommendation discussed at the April meeting was included as written here, except it referred to “Maryland hospital providers.” One CAG member commented that the recommendation should include the impact on cardiac services too. Commission staff included this recommended change in the final report, based on the discussion at the December CAG meeting and comments at the April CAG meeting that there should be symmetry in the recommended standards for cardiac and PCI services. In reviewing the recommendation, Staff concluded that referring to programs is a more accurate reflection of the CAG’s consensus because the CAG’s relevant recommendation at the December meeting referred to the impact on Maryland cardiac surgery programs, not to the impact on hospitals.

- **Minimum Volume Standards.** *The Commission will approve a new cardiac surgery program only if an applicant demonstrates that the proposed program can attain sufficient patients to meet the minimum start-up volume of 200 cases annually within two years. **new*
- **Service to Minority and Indigent Populations.** *In a comparative review of applications in which all applicants have met all policies and standards, the Commission will give preference to the applicant with an established cardiovascular disease prevention and early diagnosis program with particular outreach to minority and indigent patients in the hospital's Regional Service Area. In evaluating the applicant's implemented program, the Commission will consider:*
 - 1) *The applicant's demonstrated record of serving minority and indigent patients with cardiovascular diseases; and*
 - 2) *The applicant's demonstrated record of establishing a program for outreach to the minority and indigent populations with cardiovascular disease.*

Program Closure

- *Program closure should be considered for cardiac surgery programs with a one star composite rating for coronary artery bypass graft (CABG) surgery using the rating scale developed by STS-ACSD for four consecutive six-month reporting periods or cardiac surgery case volume of less than 100 cases for two consecutive years. **new*
- *Both cardiac surgery and PCI programs should be given an opportunity to address deficiencies identified before program closure is ordered by the Commission. **new*

The CAG spent a limited amount of time discussing the regulatory process. Commission staff asked the CAG for feedback at the April meeting on a proposal that Certificates of Ongoing Performance be required every five years, with continuous monitoring of programs through analysis of the National Cardiovascular Data Registry and Society for Thoracic Surgery data and information collected through on-site audits of hospitals. If the information reported to MHCC raised concerns, it would trigger a focused review of a program. A focused review is an investigation of the concerns identified, which may include requests for additional information, additional analysis and auditing of data, and a site visit by auditors and/or MHCC staff. MHCC staff proposed that, if the focused review validates concerns regarding compliance with regulations, a hospital would be required to file a plan of correction within 30 days. The CAG expressed support for this approach, but it did not discuss other additional details included in the staff proposal, such as the frequency of follow-up reports to the Commission or the maximum time period for the initial plan of correction proposed (one year). None of the CAG members objected to the proposed five-year period for renewals, but the CAG did not specifically endorse five years as the ideal period between renewals.

The current Chapter includes utilization projections for cardiac surgery that are based on the historic three-year trend in use rates projected forward three years in conjunction with

population projections and an assumption that migration patterns between health planning regions will not change between the current and future projected years. One CAG member expressed concern about the size of the regions and the amount of time that had passed since the regions were created. Other CAG members suggested that the utilization projections could be useful for identifying potential over-utilization of services. Rather than spending time discussing alternative models for utilization projections, it was proposed that the CAG only consider whether there should be a utilization projection for cardiac surgery and PCI services, without specifically endorsing the current methodology. Commission staff also noted that a utilization projection methodology has not yet been developed for PCI services. The CAG reached consensus in support for having utilization projections as part of the regulatory oversight process.

The CAG recommends lowering the acceptable level of impact on the volume of other programs for cardiac surgery. The current Chapter includes a policy stating that the establishment of a new cardiac surgery program should permit existing programs operating at volumes of at least 350 cases or more annually to continue to operate at volumes of at least 350 cases annually. The CAG proposes that a volume of 200 cases be the new threshold for existing programs, for the sake of consistency with its other recommendations regarding the target volume of 200 cases for existing and new cardiac surgery and PCI programs. The target volume of 200 cases was chosen based on literature that indicates a drop in quality for PCI programs below this level. For cardiac surgery, the target volume of 200 cases was chosen based partly on literature that shows a volume-outcome relationship and that suggests programs may be providing quality services at volumes below 200 cases. The decision to recommend a target volume of 200 cases for cardiac surgery was also influenced by the current Chapter, which states that the minimum volume of cases for a cardiac surgery program should be 200 cases.

In evaluating the potential impact of a new cardiac surgery or PCI program on existing providers, the CAG recommends that only the impact on Maryland providers be considered. In part, the rationale for this recommendation is that hospitals in the District of Columbia and surrounding states are not subject to the same quality parameters that the CAG recommended for Maryland hospitals. Hospitals in the District of Columbia and surrounding states also are not subject to other Maryland regulations and cannot be controlled in any way by MHCC.

There was little discussion of most of the approval policies currently included in the Chapter. Existing policies were either identified as out-of-date by MHCC staff or quickly approved for continued future use. It was noted that the term “minority,” which is used in one of the approval policies, should be defined. One member suggested that the definition should include patients who may face language barriers. The new proposed policy that a program be able to reach a volume of 200 cases within two years was discussed at several meetings. The CAG’s recommendation for this policy is based on literature that suggests better patient outcomes at PCI programs with a volume of 200 or more cases. This policy is also consistent with the recently published ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures.⁸

⁸ Harold, J., Bass, T., Bashore, T., Brindis, R., Brush Jr., J., Burke, J., Dehmer, G., Deychak, Y., Jneid, H., Jollis, J., Landzberg, G., Levine, J., McClurken, J., Issam, M., Muhlestein, J., Pomerantz, R., Sanborn, T., Sivaram, Ch., White, C., and Williams, E. “Statement on Cardiac Interventional Procedures) Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Foundation/American Heart Association/American

The CAG strongly endorses setting volume standards for programs and providers that are consistent with national guidelines. The CAG was aware that new guidelines were anticipated following the final meeting of the CAG and endorsed the use of these guidelines before knowing the content. The CAG also strongly endorses using the volume standards for programs and practitioners as triggers for focused reviews.

For cardiac surgery programs, the CAG discussed thresholds for considering program closure. The CAG recommends that an annual case volume of less than 100 cases for two consecutive years, or a one star composite rating for coronary artery bypass surgery (CABG) from the STS-ACSD for four consecutive six-month reporting periods, be the basis for considering closure of a program. The STS-ACSD star rating system awards hospitals one, two, or three stars, based on 11 factors, with mortality rates heavily weighted (70-80 percent of total score). Approximately 74 percent of programs receive two stars; 13-14 percent of programs receive three stars; and 10-12 percent of programs receive one star. The CAG's recommendations are based on the goal of identifying true outliers with a lower quality of care. However, the CAG also noted that program closure should be preceded by a thorough review. The CAG discussed having a volume threshold below which closure of a PCI program would be considered, but the CAG was unable to reach consensus on a specific volume threshold. A few members of the CAG emphasized that a minimum volume threshold is also necessary in order to be able to accurately assess the quality of programs, and proposed 200 PCI cases as the minimum volume.

Oversight Structure

An important element closely tied to the regulatory review process recommended by the CAG is the presence of an advisory committee on the implementation of regulations. In addition, other committees and organizations are expected to be involved in the regulatory oversight process, such as a committee to review data and advise MHCC staff on its use for evaluating program quality. The specific recommendations of the CAG are summarized below. In addition, a diagram with a general example of the potential oversight structure to be established by MHCC is included in Appendix 3.

Summary of Recommendations

- ***There should be a standing advisory committee with representation of Maryland providers of cardiac surgery and/or PCI services and other appropriate organizations.***
****new**
- ***MHCC should be the authority that empanels the standing advisory committee.***
- ***The role of the committee is to provide advice on the implementation of regulations pertaining to PCI services and cardiac surgery. It should also provide advice on a***

*hospital's plan of correction, when a hospital fails to meet ongoing regulatory requirements. **new*

- *Data from hospitals should be analyzed by MHCC staff to determine hospitals' compliance with established standards for volume and quality in both PCI and cardiac surgery programs.*
- *There should be a data advisory committee or subcommittee that evaluates which quality measures to use for evaluating COPs. This committee should also provide advice on proposed risk adjustment models created to evaluate the mortality rates of hospitals' programs. **new*

Two members of the CAG led efforts to develop proposals for the regulatory oversight structure, and MHCC staff also developed a proposal. These were discussed at the final CAG meeting in April. While there was agreement on key tasks necessary for effective regulatory oversight, such as auditing data and external peer review, there were differences of opinion regarding which committees and organizations should be responsible for certain tasks. For example, it was suggested that the Maryland Consortium for PCI Appropriateness and Quality (MACPAQ)⁹ could audit data while performing the peer review function. However, MHCC proposed that providers be given flexibility to collaborate with MACPAQ or satisfy requirements for external review through other means and suggested that auditing be handled by a completely independent group without ties to a Maryland hospital. Another CAG member suggested that auditing could be done by Maryland physicians who did not have ties to the hospitals under review. Neither strong support nor opposition was voiced by CAG members on these proposals.

The CAG achieved consensus on one of the key elements of the regulatory oversight structure, specifically the necessity of a standing advisory committee to provide advice and input to MHCC staff regarding implementation of the proposed regulations. The advisory committee could also act as a resource to assist in the evaluation of a hospital's plan of correction, when a plan of correction is required because of failure to meet regulatory requirements. It was also agreed that the standing advisory committee should have broad representation from Maryland providers of cardiac surgery and PCI services, but not be exclusive to those providers. It was specifically suggested that the American College of Cardiology be represented. Finally, it was agreed that the standing advisory committee be empaneled by the Maryland Health Care Commission, rather than being an independent, incorporated non-profit organization.

It was suggested that the standing advisory committee have subcommittees focused on the following: data collection and reporting; PCI services; and cardiac surgery services. It was noted that in the future there could be a need for additional subcommittees. The subcommittee structure was also seen as allowing greater representation from providers without creating an unwieldy, large group. With the exception of the proposed data advisory committee, there were no objections to the idea of subcommittees. MHCC staff proposed that the existing Cardiac Data Advisory Committee, which is responsible for evaluating potential quality measures for use in

⁹ MACPAQ is a model for external peer review jointly established by the Johns Hopkins Health System and the University of Maryland Medical System that allows for blinded review of PCI cases, including both written clinical records and angiographic images. A detailed description is included on page 15 of this report.

public reporting, expand its responsibilities to include addressing the use of performance measures to evaluate hospitals seeking a COC or COP.

For the analysis of data related to ongoing performance review, the CAG agrees that MHCC staff should analyze ACC-NCDR and STS-ACSD data to identify signals suggesting quality of care or patient safety may be jeopardized and to identify programs with volumes below the CAG's recommended volume target levels for PCI and cardiac surgery. It was agreed that the analysis of data must be done by an independent entity, rather than Maryland physicians, in order to preserve the integrity of the process.

Requirements for New Programs

In addition to the applicable requirements for existing programs, the CAG recommends the following standard for new PCI programs.

Summary of Recommendations

- ***New sites must complete a PCI development plan that includes appropriate training in multiple care areas, e.g., emergency room, cardiac catheterization laboratory, coronary care unit, and post-procedure unit. The PCI development plan shall include logistical plans for routine cases, as well as emergency situations such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG, and primary angioplasty system failure.***

The CAG recommends keeping one of the current standards in this section of the Chapter. CAG members agree that it is essential for a new program to demonstrate that it has an adequate development plan. The CAG agrees that the plan should include logistical plans for handling different types of patient scenarios such as a detailed description of the recommended plan components in the CPORT-E Manual of Operations. The C-PORT E plan specifications were cited as an example, but an individual facility does not need to copy the C-PORT E plan. The CAG does not recommend keeping the existing standard which states, "All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MIs annually." The CAG did not address setting a minimum case volume for new primary PCI programs.

Requirements for Existing PCI Programs

The CAG reached consensus on maintaining many of the current standards for existing hospitals with PCI services. However, in a few cases the CAG recommends modifying a standard, and a few new standards were also proposed. The new standards are marked with ****new**; modified standards are marked with ***modified**; existing standards are unmarked. The CAG generally focused on concepts rather than developing and endorsing precise language. Due to the large number of recommendations, the recommendations have been grouped together under the same categories that are included in the current Chapter.

Summary of Recommendations

Institutional Resources

- *Provide primary PCI as routine, treatment of choice for all appropriate STEMI patients 24 hours per day, seven days per week.*
- *Have adequate physician, nursing and technical staff to provide cardiac catheterization laboratory (CCL) and coronary care unit (CCU) services to acute myocardial infarction (AMI) patients 24 hours per day, seven days per week.*
- *Provide written commitment by hospital administration signed by the hospital president/CEO to support the program.*
- *Maintain a formal written transfer agreement with a hospital providing cardiac surgery on-site for the unconditional acceptance of patients transferred for any required additional care.*
- *Establish PCI credentialing requirements for the institution.*
- *Establish a multiple care area group that meets monthly.*
- *PCI providers must participate in the ACC-NCDR's ACTION GWTG and CathPCI registries, and providers of cardiac surgery must participate in the STS-ACSD registry.*
***modified**
- *Provide an on-call coverage back-up plan for primary PCI in cases when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMIs occur at one site.* ****new**
- *Maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.*
- *Interventionalists must complete a minimum of 24 hours of continuing medical education credit (CME) in the area of interventional cardiology during every two years of practice*
***modified**
- *Maintain the dedicated staff necessary (RN recommended) for data management, reporting, and coordination with institutional quality improvement efforts.* ****new**
- *Hospitals must have a quality assurance program.*
- *Hospitals must conduct an annual external review of at least five percent of PCI cases and internal review of at least 10 percent of PCI cases performed in the past 12 months.* ****new**

Patients Suitable for Primary PCI in Settings without On-site Cardiac Surgery Are the Following:

- *Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction and Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI for Percutaneous Coronary Intervention.)* ****new**
- *Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.*
- *Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.*
- *Patients who experience a return of spontaneous circulation following cardiac arrest and present at a hospital without cardiac surgery on-site for treatment, when the treating physician(s) believe that transfer to a tertiary institution may be harmful for the patient.* ****new**

Physician Resources

- *Physicians who perform primary PCI should meet the ACCF/AHA/SCAI competency criteria, which is now a minimum of 50 PCI cases annually. A physician who is on the PCI interventionalist roster of a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period will be subject to an external review of all cases in that 24 month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.* ***modified**
- *Physicians shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 and/or completed their training before 1998 and did not seek board certification before 2003.* ****new**
- *Physicians shall obtain board certification within three years of completion of a fellowship in interventional cardiology.* ****new**
- *Physicians newly out of fellowship (less than three years) should not be required to have completed a minimum number of STEMIs during their fellowship training before being allowed to perform primary PCI alone; instead, adequate supervision should be required.* *** modified**

Volume Requirements

- *The target volume for existing programs with both primary and non-primary PCI services is 200 cases annually and the target volume for PCI operators should be at least 50 PCI cases annually. *modified*
- *A PCI program that fails to reach this target volume may be subjected to a focused review. There should not be a minimum volume standard which results in MHCC revoking approval for a hospital to perform PCI services. **new*
- *For primary PCI cases, there should be a trigger for focused review if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers. * modified*
- *The target volume for primary PCI operators should be at least 11 primary PCI cases annually.*
- *The target volume for PCI operators should be at least 50 PCI cases annually.*
- *A cardiac surgery program that fails to reach a target annual volume of 100 cardiac surgery cases will be subjected to a focused review.*

Process and Outcome Measures

- *Hospitals must participate in uniform data collection and reporting. For PCI programs, this requirement is met through participation in the ACC-NCDR, with submission of duplicate information to MHCC. For cardiac surgery programs, this requirement is met through participation in the STS-ACSD registry, with submission of duplicate information to MHCC.*
- *For primary PCI, door to balloon (DTB) time shall be used as one of the metrics to evaluate PCI programs with and without cardiac surgery on-site. DTB time shall be measured consistent with the methodology of the ACC-NCDR.*
- *Risk adjusted mortality rates shall be used to evaluate PCI and cardiac surgery programs.*
- *Additional process and outcome measures will be determined through consultation with a data advisory committee convened by MHCC.*

Discussion of Recommendations for Institutional Resources

The CAG recommends maintaining all existing standards in the Chapter that are listed in the summary table of standards, under the category “Institutional Resources.” The CAG also recommends adding four new standards that are described in greater detail below.

Although the 2011 ACCF/AHA/SCAI Guideline for PCI does not specifically endorse external review, the CAG strongly endorses the value of conducting both external and internal

reviews of cases. The CAG recommends that external review be required because good internal review is challenging for small facilities, and it is sometimes challenging for physicians to criticize their co-workers. It may also be difficult for some physicians to accept negative judgments from co-workers.

The CAG made suggestions concerning which aspects of the external and internal review process should be required. The CAG emphasizes that angiographic review is necessary to evaluate the appropriateness of PCI services and cardiac surgery. The CAG notes that there is less reason to be concerned about inappropriate cardiac surgeries because there is a second opinion built into the process, the cardiologist who refers to a cardiac surgeon. However, the CAG agrees that the appropriateness of cardiac surgery should be evaluated too. The CAG recommends that annually at least ten percent of randomly selected cases be reviewed internally and at least five percent of randomly selected cases be reviewed externally, with a minimum of ten cases reviewed per physician. The number of cases the CAG proposes for review was chosen based on what CAG members believe is typical and necessary for adequate review.

The CAG had the opportunity to learn about one particular model of external peer review that includes a review of angiographic images through a presentation by Dr. Julie Miller at the February CAG meeting. The program, known as the Maryland Consortium for PCI Appropriateness and Quality (MACPAQ), was jointly established by the Johns Hopkins Health System and the University of Maryland Medical System. The program was established to minimize the potential for physician bias by removing identifying information from patient records. The program allows physicians to review the blinded patient records, including the angiogram with analysis of stenosis severity by a quantitative computer program to evaluate the appropriateness of care based on clinical practice guidelines. The results of the reviews are returned to individual physicians and hospitals. The goal of the program is physician education; it is not intended to be punitive. CAG members expressed strong support for the model, and the idea of requiring participation by all PCI and cardiac surgery programs in Maryland was discussed. However, the CAG agreed that hospitals should be granted flexibility in meeting the requirements for external review.

It is essential that PCI programs have physician and cardiac catheterization laboratory (CCL) team coverage 24 hours a day, seven days of the week. This is done through a combination of regular business hours for hospitals' CCLs and on-call coverage by interventionalists. Some hospitals allow physicians to be on-call at multiple hospitals while other hospitals do not allow coverage of multiple hospitals. Individual hospitals make their own decisions. The CAG considered whether physicians should be allowed to have on-call coverage at multiple hospitals. The CAG consensus is that hospitals should continue to decide whether physicians can have on-call coverage at multiple hospitals because, depending on the hospitals' locations, it could be reasonable to allow on-call coverage at multiple hospitals. It was also noted that the limited number of interventionalists may not allow for a policy that strictly limits on-call coverage to only one hospital. Instead, the CAG agrees that hospitals that allow on-call coverage of multiple hospitals should have a back-up plan, should the on-call physician not be available.

In addition to round-the-clock coverage for CCLs, the CAG agreed that a minimum level of continuing medical education (CME) credits should be required for interventionalists. The CAG agrees that 24 CME hours for interventional training over a two-year period should be required. The two-year period rather than an annual requirement was seen as a way to provide flexibility to physicians. The current Chapter includes a requirement that institutions design and implement a formal continuing education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit. However, the current standard does not specify the amount of training required.

The CAG agrees that a requirement for programs to have a quality assurance program is essential. Many of the necessary elements for such a program are included in other standards, such as appropriate use assessment, external review of cases, and data collection.

One of the essential elements for monitoring and evaluating the quality of care for hospitals' PCI and cardiac surgery programs will be data collected and reported to MHCC. Consequently, the CAG recommends that there be dedicated staff for data collection activities. The CAG agrees that it is undesirable to specify the number of full-time equivalent staff required for data processing. Instead, the CAG recommends a requirement for dedicated staff to handle the data collected and reported to MHCC.

Discussion of Recommendations for Patients Suitable for Primary PCI in Settings without On-Site Cardiac Surgery

Before the February CAG meeting, by email, some members suggested that the current recommendations for suitable patients are problematic. Many patients presenting with new or presumably new left bundle branch block (LBBB) do not have confirmed STEMI. In addition, by definition rescue PCI is not primary PCI. It was suggested that national guidelines be referenced instead, specifically the 2011 ACCF/AHA/SCAI Guideline for PCI. The relevant tables from these Guidelines are included in Figure 2. The CAG reached consensus on referencing the ACCF/AHA/SCAI Guidelines, but it was also suggested that the issue of whether patients in cardiogenic shock could be treated by primary PCI at hospitals without on-site cardiac surgery should be explicitly addressed. The CAG agrees that the language in the current Chapter regarding patients in cardiogenic shock is acceptable.

Figure 2: Proposed Standards for Selection of Primary PCI Patients and Emergency Aortocoronary Bypass Surgery in Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with:

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired.
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with:

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support

Source: American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography Intervention Guideline for PCI (2011). Table 7.

Although the CAG is making recommendations regarding patients suitable for primary PCI in settings without on-site cardiac surgery, for non-primary PCI patients, the CAG specifically chooses not to endorse the current standards of the ACCF/AHA/SCAI Guideline for PCI (2011) or the standard of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update (2012). The CAG disagrees with some aspects of these standards, and recommends that outcomes be used to evaluate whether physicians made the correct decisions.

In addition to guidelines on patient suitability and the current definition included in the Chapter, the CAG was asked to consider the suitability of patients who experience a return of spontaneous circulation after cardiac arrest. The Maryland Institute for Emergency Medical Services Systems (MIEMSS) has a protocol for these patients that calls for transport to a Cardiac Interventional Center. Some Maryland hospitals have expressed concerns about performance of primary PCI on such patients under our current definition of “suitability.” The CAG discussed this issue and agreed that the Maryland EMS protocol is reasonable.

Discussion of Recommendations for Physician Resources

In addition to the recommendations regarding physician case volume, the CAG recommended that interventionalists be board certified in interventional cardiology with only a few exceptions. Board certification is a way to assure that the knowledge of interventionalists performing PCI meets high standards. Some interventionalists who started practicing before board certification became available may not be board certified. The CAG agrees that board certification should not be required for those who began practicing before the time board certification became available. This approach was adopted in Massachusetts, and the CAG recommends that Maryland adopt similar regulatory language, which is shown below.

(b) Experienced interventionalists who performed interventional procedures prior to 1998 and/or completed their training before 1998 and did not seek board certification prior to 2003 are exempt from the board certification in interventional cardiology requirement, but must document that their procedural volume and outcomes meet accepted national standards. (Source: 105 CMR 130.940 (G)(3))

The CAG agrees that the CCL medical director should be board certified. The CAG considered whether there should also be an experience requirement of 500 lifetime cases for the CCL medical director, which was discussed in the 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. The consensus of the CAG is that there should not be a requirement regarding the number of lifetime cases for a CCL Director. Such a requirement is seen as unnecessary and not indicative of the quality of the CCL Director. There were also concerns that some current CCL directors may not meet the requirement.

The current Chapter has a standard for physicians newly out of fellowship (less than three years) that provides that such physicians should have completed a minimum of 50 STEMIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone. This standard was not specifically endorsed by the CAG. Instead, the CAG proposes that national guidelines be followed. However, the 2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures¹⁰ did not include a recommendation on the minimum volume of STEMI cases a fellow should perform before being allowed to perform primary PCI alone. The CAG also has reservations about limiting the practice of new fellows and proposes that adequate supervision of fellows be required. The CAG recommends that physicians be required to pass a board exam within three years of completing a fellowship, which is consistent with other specialties.

¹⁰ Harold, J., Bass, T., Bashore, T., Brindis, R., Brush Jr., J., Burke, J., Dehmer, G., Deychak, Y., Jneid, H., Jollis, J., Landzberg, G., Levine, J., McClurken, J., Issam, M., Muhlestein, J., Pomerantz, R., Sanborn, T., Sivaram, Ch., White, C., and Williams, E. "Statement on Cardiac Interventional Procedures) Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Foundation/American Heart Association/American College of Physicians Task Force on Interventional Procedures : A Report of the American College of Cardiology ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery." Online May 8, 2013. < <http://circ.ahajournals.org/content/early/2013/05/07/CIR.0b013e318299cd8a>>.

Discussion of Recommendations for Volume Requirements

The current Chapter includes volume requirements for primary PCI programs without on-site cardiac surgery. The standard provides that “all institutions should perform a minimum of 36 and optimally 49 primary PCI procedures annually.” It is noted that the minimum volume standard should only be considered acceptable in areas of the State where access to a high volume program is not available. The 2013 ACCF/AHA/SCAI Clinical Competency Statement endorsed a minimum of 36 primary PCI cases for institutions, while noting that some exceptions may be reasonable if the institution meets a critical access need. The CAG agreed prior to the publication of this Statement that a program in an urban/suburban location should be subject to a focused review if it falls below 49 primary PCI procedures annually, and a primary PCI program located in a rural area should be subject to a focused review if it falls below 36 primary PCI procedures annually. This recommendation is consistent with the 2013 ACCF/AHA/SCAI Clinical Competency Statement.

The 2013 ACCF/AHA/SCAI Clinical Competency Statement lowered the recommended annual PCI case volume for interventional cardiologists from 75 cases annually to an average of 50 cases per year over two years. This recommendation was not based on strong evidence from literature, but rather reflects expert opinion developed because of the lack of evidence to support a specific volume of cases. Furthermore, the majority of interventional cardiologists in the U.S. currently perform fewer than 75 cases annually.

While the concept of focused reviews for physicians who fall below a particular threshold was endorsed, the implementation of this standard may be problematic. At the February CAG meeting, Ben Steffen, Executive Director of MHCC, emphasized that the Commission’s regulatory oversight authority is limited to cardiac services; it does not encompass regulation of physicians. One CAG member pointed out that it is not clear who should be responsible for the focused reviews of physicians, given that many physicians operate at multiple locations. However, this issue could be addressed by making each hospital responsible for the review of cases performed at its hospital. The CAG agreed to review the language in other states’ regulations pertaining to focused reviews as a starting point for guidance, but found that the regulations of other states do not provide guidance on this issue.

Discussion of Process and Outcome Measures

Hospitals with PCI programs have been required to participate in the ACC-NCDR since July of 2010. Hospitals with cardiac surgery services are not currently required to participate in the STS-ACSD registry, but all Maryland hospitals with cardiac surgery services currently participate in the STS-ACSD registry. The CAG strongly agrees that use of the STS-ACSD registry would minimize the inconvenience and cost of data collection.

MHCC has been evaluating hospitals’ compliance with a door-to-balloon (DTB) time standard that 75 percent of primary PCI cases must achieve a DTB of 90 minutes or less, regardless of whether the patient is a transfer from another hospital or whether patient complications and other non-system delays extended the DTB time. The ACC-NCDR benchmark for primary PCI DTB time excludes those cases. MHCC defines the start of the clock

for DTB measurement as the time when the patient arrives at a hospital, or the time of the first ECG that identifies the patient as having STEMI if the patient is already hospitalized, or the time of the second ECG if the first ECG was negative. CAG members feel strongly that it is not fair to hold a receiving hospital accountable for transfer patients because it has no control over how much time the transfer takes, which is included in the current MHCC measure of DTB time. Although the CAG recommends excluding transfer patients from measurements of a DTB time that is used to evaluate the quality of programs, the CAG recommends that the MHCC track the DTB time for transfer cases separately, as a way to evaluate the efficiency of the system for handling patients that require primary PCI.

Although the CAG reached consensus on the use of the ACC-NCDR benchmark for DTB time, several CAG members expressed concerns about the potential to “game” the statistics by labeling cases as having delays due to non-system problems. It was suggested that the excluded cases should be monitored to prevent such “gaming.”

The CAG discussed using the star rating system of the STS-ACSD registry as the initial outcome reporting measure, and the CAG recommends its use for evaluating the quality of programs. There were some concerns about whether the star rating reports would be misused for advertising, and there was also discussion about whether the public is best served by a composite measure or individual outcome measures. However, the CAG agrees that it would be appropriate to use the star rating as an initial outcome reporting measure and a trigger for focused reviews.

The CAG agrees that risk adjusted mortality rates for primary PCI cases, elective PCI cases, and cardiac surgery should be used as outcome measures. It is essential to use risk adjusted mortality rates, rather than unadjusted rates, in order to accurately compare programs. Some hospitals may treat a greater number of patients that, due to co-morbidities or other factors, are at much greater risk of death. Although these programs may have a higher (unadjusted) mortality rate for patients than other programs, these programs may not be providing worse care. The CAG discussed how risk adjustment should be approached, and agreed that a model should be developed based only on Maryland hospitals, rather than relying on national data.

Although the CAG agrees on only a few measures for evaluating outcomes and quality of patient care, the CAG recommends that other outcome measures should be considered through consultation with a committee or subcommittees dedicated to evaluating the use of ACC-NCDR and STS-ACSD. MHCC staff suggested that this could be handled by an existing group, the Cardiac Data Advisory Committee, which was convened for the purpose of evaluating the use of cardiac data in public reporting. Some members of the CAG expressed support for this idea, but the CAG does not specifically endorse the Cardiac Data Advisory Committee as the best resource for considering the use of additional outcome measures.

Other Issues for Future Discussion

The CAG agrees that certain issues should be deferred for later discussion by a standing advisory group for cardiac surgery and PCI services. The current Chapter includes policies regarding minimum volume requirements for both programs dedicated to pediatric cardiac surgery and programs with both adult and pediatric cardiac surgery. The CAG members prefer

not to make recommendations on these policies because the CAG does not include pediatric cardiologists or pediatric cardiac surgeons. Similarly, the CAG chooses not to make recommendations regarding outcome reporting for pediatric cardiac surgery programs. The CAG notes that the field of pediatric cardiac surgery is rapidly evolving, which makes an evaluation of the appropriateness of care more challenging. There are only two hospitals in Maryland that have pediatric cardiac surgery programs, and neither of these hospitals is dedicated solely to pediatric cardiac surgery.

Appendix 1: House Bill 1141

Chapter 418

(House Bill 1141)

AN ACT concerning

Maryland Health Care Commission – Cardiac Surgery and Percutaneous Coronary Intervention Services

FOR the purpose of requiring, with a certain exception, a certificate of need for the establishment of percutaneous coronary intervention (PCI) services; requiring, beginning on a certain date, an acute general hospital to have a certificate of conformance before the hospital may establish ~~primary~~ emergency PCI services or ~~nonprimary~~ elective PCI services; prohibiting the Maryland Health Care Commission from issuing a certificate of conformance unless the Commission finds that the proposed ~~primary~~ emergency PCI services or proposed ~~nonprimary~~ elective PCI services meet certain standards; providing that a certificate of conformance is not required, notwithstanding certain provisions of this Act, for an acute general hospital to establish ~~primary~~ emergency PCI services or elective PCI services under certain circumstances; requiring an acute ~~care~~ general hospital that provides cardiac surgery or PCI services under certain authorization to obtain and maintain a certificate of ongoing performance to continue to provide cardiac surgery services, ~~primary~~ emergency PCI services, or ~~nonprimary~~ elective PCI services; requiring an acute general hospital that is providing ~~nonprimary~~ elective PCI services under a research waiver issued by the Commission and does not meet certain requirements to obtain a certificate of conformance for its ~~nonprimary~~ elective PCI services before it may obtain a certificate of ongoing performance to provide the ~~nonprimary~~ elective PCI services; requiring the Commission to adopt certain regulations; requiring the regulations to include certain items; requiring the Commission to establish a clinical advisory group for a certain purpose; requiring the Commission to develop certain recommended regulations, post the recommended regulations on its Web site, and submit the recommended regulations to the Governor and certain legislative committees for review and comment; establishing certain parameters for the process established by the Commission for issuing a certificate of conformance; authorizing a certain hospital, notwithstanding certain provisions of this Act, to provide ~~nonprimary~~ elective PCI services until the Commission takes ~~certain actions~~ a certain action; requiring the Commission to consider a certain factor in issuing a certificate of conformance; requiring a certain process and a certain requirement established in regulation to operate and be implemented in certain manners; providing that certain requirements of this Act do not apply to a hospital that provided cardiac surgery services and PCI services on a certain date until the Commission takes certain actions; defining certain terms; and generally

relating to the regulation of cardiac surgery and percutaneous coronary intervention services by the Maryland Health Care Commission.

BY repealing and reenacting, without amendments,

Article – Health – General

Section 19–120(j)(1)

Annotated Code of Maryland

(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments,

Article – Health – General

Section 19–120(j)(2)

Annotated Code of Maryland

(2009 Replacement Volume and 2011 Supplement)

BY adding to

Article – Health – General

Section 19–120.1

Annotated Code of Maryland

(2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

19–120.

(j) (1) A certificate of need is required before the type or scope of any health care service is changed if the health care service is offered:

(i) By a health care facility;

(ii) In space that is leased from a health care facility; or

(iii) In space that is on land leased from a health care facility.

(2) This subsection does not apply if:

(i) The Commission adopts limits for changes in health care services and the proposed change would not exceed those limits;

(ii) The proposed change and the annual operating revenue that would result from the addition is entirely associated with the use of medical equipment;

(iii) The proposed change would establish, increase, or decrease a health care service and the change would not result in the:

1. Establishment of a new medical service or elimination of an existing medical service;

2. Establishment of [an open heart] A CARDIAC surgery, organ transplant surgery, or burn or neonatal intensive health care service;

3. **EXCEPT AS PROVIDED IN § 19-120.1 OF THIS SUBTITLE, ESTABLISHMENT OF PERCUTANEOUS CORONARY INTERVENTION SERVICES;**

[3.] 4. Establishment of a home health program, hospice program, or freestanding ambulatory surgical center or facility; or

[4.] 5. Expansion of a comprehensive care, extended care, intermediate care, residential treatment, psychiatry, or rehabilitation medical service, except for an expansion related to an increase in total bed capacity in accordance with subsection (h)(2)(i) of this section; or

(iv) 1. At least 45 days before increasing or decreasing the volume of one or more health care services, written notice of intent to change the volume of health care services is filed with the Commission;

2. The Commission in its sole discretion finds that the proposed change:

A. Is pursuant to the consolidation or merger of two or more health care facilities, the conversion of a health care facility or part of a facility to a nonhealth-related use, or the conversion of a hospital to a limited service hospital;

B. Is not inconsistent with the State health plan or the institution-specific plan developed and adopted by the Commission;

C. Will result in the delivery of more efficient and effective health care services; and

D. Is in the public interest; and

3. Within 45 days of receiving notice under item 1 of this item, the Commission notifies the health care facility of its finding.

19-120.1.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) “CERTIFICATE OF CONFORMANCE” MEANS AN APPROVAL ISSUED BY THE COMMISSION THAT ALLOWS AN ACUTE GENERAL HOSPITAL TO ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES OR ~~NONPRIMARY~~ ELECTIVE PCI SERVICES WITHOUT A CERTIFICATE OF NEED.

(3) “CERTIFICATE OF ONGOING PERFORMANCE” MEANS AN APPROVAL ISSUED BY THE COMMISSION THAT THE CARDIAC SURGERY SERVICES, ~~PRIMARY~~ EMERGENCY PCI SERVICES, OR ~~NONPRIMARY~~ ELECTIVE PCI SERVICES PROVIDED BY AN ACUTE GENERAL HOSPITAL MEET STANDARDS EVIDENCING CONTINUED QUALITY.

(4) ~~(H)~~ “NONPRIMARY ELECTIVE PCI” MEANS PCI CAPABLE OF RELIEVING CORONARY VESSEL NARROWING ASSOCIATED WITH CORONARY ARTERY DISEASE UNRELATED TO ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (ALSO KNOWN AS “NONPRIMARY PCI”) INCLUDES PCI PROVIDED TO A PATIENT WHO IS NOT SUFFERING FROM AN ACUTE CORONARY SYNDROME, BUT WHOSE CONDITION IS APPROPRIATELY TREATED WITH PCI BASED ON REGULATIONS ESTABLISHED BY THE COMMISSION.

~~(H) “NONPRIMARY PCI” INCLUDES ELECTIVE PCI.~~

(5) “EMERGENCY PCI” (ALSO KNOWN AS “PRIMARY PCI”) INCLUDES PCI CAPABLE OF RELIEVING CORONARY VESSEL NARROWING ASSOCIATED WITH STEMI OR, AS DEFINED BY THE COMMISSION IN REGULATIONS, STEMI EQUIVALENT.

~~(5)~~ (6) “PCI” MEANS PERCUTANEOUS CORONARY INTERVENTION.

~~(6)~~ (7) (I) “PERCUTANEOUS CORONARY INTERVENTION” MEANS A PROCEDURE IN WHICH A CATHETER IS INSERTED INTO A BLOOD VESSEL AND GUIDED TO THE SITE OF THE NARROWING OF A CORONARY ARTERY TO RELIEVE CORONARY NARROWING.

(II) “PERCUTANEOUS CORONARY INTERVENTION” INCLUDES A VARIETY OF CATHETER-BASED TECHNIQUES, INCLUDING BALLOON ANGIOPLASTY.

~~(7) "PRIMARY PCI" MEANS PCI CAPABLE OF RELIEVING CORONARY VESSEL NARROWING ASSOCIATED WITH ST SEGMENT ELEVATION MYOCARDIAL INFARCTION.~~

(8) "STEMI" (ST-SEGMENT-ELEVATION MYOCARDIAL INFARCTION) MEANS A TYPE OF HEART ATTACK OR MYOCARDIAL INFARCTION THAT IS CAUSED BY A PROLONGED PERIOD OF BLOCKED BLOOD SUPPLY, WHICH AFFECTS A LARGE AREA OF THE HEART MUSCLE AND CAUSES CHANGES ON AN ELECTROCARDIOGRAM AND IN THE BLOOD LEVELS OF KEY CHEMICAL MARKERS.

(B) (1) BEGINNING JULY 1, 2012, BEFORE AN ACUTE GENERAL HOSPITAL MAY ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES OR ~~NONPRIMARY~~ ELECTIVE PCI SERVICES, THE HOSPITAL SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FROM THE COMMISSION.

(2) THE COMMISSION MAY NOT ISSUE A CERTIFICATE OF CONFORMANCE UNLESS THE COMMISSION FINDS THAT THE PROPOSED ~~PRIMARY~~ EMERGENCY PCI SERVICES OR PROPOSED ~~NONPRIMARY~~ ELECTIVE PCI SERVICES:

(I) ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES;

(II) WILL RESULT IN THE DELIVERY OF MORE EFFICIENT AND EFFECTIVE HEALTH CARE SERVICES; AND

(III) ARE IN THE PUBLIC INTEREST.

(C) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL HOSPITAL TO ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES IF:

(1) THE ACUTE GENERAL HOSPITAL WAS PROVIDING ~~PRIMARY~~ EMERGENCY PCI SERVICES ON JANUARY 1, 2012; AND

(2) THE COMMISSION DETERMINES THAT THE ~~PRIMARY~~ EMERGENCY PCI SERVICES ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES.

(D) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL HOSPITAL TO ESTABLISH ELECTIVE PCI SERVICES IF:

(1) ON JANUARY 1, 2012, THE ACUTE GENERAL HOSPITAL WAS PROVIDING ELECTIVE PCI SERVICES THROUGH THE C-PORT E REGISTRY UNDER AUTHORITY OF A RESEARCH WAIVER ISSUED BY THE COMMISSION;

(2) THE COMMISSION FINDS THAT THE C-PORT E STUDY PRODUCED RESULTS THAT SHOULD GUIDE PUBLIC POLICY; AND

(3) THE COMMISSION DETERMINES THAT THE ELECTIVE PCI SERVICES PROVIDED BY THE ACUTE GENERAL HOSPITAL CONTINUE TO BE CONSISTENT WITH:

(I) THE REQUIREMENTS OF THE C-PORT E REGISTRY;
AND

(II) EXCEPT FOR THE REQUIREMENTS UNDER COMAR 10.24.05.05, THE REQUIREMENTS FOR MAINTAINING A RESEARCH WAIVER UNDER COMAR 10.24.05 AND 10.24.17, TABLE A-1.

~~(D)~~ (E) (1) THIS SUBSECTION APPLIES TO AN ACUTE ~~CARE~~ GENERAL HOSPITAL THAT PROVIDES CARDIAC SURGERY OR PCI SERVICES UNDER:

(I) A CERTIFICATE OF NEED ISSUED UNDER § 19-120 OF THIS SUBTITLE;

(II) A CERTIFICATE OF CONFORMANCE ISSUED UNDER THIS SECTION; OR

(III) AN EXCEPTION FROM THE CERTIFICATE OF CONFORMANCE REQUIREMENTS UNDER SUBSECTION (C) OR (D) OF THIS SECTION.

(2) AN ACUTE GENERAL HOSPITAL SHALL OBTAIN AND MAINTAIN A CERTIFICATE OF ONGOING PERFORMANCE TO CONTINUE TO PROVIDE:

(I) CARDIAC SURGERY SERVICES;

(II) ~~PRIMARY~~ EMERGENCY PCI SERVICES; OR

(III) ~~NONPRIMARY~~ ELECTIVE PCI SERVICES.

~~(E)~~ (F) AN ACUTE GENERAL HOSPITAL THAT IS PROVIDING ~~NONPRIMARY~~ ELECTIVE PCI SERVICES UNDER A RESEARCH WAIVER ISSUED BY

THE COMMISSION AND DOES NOT MEET THE REQUIREMENTS OF SUBSECTION (D) OF THIS SECTION SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FOR ITS ~~NONPRIMARY~~ ELECTIVE PCI SERVICES BEFORE THE ACUTE GENERAL HOSPITAL MAY OBTAIN A CERTIFICATE OF ONGOING PERFORMANCE TO PROVIDE THE ~~NONPRIMARY~~ ELECTIVE PCI SERVICES.

~~(F)~~ (G) (1) THE COMMISSION SHALL ADOPT REGULATIONS THROUGH AN UPDATE TO THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES TO IMPLEMENT THIS SECTION.

(2) THE REGULATIONS SHALL:

(I) ADDRESS QUALITY, ACCESS, AND COST;

(II) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR OBTAINING A CERTIFICATE OF CONFORMANCE;

(III) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR OBTAINING AND MAINTAINING A CERTIFICATE OF ONGOING PERFORMANCE;

(IV) SET AN APPROPRIATE TIME PERIOD FOR THE EXPIRATION OF A CERTIFICATE OF ONGOING PERFORMANCE; ~~AND~~

(V) REQUIRE, AS A CONDITION OF THE ISSUANCE OF A CERTIFICATE OF CONFORMANCE OR A CERTIFICATE OF ONGOING PERFORMANCE TO AN ACUTE GENERAL HOSPITAL WITHOUT ON-SITE CARDIAC SURGERY SERVICES, THAT ~~AN THE~~ ACUTE GENERAL HOSPITAL AGREE TO VOLUNTARILY RELINQUISH ITS AUTHORITY TO PROVIDE ~~CARDIAC SURGERY SERVICES, PRIMARY EMERGENCY PCI SERVICES, OR NONPRIMARY ELECTIVE~~ PCI SERVICES IF THE HOSPITAL FAILS TO MEET THE APPLICABLE STANDARDS ESTABLISHED BY THE COMMISSION;

(VI) ESTABLISH A PROCESS FOR AN ACUTE GENERAL HOSPITAL THAT IS OUT OF COMPLIANCE WITH MINIMUM STANDARDS FOR A CERTIFICATE OF ONGOING PERFORMANCE TO RETURN TO GOOD STANDING;

(VII) REQUIRE THAT AN ACUTE GENERAL HOSPITAL, EXCEPT FOR AN ACUTE GENERAL HOSPITAL LOCATED IN A PART OF THE STATE THAT DOES NOT HAVE SUFFICIENT ACCESS TO EMERGENCY PCI SERVICES, HAVE PROVIDED EMERGENCY PCI SERVICES IN ACCORDANCE WITH ESTABLISHED STANDARDS BEFORE SEEKING A CERTIFICATE OF CONFORMANCE FOR ELECTIVE PCI SERVICES;

(VIII) PROHIBIT AN ACUTE GENERAL HOSPITAL FROM PROVIDING ELECTIVE PCI SERVICES UNLESS THE ACUTE GENERAL HOSPITAL ALSO PROVIDES EMERGENCY PCI SERVICES;

(IX) INCORPORATE, TO THE EXTENT APPROPRIATE, THE STANDARDS FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES, AND ELECTIVE PCI SERVICES RECOMMENDED BY THE CLINICAL ADVISORY GROUP ESTABLISHED UNDER PARAGRAPH (3) OF THIS SUBSECTION;

(X) INCLUDE REQUIREMENTS FOR PEER OR INDEPENDENT REVIEW, CONSISTENT WITH THE ACCF/AHA/SCAI GUIDELINES FOR PERCUTANEOUS CORONARY INTERVENTION (REPORT OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION TASK FORCE ON PRACTICE GUIDELINES AND THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS), OF DIFFICULT OR COMPLICATED CASES AND FOR RANDOMLY SELECTED CASES; AND

(XI) FOR A CERTIFICATE OF CONFORMANCE FOR ELECTIVE PCI SERVICES, GIVE WEIGHT TO THE EXPERIENCE, PERFORMANCE, INVESTMENT, AND SCOPE OF INTERVENTIONAL CAPABILITIES OF AN APPLICANT HOSPITAL THAT WAS PROVIDING EMERGENCY PCI SERVICES ON JANUARY 1, 2012.

(3) (i) THE COMMISSION SHALL ESTABLISH A CLINICAL ADVISORY GROUP TO ADVISE THE COMMISSION AND RECOMMEND STANDARDS FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES, AND ELECTIVE PCI SERVICES FOR INCLUSION IN REGULATIONS ADOPTED UNDER THIS SUBSECTION.

(ii) THE CLINICAL ADVISORY GROUP SHALL BE COMPOSED OF EXPERTS IN CARDIAC SURGERY SERVICES AND PCI SERVICES, INCLUDING:

1. CLINICIANS AND REPRESENTATIVES FROM HOSPITALS IN THE STATE WITH AND WITHOUT ON-SITE CARDIAC SURGERY SERVICES AND WITH AND WITHOUT PCI SERVICES;

2. AT LEAST ONE REPRESENTATIVE OF AN ACUTE GENERAL HOSPITAL THAT IS NOT PART OF A MERGED ASSET SYSTEM AND PROVIDES ONLY EMERGENCY PCI SERVICES; AND

3. OTHER PERSONS WITH NEEDED EXPERTISE FROM INSIDE AND OUTSIDE THE STATE.

(4) (I) ON OR BEFORE SEPTEMBER 30, 2013, AFTER OBTAINING ADVICE FROM THE CLINICAL ADVISORY GROUP AND OTHER APPROPRIATE STAKEHOLDERS, THE COMMISSION SHALL:

1. DEVELOP RECOMMENDED REGULATIONS UNDER THIS SUBSECTION;

2. POST THE RECOMMENDED REGULATIONS ON ITS WEB SITE FOR PUBLIC COMMENT; AND

3. SUBMIT THE RECOMMENDED REGULATIONS TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE.

(II) THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE SHALL HAVE 60 DAYS FROM RECEIPT OF THE RECOMMENDED REGULATIONS FOR REVIEW AND COMMENT.

SECTION 2. AND BE IT FURTHER ENACTED, That the process established by the Maryland Health Care Commission for issuing a certificate of conformance, as required under § 19-120.1 of the Health – General Article, as enacted by Section 1 of this Act:

(1) shall be similar to the process through which the Commission grants an exemption from certificate of need requirements for merged asset systems; ~~and~~

(2) may not allow interested party status; and

(3) shall consider, for a certificate of conformance to establish elective PCI services, applications from acute general hospitals that were providing emergency PCI services on January 1, 2012, before considering applications from other acute general hospitals.

SECTION 3. AND BE IT FURTHER ENACTED, That, in making a decision to issue a certificate of conformance, the Maryland Health Care Commission shall consider the circumstances of a hospital that is the sole hospital in a county.

SECTION ~~3~~ 4. AND BE IT FURTHER ENACTED, That, ~~notwithstanding:~~

(a) Notwithstanding any other provision of this Act, an acute general hospital whose research waiver for ~~nonprimary~~ elective PCI services was extended by the Maryland Health Care Commission under COMAR 10.24.05 and that continues to

meet the requirements under COMAR 10.24.05 may provide ~~nonprimary~~ elective PCI services under the authorization that existed on January 1, 2012, until the Commission:

(1) ~~makes one of the determinations or findings provided under COMAR 10.24.05.05; and~~

~~(2) depending on the results of the C-PORT E study and the Commission's actions taken under COMAR 10.24.05.05A(1) and B, a determination under § 19-120.1(d)(3) of the Health – General Article, as enacted by Section 1 of this Act;~~

(2) considers the hospital's application under § 19-120.1(b) of the Health – General Article, as enacted by Section 1 of this Act, for a certificate of conformance for its ~~nonprimary~~ elective PCI services; or

(3) makes a determination under COMAR 10.24.05 to terminate the hospital's authority to provide elective PCI services.

(b) On or before December 31, 2012, the Commission shall determine for each hospital providing elective PCI services on January 1, 2012, through the C-PORT E registry under authority of a research waiver issued by the Commission, whether the conditions of § 19-120.1(d)(3) of the Health – General Article are satisfied.

SECTION 5. AND BE IT FURTHER ENACTED, That the process established in regulation under § 19-120.1(g)(2)(vi) of the Health – General Article, as enacted by Section 1 of this Act, for an acute general hospital that is out of compliance with minimum standards for a certificate of ongoing performance to return to good standing shall operate in a manner consistent with the process and underlying principles that:

(1) guided the Maryland Health Care Commission in its oversight of hospitals providing emergency PCI services and elective PCI services under a waiver and a research waiver, respectively; and

(2) provided a reasonable opportunity for an acute general hospital that was out of compliance with performance standards to come into compliance.

SECTION 6. AND BE IT FURTHER ENACTED, That the requirement established in regulation under § 19-120.1(g)(2)(v) of the Health – General Article, as enacted by Section 1 of this Act, as a condition of the issuance of a certificate of conformance or a certificate of ongoing performance for an acute general hospital without on-site cardiac surgery services to agree to voluntarily relinquish its authority to provide emergency PCI services or elective PCI services if the hospital fails to meet the applicable standards established by the Maryland Health Care Commission, shall:

(1) be implemented in a manner consistent with the regulations and underlying principles of the Commission in its oversight of hospitals providing emergency PCI services and elective PCI services under a waiver and a research waiver, respectively; and

(2) require an acute general hospital without on-site cardiac surgery services to:

(i) notify the Commission of the occurrence of specified events; and

(ii) subject to Section 5 of this Act, on written notice from the Commission, immediately relinquish its authority to provide PCI services.

SECTION 7. AND BE IT FURTHER ENACTED, That:

(a) The requirements of § 19-120.1(e) of the Health – General Article, as enacted by Section 1 of this Act, do not apply to a hospital that provided cardiac surgery services and PCI services on January 1, 2012, until:

(1) the Maryland Health Care Commission consults with the clinical advisory group established under § 19-120.1(g)(3) of the Health – General Article, as enacted by Section 1 of this Act, and other appropriate stakeholders on appropriate standards for ongoing performance for cardiac surgery services and PCI services at acute general hospitals with on-site cardiac surgery services;

(2) the Commission develops recommendations for actions, including any changes in State law, that are necessary to enhance the Commission's ability to monitor ongoing performance and compliance with quality standards related to cardiac surgery services and PCI services at hospitals with on-site cardiac surgery services;

(3) the Commission:

(i) reports its recommendations to the Governor and, in accordance with § 2-1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee; and

(ii) posts the report on its Web site for a 60-day review and comment period; and

(4) the Commission adopts regulations to implement the recommendations.

(b) The Commission shall report its recommendations and post its report under subsection (a)(3) of this section on or before December 1, 2013.

(c) The report, recommendations, and regulations under subsection (a) of this section shall include:

(1) a mechanism for an acute general hospital with on-site cardiac surgery services that is out of compliance with performance standards for cardiac surgery services or PCI services to return to good standing; and

(2) a process through which the authority for an acute general hospital with on-site cardiac surgery services to provide cardiac surgery services and PCI services may be revoked for failure to meet performance standards.

SECTION ~~4~~ 8. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2012.

Approved by the Governor, May 2, 2012.

**Appendix 2: CAG Meeting Summaries for
September 2012-April 2013**

Maryland Health Care Commission
Clinical Advisory Group on Cardiac Surgery and PCI Services
Meeting Summary: Meeting of September 27, 2012
BWI Hilton, Baltimore, MD

Advisory Group members present:

Loren Hiratzka, MD, Co-Chair	Lisa Myers, RN
David Williams, MD, Co-Chair	Michael Peskin, MD
Thomas Aversano, MD	Rich Pomerantz, MD
Charles Chambers, MD	Jeffrey Quartner, MD
Greg Dehmer, MD	Shahid Saeed, MD
George Groman, MD	Sharon Sanders, RN
Christopher Haas, DO	Mitchell Schwartz, MD
Deborah Harper, RN	Tim Shanahan, DO
Peter Horneffer, MD	John Shuck, MD
Keith Horvath, MD	Stafford Warren, MD
Paul Massimiano, MD	David Zimrin, MD

Advisory Group members present via phone:

Sridhar Chatrathi, MD	Lori Hollowell, RN
Yuri Deychak, MD	Gary Walford, MD

Regrets:

James Gammie, MD

Staff: Ben Steffen, Paul Parker, Christina Daw

Guests: Edward Hannan, PhD and Sharon-Lise Normand, PhD,

In opening remarks, Ben Steffen, Acting Executive Director of the Maryland Health Care Commission (MHCC), related that during the recent Maryland legislative session, the Commission urged the General Assembly not to write standards for cardiac services into statute. The Commission pointed out that it intended to follow its customary practice of convening an advisory group with clinical expertise to assist staff in arriving at decisions on standards for cardiac services. The requirement for such an advisory group was ultimately put into the legislation, HB1141.

Presentation by Paul Parker, Director, Center for Hospital Services, MHCC Oversight of Regulated Cardiac Services in Maryland (PowerPoint slides attached)

Mr. Parker reviewed Maryland's recent regulatory history regarding cardiac surgery, primary PCI, and non-primary PCI and explained how the Commission's regulation of PCI has evolved, first to permit hospitals to join the CPORT and CPORT-E studies to take place and how the Commission responded to the two CPORT research trials. He noted that the 2012 legislation creates a new framework for regulatory oversight of these services within the traditional Certificate of Need (CON) framework for regulating health care facility capital projects. Establishing a cardiac surgery program will continue to require a CON- but there will be formal requirements for ongoing performance review after establishment of such surgery programs. PCI will be regulated through a Certificate of Conformance process created in the 2012 legislation and programs established will

also be subject to formal requirements for ongoing review of performance.

Mr. Parker briefly summarized MHCC's efforts in hospital performance evaluation (separate from the charge of this Advisory Group), touching specifically on the evaluation of cardiac service-related performance. He stated that the Hospital Performance Evaluation Guide (MHCC's means of public reporting) includes 29 process of care measures, including: six measures for acute myocardial infarction and four for heart failure; six outcome measures, including 30-day mortality rate, and standardized readmission for AMI and heart failure; 10 measures under the Surgical Care Improvement Project, including an infection prevention measure for cardiac surgery and drug management measure for post-operative cardiac surgery patients. In the near future, the Hospital Performance Evaluation Guide will also publish surgical site infection rates for three surgical categories, including CABG, and will also be reporting risk-adjusted cardiac surgery PCI mortality rates based on NCDR reporting. Mr. Parker pointed out that CAG member Gary Walford, M.D. is Chair of the MHCC Cardiac Data Advisory Committee, which advises staff on data issues specifically for public reporting.

MHCC's regulatory programs have used performance evaluation measures on a limited basis. Volume requirements were instituted in the late 1990's for cardiac surgery services, and are only applicable to the two newest CON-approved cardiac surgery programs. A program for establishing primary PCI programs in non-surgical (non-SOS) hospitals through "waiver" from the surgery/PCI co-location requirement of the State Health Plan (SHP) followed CPORT. Waivers have been reconsidered every two years and programs must meet ongoing volume and quality assessment standards for waiver renewal. In 2008, research waivers were granted to eight non-SOS hospitals to participate in CPORT-E as providers of non-primary PCI (npPCI) and those research waivers continue today, with programs required to meet Commission and Registry requirements.

Mr. Parker pointed out that there are clear concerns about the appropriate use of PCI in Maryland that served as context for the recent legislation. He noted that consumers may be confused about the benefits of the service and that all stakeholders are concerned about potential provider misconduct. MHCC authority to provide oversight under Maryland law prior to 2012 was uneven, as cardiac surgery, but not PCI, was a categorically regulated service. The conclusion of the C-PORT E research trial created some uncertainty in the health care community about the future of npPCI research waiver programs going forward. Mr. Parker that the process of updating regulations in the SHP to implement the new regulatory framework for PCI and cardiac surgery services is anticipated to culminate in recommended regulations, and also a December 2013 report containing recommendations regarding ongoing performance and compliance for hospitals with on-site cardiac surgery services.

Dr. Williams noted that the Group's charge, to recommend standards for use in the new regulatory process, will be a challenge with several murky issues, particularly related to PCI.

Following Mr. Parker's presentation, Dr. Groman asked how MHCC will deal with dilution that may arise when new hospitals want permission to start cardiac or PCI programs, which are likely to reduce volume at existing programs.

Mr. Parker responded that the Commission is not necessarily ready to abandon volume standards altogether. The Commission would like to see a regulatory process where the use of data systems

allowing measurement of hospital performance become the primary factor in decision-making on the number and distribution of programs rather than just volume standards. It was argued by some, in the 2011 Technical Advisory Group used to make recommendations on a new regulatory framework that market competition and quality might be used exclusively in regulating PCI but this position was not adopted by the Commission in its report to the legislature. Mr. Steffen observed that there is a sense that volume is only one component of the needed standards.

Dr. Shuck asked about hospitals that want to do a program, but don't have volumes?

Dr. Williams noted that this issue is part of the Group's charge. He also raised the following questions that the Group will address: What are the criteria for quality programs? Is volume part of that? He noted that the landscape has changed regarding volume, so there is a need to be innovative and describe what the Group thinks is the best process.

Mr. Steffen noted that a conclusion that could be drawn from the discussion of the legislation in the General Assembly is that volume may be one component. The General Assembly was cautious in expanding authority for hospitals performing pPCI to perform npPCI. It recognized that guidance was needed to determine criteria for allowing new programs.

Ms. Daw added that while this meeting focuses on other State's oversight and how it is structured, the following meeting will focus on specific research findings and updated guidelines.

Dr. Williams added that, to start the process, the Group needs to expand its knowledge base and learn from others. To that end, the meeting agenda includes reports from New York and Massachusetts.

Presentation by Edward Hannan on New York State's Cardiac Surgery/PCI Reporting Systems: Data Systems, Data Collection, Auditing, and Monitoring. (PowerPoint slides attached)

Dr. Hannan reviewed the history and role of the cardiac databases used in New York. The Department of Health (DOH), which oversees quality in cardiac services, convened a Cardiac Advisory Committee (CAC) in the 1970s to study outcomes and advise the state's CON program. After tracking cases, deaths, and mortality, the DOH decided in the 1980s to develop a registry to account for patient risk factors and determine differences in quality of care. This registry predates STS and NCDR. Each hospital with a CON must participate and must have a designated data manager with clinical training.

New York's data collection process is web-based and uses software that allows hospitals to extract data and adapt software for their own purposes. Quality assurance consists of validation routines, and the accuracy of in-hospital mortality is assured by matching with data from the Statewide Planning and Research Cooperative System (SPARCS). Vital statistics data and National Death Index data are used to match out-of-hospital deaths. Auditing is a critical part of the process to ensure data integrity. Designated data managers with clinical expertise function in all hospitals. Hospitals and cases are chosen for review, based on targeted detection of over-reporting risk factors used in risk adjustment, and on time since last audit. The auditing process and getting mortality data causes delay in reports; however, the DOH decided that a later report with better data was preferable to an earlier report with flawed data. Approximately one-quarter of hospitals

are visited each year and audits are designed to detect over-reporting of risk factors. The software can provide risk-adjusted mortality for surgeons.

Hospitals not surprised by end-of-year reporting because they get information throughout the year and can make improvement efforts based on the data. The outcomes reviewed are risk-adjusted and include 30-day mortality and 30-day readmissions, as well as statistics for three patient types for cardiac surgery. They exclude shock patients and other potential exclusions are under discussion by the CAC. PCIs are reported every year, on a 3-year combined rolling basis. They have volume standards, with the minimum volume for adult cardiac surgery set at 100 and, for pediatric cardiac surgery, the minimum volume is 75. The required minimum volume for PCI is 150. Letters are sent to hospitals with higher than expected mortality throughout the year. A hospital is asked to respond and give reasons for the mortality data that gave rise to the letter. These responses are reviewed by DOH and the CAC; there may be site visits, with ensuing reports. Hospitals are then asked to respond to the site visit review. Over the last twenty years, two to three hospitals have had to discontinue services temporarily after site visits. Administrators and program directors have responded to public releases of data. The consensus is that the data are objective and validated and that the system is clinically relevant. Also, feedback from providers is used to improve the system through the CAC.

Presentation by Sharon-Lise T. Normand, PhD, of the Harvard Medical School and the Harvard School of Public Health: Massachusetts Data Analysis Center (PowerPoint slides attached).

Dr. Normand noted her role as a statistician, rather than as a clinician. She noted that Massachusetts learned from the NY experience. Massachusetts reviews 30-day risk adjusted mortality in cardiac surgery. With PCI, reports are published on two separate groups; one includes shock patients (unlike New York). For PCI, in-hospital mortality is reviewed, though, at this time, all agree it is better to get 30-day follow-up rather than in-hospital mortality. The state may look at appropriateness in the future. Massachusetts decided to use NCDR for PCI and STS for cardiac surgery. The disadvantages are that one has no control over the data, and it takes a long time to change the data. Data vendors need to be certified, and quality varies dramatically. Massachusetts requires a high level of rigor for required auditing. Massachusetts hospitals are compared to other Massachusetts hospitals, rather than benchmarking nationally. This was a key decision made by the Massachusetts Department of Public Health (DOPH).

Massachusetts monitors hospitals and has had program closures. It also monitors physicians, but soon that will no longer be public. There are three-year rolling reviews, with analysis of physicians. In Massachusetts, hospitals perform dual submissions - to a Data Analysis Center (DAC) and to national organizations. The DAC data includes names of patients and doctors. Elements requested by physicians are included; for example, interventionalists wanted to record risk factors of some patients. Hospitals are mandated to send data to the state, or risk program closure. The state obtains more identifiable data in order to assure quality and reviews medical charts to verify data elements, such as shock (like NY).

Regarding funding of the DAC, the initial funding came from taxes. The DOPH funded \$1.5 million in 2002, which covered a project manager, 0.5 FTE programmers, 1 FTE program staff person, and 1 FTE for chart abstraction. Hospitals are responsible for joining STS and NCDR and for collecting and submitting data. The hospital has to have 0.5 or 1 FTE dedicated to this effort,

with the participation outlay by the hospital. Current funding has increased to \$3.5 million for five years. The need for programmers was initially underestimated as was the need for a full-time data manager. Hospitals pay a base rate, and an additional sum based on volume of PCI and cardiac surgeries (with volume data provided by the Massachusetts Research and Education Association [MREA]). The hospital signs a contract with DOPH, Harvard Medical School (HMS), and the MREA. The data are owned by DOPH. Adjudication and chart abstraction are done on a volunteer basis by physicians at participating hospitals. The hospitals must pay to belong to STS and NCDR and must still have a data collection manager. The hospitals use the same data collection instrument but with added elements for submission to Massachusetts. The DOPH made a decision to have HMS perform the data analysis rather than NCDR/ACC or STS, to limit delays in getting final data. HMS has a higher level of threshold for quality, so hospitals usually present data to HMS first, before doing submissions to NCDR/STS. HMS requires better data and has much stronger expertise. Data are accessible for public use purposes. Massachusetts' scope of auditing is similar to New York. Also, the DAC conducts various *ad hoc* analyses for the state.

Dr. Normand concluded with remarks on lessons learned. She noted that last year, on the HMS campus, 650 records were adjudicated for CABG and 561 for PCI, all on volunteer basis. Adjudication is very demanding, involving lots of work undertaken twice per year. The chiefs of cardiac surgery hospitals spend many hours on this task. Data managers also participate in adjudication. Data collection instruments are the national instruments but many of the national elements are collected for reasons not related to public reporting, but the benefit of the other data is having additional data for quality and safety issues. Dr. Normand recommended having an independent entity analyze data. One needs a data analysis center that is not connected to a hospital or to doctors. She pointed out that, for example, HMS 'has no skin in the game' as to whether there are too many surgeries or PCIs.

Post-presentation discussion

Poor performance: If a program or individual falls out of compliance, what happens? Is there an appeals process? How does a program or doctor get back in?

Dr. Normand noted that, in Massachusetts, a hospital is notified long before performance issues become public. DOPH may ask the identity of a hospital with a problem and ask for summaries. The hospital is notified, though hospitals sometimes ignore notification. In some cases, one individual is causing the problem. DOPH has to determine whether to suspend a program or an individual. DOPH may go to the Board of Medicine. A determination to suspend a program is based on several considerations, e.g., if it is a cardiac surgical hospital, what is the impact on PCI? What is the proximity of another hospital that provides the service? Doctors are monitored and reviewed all along. The DOPH decides whether to send information on an individual physician to the medical board.

Dr. Hannan noted that, in NY, outliers are indicated in public reports. Based on consistent outlier status, a site review is triggered in order to determine if there are quality of care concerns that justify suspension or probation. The information goes to DOH, which decides on a course of action.

Dr. Normand noted that if an issue arises in Massachusetts, the Advisory Committee may make recommendations but, if a problem appears serious, an outside entity goes in for a site visit, for which the hospital must pay.

Relative advantages and disadvantages of NCDR / STS and state-specific, custom-designed systems based on expressed needs.

Dr. Hannan noted differences between data systems in New York and Massachusetts. NY does not use STS or NCDR. He noted there are advantages to having the same data. NY is trying to align with NCDR and STS as much as possible, to make it easier for hospitals. While there are good points to having a national system, the disadvantage is that these national data systems are so large - more so with NCDR than STS. There is a large cost in collecting and coding data. Down the road, a good system might make elements in a state system be based as much as possible on national data elements. He suggested not requiring hospitals to report entire NCDR data sets, but rather requiring them to submit a subset of data for state quality assessment. A state system that can augment what states report on national systems has the advantage of greater data quality and higher-value analysis. Compared to national standard systems, a state may have greater value in its analysis system and data quality. Importantly, a state system can integrate outcomes from 30-day mortality.

Dr. Normand recommended that states do their own analysis. For example, Massachusetts adjudicates every shock case for CABG. Adjudication reveals if the hospital is not a stickler for how definitions are used, which makes a difference. They found that reviews of reported shock cases resulted in later down-coding of 50% of the cases because they did not meet the definition of shock. At times, having a hospital report a subset of data is helpful. Despite burdens to the hospital of a national data set, Massachusetts closely examines a smaller set of data elements. Dr. Normand suggested that data adjudication is something that national organizations cannot do.

Dr. Aversano inquired about the adequate level of data (percentage of cases) to be audited. He noted that the whole foundation of risk adjustment problematic if reports are incorrect (citing the example of 50% of shock cases). Are 500 cases sufficient for auditing?

Dr. Hannan stated that if a high number of case reports look bad, then auditing expands to every case with that risk factor. The more auditing, the better, and the more resources for auditing, the better.

Dr. Hannan was asked about resource requirements in New York. He calculated that each case reviewed by the utilization review entity costs \$100-150, with 50 cases reviewed annually at one-quarter of the state's 80 hospitals. If a hospital's data appear to have considerable problems, the onus is on the hospital to pay for data review. The concern is how to best use resources. You want to identify over-reporting of risk factors as well and as inexpensively as you can.

Dr. Normand noted that some research papers have considered the value of adjudication and this literature has not necessarily showed much benefit. However, this adjudication is used for surveillance, not in a clinical trial and, for a surveillance program, the tolerance for variables is different than in clinical trials. How much auditing is needed is a complicated question, including considerations of volume, how data are used, and whether there is a scientific goal.

Dr. Hannan noted his finding that a hospital's risk-adjusted status changes dramatically after auditing. To get the best bang for the buck, one might identify 10-12 significant risk factors and then audit for those factors.

Dr. Zimrin asked how patients were chosen for review. Dr. Normand responded that each year, there is a consensus reached on what variables to examine, and that a subset of random audits are also conducted. She noted that the auditing ensures confirmation of case conclusions. The risk factors may change from year to year, but, for some measures, there is 100% auditing.

Dr. Williams asked what would be the differences in and the impact on review if a state did not have a state system, as in Massachusetts or New York, that requires extensive resources? Dr. Normand suggested that, if a state relied on ACC and STS, it would not be focusing on public accountability and public reporting. She voiced reluctance to trust the validity and completeness of such data.

Dr. Hannan agreed with Dr. Normand that the assessment of hospitals would be different if a state relied on STS and NCDR data. He noted that some hospitals report with better accuracy than others. Hospitals would be compared to other hospitals nationally rather than to its state peers. The main issue (regarding the value of these systems) depends on whether one believes that statewide systems have improved quality as a result of public reporting. Some research articles show that state public reporting is associated with improved quality of care, but others say not. A belief that public accountability, with accurate data, improves quality of care is key.

Dr. Shanahan asked, if the state finds an actual event and investigates it, do other investigations take place at same time? Dr. Hannan noted that he was not sure whether or not JCAHO received information about DOH findings. He noted that the New York DOH pays for the effort and that, unlike in Massachusetts, hospitals do not pay. Funding was almost cut last year, but the program was saved due a Commissioner that is interested in outcomes.

Dr. Groman noted that NCDR has 180 data elements. Dr. Hannan pointed out that NY's database has 40 elements. Dr. Horvath noted that the larger number of data elements in NCDR supports rich data analysis, particularly with respect to risk factors.

Ms. Harper asked how long it took to get data that NY and Massachusetts were comfortable with? Dr. Hannan stated that Maryland can learn from NY and noted that it is difficult to give a number of years to be satisfied with validation. The data system requires extensive auditing. He cautioned that one cannot assume that data are accurate. A good system depends on money for auditing. Dr. Hannan pointed out that Massachusetts relies on doctors to audit each other, but that does not believe that would work in NY because of the size of the state and the number of hospitals.

Other out-of-state members were asked to talk about their state experience. Dr. Hiratzka noted that in Ohio, there are relatively no restrictions on setting up programs. Dr. Dehmer noted that Texas is "wide open" in that there is no CON or other regulatory oversight. The Texas Department of State Health Services collects administrative data (which has its flaws) across a broad spectrum of procedures (THCIC). For cardiology, they collect CABG volume and mortality. While Texas states that the data collected on PCI volume and mortality and AMI volume and mortality are risk adjusted, it does not publish the adjustment algorithm. The data are at least two years behind, in comparison with Massachusetts and NY. The data appear to be ignored in Texas, and the media do

not seize on adverse reports. Dr. Dehmer noted that he never saw a report on a hospital with higher than average mortality. He noted that, however, the reports are enlightening in terms of volume, e.g., the high number of low volume cardiac surgery and PCI programs, with some programs performing fewer than 50 PCIs per year.

Dr. Chambers noted that, in Pennsylvania, public reporting is done for surgeries but not for PCI. In 2003-05, the DOH developed measures regarding PCI data, when 9-10 non-surgical hospitals were given permission to do PCI. The non-SOS hospitals are required to do quarterly reporting of all cases, with immediate review of all emergency cases. Pennsylvania is assessing its next step, following the CPORT E results.

Dr. Hannan also noted that in Pennsylvania, the Healthcare Cost Containment Council reports administrative data quarterly for CABG and PCI, comparing the data with MEPS data and accounting for clinical complexity.

Dr. Shuck noted that Delaware is wide open in allowing programs.

Dr. Hannan noted that Michigan uses the STS data base in an ambitious effort to work on quality control.

Dr. Massimiano related that, in Virginia, the cardiac surgery programs have voluntarily participated in quality review through a robust reporting system.

Dr. Hiratzka asked how can Maryland best use clinical information systems in oversight?

Ms. Daw noted that a comparison with other states with respect to regulation of PCI is included in the background materials provided to the Group. Some states monitor PCI through licensure, while others monitor through CON procedures. Ms. Daw asked how other states approach numerical volume performance thresholds - how is the decision made about whether a program is suspended or closed?

Dr. Williams noted that there are variable, but inconsistent, approaches to responding to volume issues. Dr. Dehmer stated that the volume threshold comes from guidelines drafted by clinical societies/professional associations. The Clinical Competency Writing Committee is fairly far along in a new document on clinical competency. The volume threshold number is being re-evaluated. Indeed, the average interventionalist in the U.S. does not do 75 cases per year, but does a much lower number of PCIs. He said that the average is declining at both national and individual levels. The new document recognizes these trends. He noted that it was likely that by the time the Group finishes its work, the final clinical competency document will be published.

Mr. Steffen noted that, although Maryland requires NCDR participation, it doesn't have time to develop a state-specific cardiac database with anything like the maturity of data systems such as those in NY. He asked Dr. Hannan, if NY were to start today, would NY rely on national data systems? Dr. Hannan recommended accommodating hospitals submitting data to NCDR and STS, and for those do not, one might select important key elements. One could do the job with fewer than 20 elements, and validation is critically important.

Mr. Steffen inquired about the operational costs. Dr. Hannan responded that NY hospitals have their own data coordinators - 0.5 or 1 FTE for PCI, and the same for surgery. The total cost is around \$1.3 million annually. There are 2.5 data analysts, while 6 FTEs are involved in data validation.

Dr. Dehmer observed that it is not feasible to get risk-adjusted mortality for patients if doctors perform very few annually. The PCI flash point in Maryland was about the appropriateness of elective PCI. He pointed out that a provider's case mortality might be great, but that appropriateness is a more key consideration.

Dr. Hannan noted that NY conducted a study that found that 14% of PCIs were inappropriate. In 2012, the New York DOH is assessing appropriateness by hospital, and may adjust reimbursement based on its review of appropriateness. However, there are challenges to assessing appropriateness at the hospital level. With npPCI, one has the statistical power to take a look at the individual level, relative to volume and outcome rate. However, one needs different measures for pPCI, because of the low case volume.

Drs. Williams and Dr. Hiratzka concluded the discussion, and noted that the next meeting will focus on specific measures or guidelines following research findings and updates. In general, earlier meetings will focus on PCI, while later discussion will focus on cardiac surgery.

The meeting adjourned at 3:35 p.m.

**Maryland Health Care Commission's
Clinical Advisory Group on Cardiac Surgery and PCI
Final Summary of Meeting: October 11, 2012**

CAG members present in person:

Loren Hiratzka
Michael Peskin
Deborah Harper
Lisa Myers
George Groman
Yuri Deychak
Gregory Dehmer
Charles Chambers
Keith Horvath
Stafford Warren

Gary Walford
Peter Horneffer
James Gammie
David Zimrin
Jeffrey Quartner
Mitchell Schwartz
Shahid Saeed
Sharon Sanders
Richard Pomerantz

CAG members participating by phone:

David Williams
Tom Aversano

John Shuck
Chris Haas

Staff:

Ben Steffen
Paul Parker
Suellen Wideman

Christina Daw
Theresa Lee

1. Presiding Co-Chair **Loren Hiratzka, MD**, opened the meeting and asked for introductions.
2. There were no comments on the summary from the September 27 meeting.
3. **Dr. Hiratzka** presented the following statement in a document, initiated by MHCC Staff, describing scope of the Clinical Advisory Group. The statement is as follows:

Purpose of Clinical Advisory Group (CAG), as stated in HB1141: "To advise the Commission and recommend standards for cardiac surgery services, emergency PCI services, and elective PCI services for inclusion in regulations.

Scope of the CAG's Charge: The CAG is charged with making recommendations to the MHCC. The MHCC Staff looks to the CAG to offer advice on appropriate systems of oversight for cardiac surgery and PCI services, and also identify appropriate measures for these services.

Staff requests that the CAG:

- a. Identify key findings from research and key guidelines that are relevant to requirements for the establishment of cardiac surgery and/or PCI services, as well as standards of ongoing performance that should be required for the continuation of such services;
- b. Rank factors that the Commission should use in considering the establishment of cardiac surgery and/or PCI services and ongoing review of existing programs (including: *who*

reviews; what data are reviewed; the frequency of reviews; and “red flags” that will trigger elevated oversight);

- c. Determine points of accountability that can inform the Commission in decision-making;
- d. Evaluate appropriate data sources to support program monitoring;
- e. Identify key considerations for the Commission in determining circumstances under which it should accept applications to create a cardiac surgery service, or initiate pPCI or npPCI services at a non-SOS hospital. Issues include a balancing of access to services and impact on existing providers; and
- f. Suggest appropriate duration for certificates.”

Dr. Hiratzka noted that the MHCC seeks recommendations, rather than rules.

4. **Charles Chambers, MD** presented on the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, and on the 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards. (Slides attached.)

Dr. Chambers emphasized the following points.

- The PCI guidelines are couched in statements of the class of recommendation and the level of evidence, based on evidence from the research literature.
- Recommendations for PCI practice include the ongoing utilization of the heart team approach.
- Peer review is particularly important, including outcome driven reviews, evaluation of appropriateness of patient, and random reviews. It will be key to identify the basic components of such peer review.
- Board certification of CCL medical director and all interventionalists is highly recommended, but may be challenging.

The following were key comments made in the discussion of Dr. Chambers’ presentation.

- More than one argued for requirement of board certification for operators.
- The recommended operator volume of 75/year has been around for several years; many do not consider it an absolute threshold, and the upcoming revised statement on Clinical Competency may have new recommendations on volume.
- Regarding peer review, there are many forms, both internal and external. While the guidelines do not specify external review, it is challenging for small facilities to conduct high-quality internal peer review.

5. **Tom Aversano, MD** presented results from the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT-E) study (slides attached), discussed the study’s lessons for policy application, and residual concerns post-study.

The CPORT-E study was a randomized trial comparing medical, economic and quality of life outcomes of non-primary PCI at hospitals with and without on-site cardiac surgery.

Following were key points:

- One of the major motivations for the CPORT-E study was to help sustain stand-alone PCI programs.
- Results: Compared with patients randomized to SOS hospitals,
 - Six week mortality is non-inferior, and
 - Nine month MACE are inferior at non-SOS hospitals.

Dr. Aversano stated the following cautions:

- The patient inclusion and exclusion criteria at non-SOS hospitals are key to the results.
- One of the requirements in CPORT was a rigorous program development. However, this effort is much more than a list of requirements, such as a “quality and error management program.” Site-related political issues, e.g., who covers patients when there are multiple groups, who is on-call in emergency, must be addressed in order for the program to proceed smoothly.
- In terms of policy, while PCI can be performed safely and effectively in hospitals without SOS, the results do not suggest that PCI should be performed in non-SOS hospitals.
- While hospitals can safely perform PCI with institutional volumes of > 200 per year, it has not been established that hospitals can safely perform PCI with institutional volumes of 150 or fewer per year.
- While the results may help policymakers optimize access to PCI service (through programs at non-SOS hospitals), they do not prescribe the optimal geographic distribution of PCI services. The latter must be addressed at the state level.

Dr. Aversano expressed the following concerns going forward post-study at non-SOS hospitals.

- The longer time from the study, the more the data collection and monitoring will deteriorate.
- The definition of quality may be compromised, perhaps to the point of equating quality with a volume number.
- The PCI development program will not be rigorous in preparation at new startup programs.
- There may be unintended consequences of expanded PCI services, in terms of diluting the volume, experience, or quality of existing programs.
- Another unintended consequence of emphasis on institutional volume criteria, may be the performance of inappropriate procedures.

The following key individual points were made in the following discussion:

- Institutional experience is key.
- It will be particularly important to know how to measure quality, and how to prevent volume goals from leading to inappropriate procedures.
- Institutional volume criteria must be reasonable.
- There is a concern about patients appropriate for surgery, being treated with PCI, even unconsciously, in order to meet a volume threshold. On the other hand, there is a similar concern that at SOS hospitals, there may be a bias of performing surgery on complex patients, when PCI may be appropriate.
- One member noted that his hospital has had to deal with low-volume operators. As a practice, when an operator hits a low volume, the program reviews every case. Also, the operators are given time to increase numbers. An operator has two years to reach a volume target.
- In implementing guidelines or standards, a key question is, Who’s accountable to whom? Practitioners should be expected to make clinical judgment, while specific clinical guidelines may not apply to all patients.

- Some members voiced a strong sense that standards should not be set out specifically in statute or regulations; rather, quality reviews may address adherence to specific national guidelines.
 - Oversight needs to include rigorous quality review onsite, with the institutional program, including the CCL medical director, being accountable to the state regulators. Having a strong quality review program onsite is more fundamental, and preferable to specific prescriptions.
 - While one needs to monitor volume to do an evaluation, of greatest importance is the institutional quality review.
6. The group reviewed current Maryland standards, presented by Christina Daw.
- The following standards for non-SOS hospital PCI programs had agreement from the group.
- ACC/AHA development program
 - Hospital administration commitment the PCI program
 - Availability and adequate staff 24/7 for pPCI
 - Written transfer agreement with SOS hospital
 - Written transport agreement with advanced cardiac life support / emergency service
 - Regular meetings for case review
 - Multiple care group monthly meeting
 - QA process – but need to define further what is required for ongoing QA.
 - CME courses required (3/yr)
 - Required on-call participation for operators
 - Operators meet credentialing requirements for institution, plus be board-certified.
 - Required participation in ACTION GWTG / CathPCI registries.

Regarding volume standards, these were seen as guidelines or red flags to indicate the need for further investigation. Everyone is awaiting revised ACC/AHA/SCAI clinical competency guidelines, and there was an expressed preference for holding off on specific numerical targets until the new guidelines have been published.

One member noted that hospitals know their doctors best; they can do proctoring and have special consideration as needed. Some hospitals employ doctors who have accumulated lifetime experience even, though they now have lower numbers. The greater focus should be on focus on quality and outcomes.

Another noted the need to now focus on appropriateness of procedures, not just “success”.

There was a brief discussion of a recent study on the effect of public reporting on treatment outcomes, and a suggestion that we need to carefully determine (through the MHCC Cardiac Data Advisory Committee) what to report in Maryland, and take care to minimize avoidance of complex or difficult patients.

7. After instructing the group to send further comments to Christina Daw, Dr. Hiratzka adjourned the meeting.

**Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Final Summary of Meeting: November 8, 2012**

CAG members present in person:

Loren Hiratzka
David Williams
Michael Peskin
Deborah Harper
Lisa Myers
George Groman
Yuri Deychak
Gregory Dehmer
Charles Chambers
Tom Aversano
Christopher Haas

Timothy Shanahan
Stafford Warren
Gary Walford
Peter Horneffer
James Gammie
David Zimrin
Jeffrey Quartner
Mitchell Schwartz
Shahid Saeed
Sharon Sanders
Richard Pomerantz

CAG members participating by phone: John Shuck

Staff:

Ben Steffen
Theressa Lee
Kendall Kodey

Suellen Wideman
Christina Daw

1. Presiding Co-Chairs **David Williams, MD**, and **Loren Hiratzka, MD**, opened the meeting and asked for introductions.
2. There were no comments on the summary from the October 11 meeting.
3. Dr. Williams reiterated points regarding the scope of the Clinical Advisory Group, and noted the following key questions to be considered by the group:

What factors are key in establishing program?

What factors are key in continuation of established programs?

What are means of monitoring (what information should be provided to the Commission to help it monitor)?

In addition (though not explicitly stated) the group might be expected to weigh in on steps to terminate a program when such an action might be warranted. Dr. Chambers encouraged the group to address compliance as well as closure.

4. Dr. Williams led the group through a discussion document, *Summary of current national guidelines, CPORT-E criteria, and current Maryland standards*. This document, prepared by staff, incorporated current national ACC/AHA/SCAI guidelines and expert consensus documents, as well as standards currently in place in Maryland.

Sources of draft provisions:

2011 PCI GL = 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. ACCF, AHA Task Force on Practice Guidelines, SCAI, Glenn N. Levine, et al. *Journal of the American College of*

Cardiology, published online Nov. 7, 2011.

2012 ECD = 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. ACCF Task Force on Expert Consensus Documents, STS, SVM, Thomas M. Bashore, et al. *Journal of the American College of Cardiology*, published online May 8, 2012.

2008 Performance Measures = ACC/AHA 2008 Performance Measures for Adults with ST-Elevation and Non-ST-Elevation Myocardial Infarction. HM Krumholz, et al. *Circulation* 2008, 118:2596-2648.

(Below are standards for discussion (bullets), followed by response and points of agreement or disagreement, in bold.

I. Institutional Development and Ongoing Performance

- Provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week. Have adequate physician, nursing and technical staff to provide cardiac cath lab and coronary care unit services to acute MI patients 24/7.

There was agreement in support of these two requirements.

- Interventionalists shall be on-call at only one hospital per shift.
There were diverse opinions regarding the feasibility of restricting on-call service to one hospital at a time. Some members thought that the low probabilities of simultaneous STEMIs would render such a rule a practical non-necessity, while others pointed out that some hospitals already have such a rule and it seems reasonable and do-able. The group will gather further input on this question.
- Provide written commitment by hospital administration signed by the hospital president to support the program.
Dr. Aversano argued that this is critical for moving the program forward and committing resources along the way. The group expressed support of this requirement.
- Complete a PCI development plan to involve additional training in multiple care areas, e.g., emergency room, CCL, CCU and step-down unit. The plan shall include logistical plans including plans for recurrent ischemia or infarction, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure, and a quality and error management system. Detailed description of recommended plan components is in CPORT-E Manual of Operations.
It was agreed that a program development plan is critical, particularly for CCL staff, physicians, and post-procedure staff. A plan does not necessarily need to copy the CPORT plan specifications.
- Perform risk stratification for all CCL intervention patients.
This was deemed not necessary, hence the group agreed to delete this provision.
- Maintain at least 1.5 FTE for data management and reporting, including an RN medical data coordinator.
While there was a lack of consensus on how many FTEs are appropriate for a mandate, there was agreement that there must some level of staff dedicated 100% to PCI data collection and management. These activities must not fall by the wayside. There was general support for including this type of requirement in the program development plan.

Possible additional requirements for programs without onsite cardiac surgery.

- Provide a formal written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery. Provide a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of air or ground ambulance within 30 minutes of call.
- Alternative to above -- require agreement guaranteeing arrival of EMS within 20 minutes of call.

The group agreed that written agreements for transfer and transport between non-SOS programs and surgical hospitals are critical. Thirty minutes was the agreed on goal for transport guarantee.

- Adhere to a device selection agreement to prohibit atherectomy at non-SOS sites.
There was general agreement on the principle of avoiding atherectomy at non-SOS hospitals.

II. Institutional Case Volume

- Target volume for facilities performing both primary and elective procedures -- 200 PCI/yr; 36 pPCI/yr [current standard is 36 pPCI for rural; 49 for urban]. Programs with <200 PCI / year in two consecutive years will be reviewed on an individual basis, specifically whether their performance metrics are equivalent to accepted benchmarks, and whether they are in a geographically isolated or under-served area.

Some CAG members were concerned that if these numbers [higher than some states or programs] are targets, the PCI sites may require more stringent overview. Others were concerned about dilution of numbers, and therefore lower quality, through expanding number of sites (as discussed at the first CAG meeting). Key is to set out both safety nets for minimum quality and volume targets. There was not agreement on geographic isolation being a justification for potentially lower quality.

There was general agreement that, if a program doesn't meet volume target, a review is triggered. Also, while there was agreement that <200 PCI/year may be an appropriate number to trigger a review, there was not agreement on the appropriate number to trigger threat of closure. About half of the members present agreed that there should be an annual volume number below which programs must close; yet, there was not agreement about a specific threshold. Dr. Aversano noted that currently, volume counts are a surrogate for quality. Until we know more definitively how to monitor quality (and thus have a viable substitute for a volume threshold), we cannot get away from numbers. The issue of an absolute volume floor was tabled. It was noted that the competence of a site's staff may be as important or more important than institutional volume. The group had consensus that maintaining quality is critical.

There was general agreement that institutional volumes should be reviewed annually. Also, concern was expressed that a mandated volume minimum (related to a "death penalty") may induce unnecessary procedures.

- New programs will have two years to reach absolute minimum volume, but after than programs failing to reach this volume for 2 consecutive years will not remain open under any circumstances.
The group agreed that a new program would be allowed two years to reach the required volume. But there was also agreement that the first year of data from a newly established program must be evaluated carefully as an interim measure.
- Track outcomes through NCDR.
Some voiced concern that this item was too vague to be useful. It was pointed out that Maryland hospitals are already required to submit NCDR ACTION and CathPCI data to the MHCC. When the group discusses data in more specifics at a later meeting, the details of outcome measurement can be developed.

III. Institutional Performance

- Maintain primary PCU Door-to-Balloon time <=90 minutes in at least 75% of appropriate primary PCI cases.
Denominator would consist of 100% of cases with AMI patients presenting with ST-segment-elevation or LBBB on ECG who received primary PCI. Does not drop cases which NCDR excludes in NCDR aggregate measures.

Regularly review cases that were excluded from NCDR benchmarking (>90 minutes DTB time, for non-system or other reasons, e.g., difficulty crossing lesion.)

- Alternative measure: median time from hospital arrival to primary PCI is ≤ 90 minutes among AMI patients with ST-segment elevation or LBBB on ECG who received primary PCI.

Members voiced a preference for the average rather than median measure. The group suggested examining current NCDR exclusions more carefully before deciding whether to include all cases in the denominator. MHCC currently uses 100% of cases; staff believes that 25% outside gave enough wiggle room. Although NCDR excludes certain cases from benchmarking calculations, there should be caution about what types of examples are being dropped (for example, intubation is ok to be dropped, but a case should not be excluded because, “couldn’t get in wire.”). There were calls for more discussion of excluding transfers in D2B measurement.

The group suggesting examining more closely how STEMIs are defined. Also, want to look at an index of performance, so can compare to other systems, in terms of other patients and their mortality.

Questions arose regarding NCDR data quality. According to a member who has worked with both NCDR and STS registry data, NCDR does a fair amount of quality checks, including data logic, and can catch keystroke error. STS (cardiac surgery) registry may be relatively loose.

IV. Operator Performance / Training

- All interventionalists performing PCI shall have certification from the American Board of Internal Medicine in interventional cardiology and participate in the maintenance of certification.
- Primary PCI operators should perform at least 11 primary PCI per year. This is a target, and will be reviewed along with other measures; and it may be changed, pending revised Clinical Competence statement.
- The target volume for total PCI per operator is 75/year, and will be reviewed along with other measures; the target may be changed, pending revised Clinical Competence statement.
- All primary PCI procedures must be reviewed by a designated QA committee, regardless of operator volume.
- Operators must complete a minimum 12 hours of CME per year.
- The CCL Medical Director will review the clinical performance of operators with < target volume, averaged over two years.

There was agreement that the Cath Lab director should be board certified. There was agreement that moving forward, all operators should be board certification in Maryland; however, there was some support for ‘grandfathering’ in some physicians with extensive interventional experience, but who were practicing prior to fellowship program. A question was raised about the number of interventionalists in Maryland who fit into this category, and thus would not meet the requirement without a provision for grandfathering them in. There was agreement on 12 CME/year in cardiology.

Regarding provider volume (11 and 75 as minimums), there was consensus that current guidelines should be the standard for a target volume. However, the rules should be crafted in such a way as to easily change when the new Clinical Competence statement is published.

V. Quality assurance/ Quality improvement

Each PCI program shall operate a quality-improvement program that routinely:

1. Reviews quality and outcomes of the entire program;
2. Reviews results of individual operators;
3. Provides peer review of difficult or complicated cases;
4. Includes risk adjustment at the program and physician levels (can be achieved through NCDR registry participation)
5. Includes random review; blinded review.

CQI Recommended Components

- Standing committee with chairman and staff coordinator
- Database and data collection
- Data analysis, interpretation, and feedback (loop)
- Goals outlined to eliminate outliers, reduce variation, and enhance performance
- Incorporation of practice standardization/guidelines
- Thresholds for intervention
- Appropriate use assessment *[tool to be determined by the program]*

Individual-level quality of care review

- Risk-adjusted outcomes, if statistical tools available.
- Individual data benchmarked against the ACC-NCDR or similar database
- Appropriateness of procedures

Laboratory-level quality of care review

- Risk-adjusted outcomes (can be achieved through NCDR registry participation.)
- Comparison with similar institutions
- Lab data benchmarked against national databases (e.g., ACC-NCDR)
- QA staffing to monitor appropriate use, complications, and outcomes
- Outcomes indicators to include MACE, PCI success.
- Weekly lab conferences
- Regular review of all primary PCI cases with results. Films must be reviewed in at least 20% of cases.
- Regular mortality and morbidity conferences and a review of all major complications.

The group agreed on the need for vigorous quality review and quality improvement programs. There was a difference of opinion about whether an angiographic or film review should be done on all primary PCIs. There was also a suggestion to review all STEMI cases, not simply pPCIs. Staff will gather further input.

There was CAG consensus (except for one member) that blinded review should not be mandated at internal peer review. The group will examine peer review methods and develop recommendations later in the CAG process. As part of that discussion, Dr. Aversano suggested examining peer review plan in development, involving review of angioplasty in the 23 hospitals Maryland hospitals. (Dr. Walford is also involved in this.) Some voiced concern that all peer review, whether internal or external, must be well-designed.

- Cath Lab director must be board certified in interventional cardiology and have performed 500 cases in lifetime experience.

The group was in agreement that CCL medical director should be board certified. Tentative agreement that 500 lifetime cases should be required experience, but there was a question of whether cases performed during fellowship should count toward that lifetime experience.

Dr. Williams noted that the group did not want to rush to finish chart, but would continue the review at the next meeting on December 13. The group also aims to begin work on cardiac surgery issues as well at the December meeting.

- 5. Dr. Williams adjourned the meeting. Staff agreed to accept further input on PCI standards via email from CAG members.**

**Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Final Summary of Meeting: December 13, 2012**

CAG members present in person:

Loren Hiratzka	Deborah Harper
David Williams	Peter Horneffer
Lisa Myers	James Gammie
Yuri Deychak	David Zimrin
Gregory Dehmer	Jeffrey Quartner
Charles Chambers	Mitchell Schwartz
Christopher Haas	Sharon Sanders
Keith Horvath	Richard Pomerantz
Paul Massimiano	

CAG members participating by phone: John Shuck, Thomas Aversano, Lori Hollowell

Staff:

Ben Steffen	Christina Daw
Paul Parker	Suellen Wideman

Presiding Co-Chairs **David Williams, MD**, and **Loren Hiratzka, MD**, opened the meeting and asked for introductions.

Dr. Williams outlined the CAG's ultimate goals – the group and MHCC staff will eventually work up a summary and, if there is not consensus, a minority report. The remaining topics for the PCI discussion will be patient selection and how PCI should be performed. The Commission is not looking for details but broad principles that relate to patient welfare. Today's meeting will focus on Cardiac Surgery; however, there are topics to finish with respect to PCI, e.g., patient selection and how should be PCI be performed. The CAG has not yet discussed PCI monitoring and how to respond to programs that don't meet guidelines; this discussion can be done together for PCI and Cardiac Surgery.

While no meeting has been planned for February, both co-chairs suggested the benefit of having more frequent meetings. Dr. Williams suggested a February meeting, and also that future meetings be longer, from 12:30-4:00, since some people are coming from a distance, and the travel takes up a day anyway.

Paul Parker expressed regret to the members representing hospitals that the topic of this meeting had changed from PCI to Cardiac Surgery on short notice. The group discussed a possible February meeting, to devote to peer review and associated topics. Members will be polled about availability for a February meeting. At the March 14 meeting (the final scheduled meeting), the CAG would pivot back to data systems and monitoring. Paul anticipates that in March staff will have discussion piece on the process for Certificate of Conformance and Certificate of Ongoing Performance. A date for a possible meeting in April was also suggested in case business had not been completed in March. MHCC staff expects that, after the final CAG meeting, a report will be sent out to the group, and then members can file dissenting opinions and minority reports. Staff will use CAG advice to develop the regulatory process mandated in HB 1141.

Christina Daw referred to handouts including maps of Maryland, highlighting the PCI and surgical sites. A map from MIEMSS shows Cardiac Interventional Centers with drive time estimates. (See maps at http://mhcc.dhmd.maryland.gov/cardiacadvisory/Pages/cardiac_advisory/Advisory_Groups_on_Cardiac_Services.aspx) She also thanked CAG members who provided comments on the previous meeting's PCI discussion document.

Presentation by Keith Horvath, MD: Society of Thoracic Surgeons' National Cardiac Database

Keith Horvath, MD, who performs cardiac surgery in Maryland and is the STS representative to the CAG described the STS National Cardiac Database (NCD). The STS NCD registry, which is 23 years old, started as a log, but it has become a premier medical database for the government and organizations to monitor and improve quality care. See slides at:

[http://mhcc.dhmd.maryland.gov/cardiacadvisory/Documents/Horvath%20STS%20Cardiac%20Database%20\(1\).pdf](http://mhcc.dhmd.maryland.gov/cardiacadvisory/Documents/Horvath%20STS%20Cardiac%20Database%20(1).pdf)

Questions:

Do all cardiac surgery hospitals participate?

Dr. Horvath: Currently 95% of all centers participate in STS NCD; urbanized areas and Certificate of Need states have high participation. Among the 5% of hospitals not participating, many are in rural locations, and are small hospitals that find that the STS NCD participation costs are too steep. For this CAG, the key is that all 10 of the cardiac surgery sites in Maryland participate in the STS database.

Data entry procedures vary by site; at Dr. Horvath's hospital data are entered from at various stages by surgeons and nurse practitioners, while administrative staff enter demographic information. Detailed data reports are generated and sent to institutions quarterly, with risk adjusted benchmarking for regional peer and national comparisons sent every 6 months. Some changes in medical practice have been made following STS' established practice of collecting data; for example increased use of Internal Mammary Artery (IMA) after measurement of IMA was systematically collected and reviewed. Duke Clinical Research Institute (DCRI) harvests the data for STS for the analysis and reports.

STS has also developed a quality measurement program, incorporating measures from the National Quality Forum National Voluntary Consensus Standards for Cardiac Surgery, as well as recommendations from the Institute of Medicine 2006 report and elements from the STS NCD. STS uses 11 NQF measures from four Quality of Care domains: perioperative care; intraoperative care, risk-adjusted mortality; and risk-adjusted morbidity. A measure of procedure volume is not included because of concern that volume is a poor surrogate for quality; however, minimum thresholds may have value. STS developed a composite score (published in *Annals of Thoracic Surgery*, 2007) and a created "star rating" system derived from the composite score; star ratings (1,2, or 3 stars) are given two times a year. A 1-star rating is lowest; 3-star rating is highest. *Consumer Reports Health* publishes the hospital star ratings annually. The report process includes initial data cleaning by STS, follow-up response by hospitals, and final version of data report. The reports are released usually 6 months or so after data comes in. The composite score is calculated using risk-adjusted mortality, risk-adjusted any-or-none morbidity, use of the internal mammary artery, and use of all evidence-based perioperative medications.

Summary of questions:

When looking at mortality ("avoidance of mortality") within the relatively small range shown in the data, can a hospital get 1 star with 92% survival, then 2 stars for 94% survival?

Dr. Horvath: Avoidance of mortality has a tight range but the measure can tell if a hospital is significantly above or below national average.

Is there a difference clinically?

Dr. Horvath: The system is trying to show whether patient care is significantly above or below average, based on the composite measure. It may be a small range for survival, but with the number of patients, it's a huge set of data.

What is the distribution of star ratings?

74% of programs are two star; 13-14% are 3 star and 10-12% 1-star; the percent of 1-star programs has decreased over time

STS Auditing: The STS data are audited at 5% of participating sites per year by completely independent auditors. The auditing consists of comparing data to the source documents in the patient record. After the first few years of the STS auditing program, reports for CABG showed 96% agreement between data expert subcommittee and audit. Next year, 8% of sites will be audited.

Other STS Activities: STS has established in-house research. In a paper from the ASCERT study, a prediction model for CABG was developed. STS database encompasses vast majority of CS performed in the United States. The database is risk adjusted, validated, and audited; it also provides composite scoring and may be able in the future to be used as a tool for comparative effectiveness research. Audit results are fed back to the sites for quality improvement purposes.

Summary of Questions:

Is there an obligation to report significant outcome?

Dr. Horvath: STS only feeds back reports to the site.

How does the STS composite score compare to MACE score?

Dr. Horvath: The STS composite score involves not only outcomes, but incorporates processes of care and other evidence-based data components, for example use of internal mammary artery.

Regarding the star rating system, does everyone get a star rating?

Dr. Horvath: Everyone always gets a rating from 1-3.

How does this approach compare to England and other countries?

Dr. Horvath: No other systems have done this risk-adjusted with composite scoring.

Dr. Hiratzka: Particularly it is unique in the range of data evaluated, including pre-, inter-, and post-op data. Follow up measurement is done for in-hospital and 30 days.

How are the documents reviewed?

Dr. Hiratzka: They use source documents, such as operative reports.

Dr. Williams: Are the data available to agencies like MHCC?

Dr. Horvath: You would have to request the data from the hospitals. In some states, they have to send the data to a state agency. [Note: In Maryland, there is not currently a state requirement that cardiac surgery hospitals submit STS data for review.]

Presentation by Loren Hiratzka, MD: CABG Volumes and Outcomes

See slides at: [http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/CABGVolumeOutcomeMHCC12-13-2012final%20\(1\).pdf](http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/CABGVolumeOutcomeMHCC12-13-2012final%20(1).pdf)

There is a volume - outcome relationship of some kind, as demonstrated by a series of studies, with large samples and varying populations. Overall, there is a significant difference in mortality -- as volume increased, mortality decreased. However, some studies showed heterogeneity in outcomes at low and high volume (For example some low volume programs had good/excellent outcomes, while other low volume programs had poor outcomes). In composite scores by volume, lower volume programs have worse composite scores, and scores tend to drop the lower the volume gets.

In research of Japanese cardiac surgery programs, findings showed increase in risk-adjusted mortality in low volume programs (over 3 years); for patients under 65, slight difference in risk-adjusted mortality; over 65, difference is much greater (increased mortality). In Japan, however, most programs have volume < 100 per year.

The key question for the CAG to address: **Is there a population benefit to limiting low volume cardiac surgery programs?**

Summary of questions:

High volume programs probably have a cardio-thoracic residency program, so someone is always available to crack open a chest. Does this make difference?

Dr. Hiratzka: It seems to be mostly process driven [rather than presence of residency program]. Rich Prager (cardiac surgeon in Michigan), has noted that in Michigan, there are many good programs with volume of 100-200, because they pick patients well and have good processes. The AHA/AHA CABG guideline committee has struggled with the volume issue. Based on data from states and Ontario, if you put a target volume at 125, most of the problem of elevated mortality disappears.

Where is the volume in Maryland?

Dr. Gammie: Median is 299 (range from 30+ to 800+)

D. Aversano: One of the arguments for volume is, if you have low volumes, it affects quality. However, it is difficult to assess quality at lower-volume programs because of the volatility of data. It takes multiple years to assess mortality at low-volume programs. How many years do you want to wait if it looks bad?

Dr. Hiratzka: By the next period(s), successive blocks of data. See if a program consistently has only a 1-star rating.

2nd Presentation by Loren Hiratzka, MD: MHCC Cardiac Advisory Group: Recommendations on Cardiac Surgery and the Development of a Cardiac Surgery Subcommittee

See slides at:

[http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/Hiratzka%20Cardiac%20Surgery%20\(MHCC\)%20Recommendations%20\(1\).pdf](http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/Hiratzka%20Cardiac%20Surgery%20(MHCC)%20Recommendations%20(1).pdf)

Dr. Hiratzka presented his draft (“straw man”) proposal for oversight of cardiac surgery in Maryland, for consideration by the CAG. Following is a summary:

1. Purpose of the Program
 - ♥ Oversee cardiac surgery program deployment and quality of cardiac surgical care for all Maryland patients and hospitals.
 - ♥ Provide opportunities for collaborative quality improvement initiatives for all participants.
2. Maryland would have a standing Clinical Advisory Committee (CAG) Cardiac Surgery Subcommittee (CSS).
 - ♥ Two representatives of each hospital providing cardiac surgery services: one surgeon, one hospital representative
 - ♥ Other clinical and administrative members of the CAG to be determined
 - ♥ MHCC to provide regulatory perspective, support staff and resources for all CAG activities
3. Functional elements of the CAG-CSS
 - ♥ Quality assessment tool to be the Society of Thoracic Surgeons (STS), Adult Cardiac Surgery Database (ACSD). The initial report metric would be the composite score “star rating” for coronary artery bypass graft surgery. Other metrics would be selected by the CSS.
 - ♥ All hospitals providing adult cardiac surgery services in Maryland agree to share 6 and 12-month STS reports with MHCC-CAG for review and reporting.
 - ♥ Pursue possibility (with STS/DCRI) regarding mechanism and cost of developing a pooled report of Maryland hospitals as well as ad hoc reports on data elements as needed by the CAG
 - ♥ Semi-annual review of quality metrics the initial elements of which should include STS ACSD Composite Star Ratings with additional elements to be selected by the CAG.
 - ♥ Semi-annual review corresponds to receipt of hospital reports from DCRI. While these reports are 6 months in arrears, the data have been subjected to quality review and audit by both STS and hospitals.
 - ♥ Semi-annual meetings with format and location to be selected by the CAG.
 - ♥ Meetings could be held in a central location. Alternatively, holding the meetings on a rotating basis in each hospital may have value in providing opportunities for more collaborative initiatives, e.g., showcasing specific programs, care patterns, and clinical areas of excellence.
4. Quality improvement initiatives
 - ♥ Examination of 1-star programs for individual program improvement opportunities
 - ♥ Examination of 3-star programs for collaborative program improvement of all hospitals.
 - ♥ Examination of additional clinical areas to improve quality of programs for all Maryland patients as determined by the CAG.
5. Suggested thresholds for focused program review
 - ♥ Two successive 6-month reporting periods with a 1-star composite rating
 - ♥ This parameter is being used by the Michigan cardiac surgery collaborative group. Use of two successive 6-month intervals would reduce the impact of adverse event clustering
 - ♥ Annual surgical case volume less than 100 (Note: A “case” would be defined as a procedure record submitted to the STS-ACSD.)
6. Program and data audit
 - ♥ Audit of data, and of process, outcome and other quality measures would require significant resources that should be provided by MHCC.
 - ♥ Options:
 - ♥ CAG-CSS perform vs external agent (STS, IFMC)
 - ♥ “Blinded” vs not blinded
 - ♥ Quality threshold: 1-star composite ratings for 4 consecutive 6-month reporting periods (Discuss?)

- ♥ Annual surgical case volume threshold: less than 100 for 2 consecutive years (Discuss?)
- ♥ Other quality thresholds to be determined by CSS

7. Threshold for approval of new cardiac surgery program

- ♥ Maintain current level of 200 surgical cases projected annually without adverse impact on other Maryland state programs. (This is the current Maryland State Health Plan rule.)
- ♥ Require participation in STS-ACSD and reporting to CAG as above. Require review of reports and data from first 6 and 12 months to assist new programs to improve quality of data submission.
- ♥ Maintain other elements per current regulations.

Feedback to Dr. Hiratzka's "straw man" proposal for oversight of cardiac surgery in Maryland

Dr. Dehmer commended Dr. Hiratzka on his proposal, and suggested that the proposal could be a model for the CAG's PCI oversight program; moreover, it could be a general model for revascularization.

There was extensive discussion of how or whether the STS registry evaluates the appropriateness of surgery -- While the STS database and analysis address with outcome after procedure; what about who gets surgery? (i.e, indications for surgery?) How does one know that hospital is doing the right surgery on right patient? It was noted that Maryland is a state where there was a visible problem related to appropriateness of procedures.

Dr. Hiratzka believed that addressing the appropriateness question will require extensive resources. Dr. Dehmer pointed out that the ACC/AHA appropriate use guideline document is expected to cover both PCI and CS. Dr. Horneffer noted that appropriateness data could be gathered in cath process.

Dr. Dehmer noted that appropriateness of care in PCI, using NCDR data, is used primarily for evaluation of very complicated patients/procedures. Example: it may be typical to do PCI on patients with single vessel coronary artery lesion, but if the patient has had previous procedures and has re-stenosed, then another PCI is not appropriate. Dr. Massimiano noted that STS data actually include indications for surgery – elective, urgent, emergent; it addressed patient diseases and co-morbidities, so that one can tease out a lot of information regarding appropriateness.

Discussion of functional elements of CAG-CSS:

Despite agreement that, in the current regulatory climate, hospitals are used to sharing data, there was concern expressed about the star rating system. Dr. Hiratzka noted the star rating format as useful as an opportunity to look at 1 & 3 stars, see why 3-star sites are doing so well. Though based on a composite score, mortality comprises 70-80% weight of the overall score. Another concern was that the star system turns into a marketing tool.

In response to concern that hospitals may push some patients out to avoid potentially adverse impact on star rating, Dr. Horvath pointed out that in New York (where this was previously a problem, once New York started doing risk-adjusted measurement, the shifting of patients seemed to have stopped. Dr. Massimiano pointed out that it may sometimes be good thing for a hospital to send hard patients to another center that can better handle the case.

Regarding the number of meetings to be held by the CAG-CSS, Dr. Massimiano was asked to describe the Virginia Cardiac Surgery Quality Initiative. Dr. Massimiano noted that in Virginia VCSQI has quarterly meetings. It looks at sets of data, using best practices and benchmarks to get hospitals to

perform as well as the best performing hospitals. There may be a movement in Maryland to duplicate VCSQI; Dr. John Conte at Johns Hopkins is working on it.

There was concern expressed regarding the delay between procedure, data entry, and feedback to the site. Per Dr. Hiratzka, the data are sent to Duke, DCRI sends it back and the hospital cleans up the data, then sends it back. This process takes about 6 months. Dr. Chambers expressed concern that this turnaround is not timely enough for effective quality improvement programs, which must respond with corrective efforts. Dr William suggested a 2-tier review program, with all deaths reported within 30 days; for certain rare events, they can have different level of responsiveness.

Threshold for focused program review [volume below 100 per year]:

Several argued that this threshold is acceptable for focused review, but not for death penalty (program closure). It was suggested that low-volume programs have scrutiny of mortality.

Regarding data audit and external review, Dr. Hiratzka asked: How much? How often? Who does it? Who supports it? Blinded vs. non-blinded?

At STS, 8% of sites will be audited; between 25-30 cases are audited at each site, and the hospital cost for the audit is in the mid 5-figures. Hospitals are chosen at random; cases are randomly selected.

Dr. Horneffer observed that if a subcommittee is non-punitive, there will be less fear about manipulating data; it may generate a climate of collegiality. Per Ms. Saunders, with so many current reviews of data on a state level, organizations will want the data audited, especially if there is public reporting.

Dr. Dehmer noted that NCDR has an audit program that emulates the STS process. An independent group examines 25 records that are all source documents and does not look at angiograms, they look at the report. A recent article by Messenger, et al ([J Am Coll Cardiol](#). 2012 Oct 16;60(16):1484-8) describes the next phase of NCDR auditing; NCDR has recognized the potential for gaming the program, so NCDR auditing will be ratcheted up.

Dr. Williams argued that “if we don’t look at angiograms, we are not doing a good job.”

Threshold for program closure [1-star composite rating for 4 consecutive 6-month reporting periods]:

Dr. Chambers argued that way to handle true outliers is needed, and the data delay in the STS process is a problem for this type of review. A timeframe of 4 successive periods of 6 months will only give problem hospitals one 6-month period to correct.

Additional concern was expressed about delays in the STS data review and feedback program, as well as the need for careful review of patient selection, appropriateness of surgical procedures.

Several suggested that the volume threshold be the same for approval of new cardiac surgery programs and for ongoing review of established programs. The straw man proposal has a volume threshold of 100 for established programs, and 200 for new programs.

Before adjourning the meeting, Dr. Hiratzka asked the CAG members to think about and provide further feedback regarding: 1) Thresholds for program review, program closure, and new program approval; 2) how to build an effective audit program; 3) elements and processes for ‘focused review’; and 4) final review processes for recommendation to close a program.

**Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Final Summary of Meeting: January 10, 2013**

CAG members present in person:

Loren Hiratzka, Co-Chair
James Gammie, M.D.
George Groman, M.D.
Christopher Haas, M.D.
Deborah Harper, R.N.
Peter Horneffer, M.D.
Keith Horvath, M.D.
Yuri Deychak, M.D.

Paul Massimiano, M.D.
Michael Peskin, M.D.
Jeffrey Quartner, M.D.
Mitchell Schwartz, M.D.
Timothy Shanahan, D.O.
Gary Walford, M.D.
Stafford Warren, M.D.

CAG members participating by phone: Lori Hollowell, R.N. and Sharon Sanders, R.N.

MHCC Staff:

Ben Steffen, Executive Director
Christina Daw
Eileen Fleck
Paul Parker
Sondra McLemore

Presiding Co-Chair **Loren Hiratzka, MD**, opened the meeting at 1:00 pm and asked for introductions. Following the introductions, he asked for any corrections or additions to the written summary of the December 13, 2012 meeting. There were none.

Before beginning the substantive part of the meeting agenda, Christina Daw and Paul Parker made preliminary remarks. Ms. Daw noted that the next two meetings of the CAG are scheduled for **February 28 and March 14, 2013** and that a tentative meeting date of **April 11** for an additional meeting, if needed, has been established. Today's meeting will focus on finishing up consideration of recommendations of the CAG for regulatory oversight of cardiac surgery but we will be circling back to PCI in February. Mr. Parker reminded the Advisory Group that we will be beginning the next two meetings one-half hour earlier, beginning at 12:30 pm, so members may want to get to the venue a little earlier for lunch before the earlier meeting time. The February and March meetings will be at the BWI Marriott Hotel, very close to today's meeting at the BWI Hilton. He also announced that Christina Daw would be leaving the MHCC staff in January to start a new job at CMS and that Eileen Fleck, Program Manager in the Center for Hospital Services would be filling Christina's role as lead staff for the CAG. Advisory Group members can communicate with Eileen via e-mail (eileen.fleck@maryland.gov). Her phone number is 410-764-3287.

Dr. Hiratzka outlined his objectives for the meeting and began by briefly reviewing the draft proposal for oversight of cardiac surgery introduced and discussed at the December, 2012 meeting, using slides that included some revisions to the material presented in December and

with some questions for discussion indicated. After this introduction, he opened the floor for discussion.

The following summarizes the primary issues touched on in the discussion that followed and the elements of the Hiratzka proposal for which consensus emerged. It also identifies areas in which further discussion and work is needed.

Structure of a cardiac surgery oversight process

There is consensus that there should be a standing Clinical Advisory Group on Cardiac Surgery and PCI, with a standing Cardiac Surgery Subcommittee (CSS). The CAG and CSS will provide clinical expertise, review data submitted from the cardiac surgery programs, and make recommendations to the MHCC on oversight criteria, quality of care, and the on-going performance review of cardiac surgery programs. The subcommittee structure is as follows.

- Two representatives of each hospital providing cardiac surgery services: one surgeon, one hospital representative.
- Other clinical and administrative members of the CAG to be determined.
- MHCC to provide regulatory perspective, support staff and resources for all CAG activities.
- The respective chairperson of cardiac surgery and the administrator responsible for hospital operations should attest to and be responsible for all reports originating from each hospital. (Having a hospital operations administrator responsible can help ensure that adequate hospital resources are committed to this project.)
- Semi-annual meetings with format and location to be selected by the CAG.

Further discussion is needed between the CAG and MHCC specifying the duties of CSS in focused program review, and the role of the CSS in program review and consideration of program closure.

Assessment of cardiac surgery quality of care.

The CAG was in agreement that the key quality assessment tool will be the Society for Thoracic Surgeons Adult Cardiac Surgery Database (ACSD).

- All hospitals providing cardiac surgery services in Maryland will be required to participate in the STS ACSD (it was noted that all currently participate), and to share STS data (from the hospitals themselves and/or STS) with the MHCC and CAG for review and reporting.
- The CAG agreed that the initial STS report metric would be the composite score for coronary artery bypass graft surgery. Other metrics are to be selected by the CSS.
- There will be semi-annual review of quality metrics, to include the STS ACSD Composite Star Ratings. Of note, the findings on these metrics will be used as a trigger for focused review and greater examination of a given program; they will not determine, by themselves, the closure of a program.

- Because of the time lag in receiving STS reports (normally 6 months until STS releases reports), case volume reports should be submitted to MHCC-CAG at time of data submission to STS.
- The CAG and MHCC will pursue innovative ways to access some or all of the STS data elements in a more timely fashion (e.g., “super user” status for reviewer, as stroke data coordinators have with national stroke registry database). The MHCC and CAG will contact STS about more direct and comprehensive ways of accessing the STS data in a more timely way. Hospitals will be able to perform quality improvement functions with more timely data.

New program application approval

The CAG agreed to continue the current regulatory requirement that a hospital must demonstrate that it can provide at least 200 surgical cases annually without adverse impact on other Maryland state programs, in order to gain approval to establish a new cardiac surgery program. ***Currently, a program is required to reach 200 cases per year after the second year of operation (hence, a two-year “ramp-up” phase).***

Review of data and reports will be performed at the first six and 12-month milestones, with special attention to improving the quality of data submission.

Thresholds for focused program review

Any of the following findings will be triggers for focused program review.

- Annual surgical case volume <100 cases.
 - Focused review of outcomes will include each death.
- Hospitals with consistent excess observed vs. predicted mortality.
- Outlier status for preoperative factors that affect the surgical risk model, or for intraoperative or perioperative outcomes.
 - The CAG noted a strong need for ongoing data auditing, so that the submitted data can be deemed reliable and accurate.
- Note: Michigan is putting in place a threshold of two successive six-month reporting periods with a One Star composite rating; nevertheless, CAG members suggested that other problems would trigger a focused review before this would occur.

Also, any program may request assistance and review from the CAG-CSS at any time.

Thresholds for program closure

The following “triggers” were accepted as reasonable bases for a review in which program closure is considered. However, CAG members noted any recommendation for program closure would be preceded by a thorough review of that program’s processes and outcomes.

- Annual case volume threshold: less than 100 cases for two consecutive years.
- Quality – One Star composite ratings for four consecutive six-month reporting periods.

- Other quality thresholds and review findings to be determined by the CSS.

External Peer Review

The CAG agreed that oversight will require systematic blinded review of process, outcome, and other quality measures. These reviews will likely require significant resources that should be provided through the MHCC.

CAG members voiced support for a regular external peer review process that would be distinct and separate from a regulatory oversight review. The former would be conducted in a non-punitive, improvement-oriented environment.

There will need to be further discussion regarding whether the CAG-CSS would be involved with this type of external peer review, or this function would be farmed out. More discussion is also needed regarding whether a model like that in place in New England or Virginia (VCSQI) consortium would be appropriate for this external review, and whether it would be separate from the CAG-CSS.

Data Audit

The CAG agreed that data auditing is necessary, and will examine whether the current random audit process by STS adequately meets that need.

Appropriate Use Criteria

The STS and CathPCI data elements were reviewed by the CAG, and it was concluded that the elements would not address the need for assessing appropriateness of cardiac surgery. Further examination by CAG members on measures of patient selection appropriateness may be required. Several members observed that delivery of PCI services currently has a more visible need for deployment of effective appropriate use determination than cardiac surgery.

Adjournment

Prior to adjourning, Mr. Parker updated the group on the December, 2012 review, by MHCC, of the qualification of the eight non-cardiac surgery hospitals that provide non-primary PCI for an exception from the requirement to obtain a certificate of conformance in order to continue the provision of non-primary PCI. This exception was provided for in the 2012 law that created the CAG. Exceptions to the COC requirements were granted to all eight of these hospitals, based on a finding that the results of the C PORT E research should guide public policy and a finding that the eight programs complied with the existing waiver requirements. Copies of the report considered by MHCC in this review were made available.

Dr. Walford noted that the MHCC website is a valuable resource on all of the issues surrounding PCI and its regulation and commended Ms. Daw for the work she has done in developing the site. Ben Steffen closed with thanks to Ms. Daw for the good work she has done in staffing the CAG up to this point. The meeting was adjourned at approximately 3:30 pm.

**Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Final Meeting Summary: February 28, 2013**

CAG members present in person:

David Williams, M.D., Co-Chair
Charles Chambers, M.D.
Yuri Deychak, M.D.
Deborah Harper, R.N.
Peter Horneffer, M.D.
Paul Massimiano, M.D.
Lisa Myers, R.N.
Michael Peskin, M.D.

Richard Pomerantz, M.D.
Jeffrey Quartner, M.D.
Shahid Saeed, M.D.
Sharon Sanders, R.N.
Mitchell Schwartz, M.D.
Gary Walford, M.D.
Stafford Warren, M.D.
David Zimrin, M.D.

CAG members participating by phone: Gregory Dehmer, M.D., Chris Haas, D.O., and John Shuck, M.D.

MHCC Staff:

Ben Steffen, Executive Director
Eileen Fleck
Theressa Lee, (via phone)

Paul Parker
Suellen Wideman

Presiding Co-Chair David Williams, M.D., opened the meeting at 12:30 pm and noted that Dr. Loren Hiratzka, the other Co-Chair, was not in attendance but would be joining the meeting by phone if possible. He briefly reviewed the meeting agenda and asked those attending the meeting to introduce themselves. He welcomed Dr. Julie Miller to the meeting and noted that she would be making a presentation on a proposed model for external peer review to the CAG later in the meeting.

Review of January 10, 2013 Meeting Summary

Following the introductions, he asked for any corrections or additions to the written summary of the January 10, 2013 meeting. It was noted by staff that Dr. Yuri Deychak had erroneously been left off of the list of members in attendance and that this would be corrected. There were no other changes. Dr. Williams noted that any changes identified later by members after further review of the summary could be sent to staff for addition or correction.

Before beginning the substantive part of the meeting agenda, Eileen Fleck reminded the Group that the next meeting of the CAG is scheduled for **March 14, 2013 at the BWI Airport Marriott** and that it was now clear that a final meeting of the CAG will be needed and is scheduled for **April 11, 2013, also at the BWI Airport Marriott**. Both meetings will begin at 12:30 pm.

Review of Recommendations Previously Discussed Regarding PCI Services

Dr. Williams asked the group to turn its attention to the Discussion Guide developed for the meeting and briefly reviewed its format and the agenda. Dr. Williams opened with a call for discussion of the points which the Guide identified as issues on which the Group has already reached consensus. Lisa Myers asked for a clarification of the Guide's intent, asking if the language used in the Guide was intended to reflect a generalized statement of issues and policies or the actual language of regulations to be developed by MHCC. Ms Fleck indicated that the Guide was not intended to represent final regulatory language or guidance.

Dr. Chambers asked if there was any intent to prohibit or limit simultaneous on-call coverage of more than one PCI site by the same physician(s) or was the intent to simply require hospitals to have a back-up plan assuring adequate coverage under such circumstances. It was clarified that the consensus identified was that there would need to be a plan for coverage in place.

It was suggested that the continuing medical education (CME) requirements could provide needed flexibility by using a longer period than one year as the time frame in which a minimum number of hours must be completed. After a brief discussion, consensus was reached that the requirement should be that interventionalists complete a minimum of 24 hours of CME credit every two years. Additionally, there was a consensus that it be specified that the standard refer to CME in "interventional cardiology."

Dr. Williams suggested that the credentialing standard specifically reference "PCI" credentialing requirements and that the completion of a PCI development plan should specify that this is a requirement only applicable to a new PCI site. There was no opposition expressed to these changes.

The meeting moved on to the second page of the Guide to discuss standards "where consensus may be near." It was noted that the first standard in this section represented an amendment to the existing standard, in that it states that hospitals must provide primary PCI as routine treatment of choice for all appropriate **STEMI** patients 24 hours per day, seven days per week (emphasis added) while the existing standard refers to "all appropriate **AMI** patients." It was noted that a current standard states "When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes," such patients can be considered suitable for primary PCI in a setting without on-site cardiac surgery. There was a brief discussion with respect to whether the revised standard would alter the current allowed practice of care. Dr. Williams and others indicated that they did not believe the change from "AMI" to "STEMI" in this standard had that effect.

It was noted that "infarction" was misspelled in the first standard.

Dr. Deychak asked if the required maintenance of one full-time equivalent dedicated staff for data management, reporting, and coordination with institutional quality improvement efforts could be reconsidered, suggesting that more flexibility based on the size of the program is more reasonable. Dr. Williams agreed and suggested that the standard could specify that an "appropriate number" of dedicated staff be in place for these responsibilities, "dedication" being

more important to assure than a specific number of staff, which will vary from program to program. This suggested change was accepted without objection.

Dr. Williams asked for clarification with respect to the comment made concerning use of the ACC/AHA Guidelines for Management of Patients with AMI and Guidelines for PCI as a basis for describing patients appropriate for PCI. The Discussion Guide noted that a commenter had stated that an unrelated congenital disorder should not be a reason to delay AMI treatment. The commenter noted his concern that some of the referenced Guidelines are dated. It was noted that there are many reasons why one would not do primary PCI and that MHCC standards should reflect the new Guidelines when they are published.

Discussion moved on to the remaining “Issues for Discussion” in the Guide. Dr Williams reviewed the list of “recommended components” of a “continuous quality improvement” program from page three of the Discussion Guide and noted the discussion of “case review” as an area on which consensus has not been reached. He suggested that hearing from Dr. Miller might be appropriate as precedent to discussion of this issue area.

The Group moved on to the discussion of the issue of Heart Team Approach. Dr. Gregory Dehmer noted that a “State-of-the-Art Paper” on this topic had recently been published in JACC, and there was a brief discussion of its conclusions. Dr. Williams noted that there are PCI procedures in which the anatomy and preferred treatment approach are so straightforward that delaying treatment with PCI to a second cardiac catheterization lab visit in order to implement a heart team approach is not reasonable. However, more complex cases should utilize this approach to treatment decisions. Therefore, a key issue is assuring that the heart team approach is used in all appropriate cases. Dr. Gary Walford suggested that an adequate and appropriate quality assurance program would assure that the heart team approach is used in all appropriate cases. External peer review, done correctly, will focus on the appropriateness of the treatment approach used, which will reflect on how treatment decisions are made.

Dr. Dehmer stated that he was sending the CAG members the JACC article via e-mail. Dr. Williams suggested that the group revisit this issue area after all have had a chance to review this paper. He also noted that, since the next issue in the Discussion Guide was External Peer Review, it would be an appropriate time to hear Dr. Miller’s presentation.

Presentation by Julie Miller, M.D. on Proposal for External Peer Review

Dr. Miller began her presentation on the External Peer Review (EPR) program for PCI jointly established by Johns Hopkins Health System and the University of Maryland Medical System (Maryland Academic Consortium for PCI Appropriateness and Quality of MACPAQ) and the proposed expansion of this program for use throughout Maryland. Questions and discussion occurred throughout this presentation.

This presentation can be viewed at

http://mhcc.dhmh.maryland.gov/cardiacadvisory/documents/cag_miller_slides_201

A paper prepared by Dr. Miller on the proposal can be viewed at

<http://mhcc.dhmh.maryland.gov/cardiacadvisory/documents/Proposal%20for%20External%20Peer%20Review%20-%20Dr.%20Miller.pdf>

The questions and discussion during and after this presentation are summarized at this point in the Meeting Summary.

Dr. Chambers asked about research comparing the effectiveness of EPR and internal peer review (IPR) and the evidence of superiority of one approach when compared to the other. Dr. Miller answered that such findings are not available for PCI specifically but there is research concluding that EPR has provided greater benefit, overcoming the problems with internal peer review, when these approaches have been used to improve quality and safety in other types of health care service. She conceded that data providing definitive support is limited at this point in time. Dr. Chambers asked if the Maryland hospitals experiencing problems with inappropriate PCI had internal peer review programs. Dr. Miller replied that they did. Their effectiveness was obviously limited.

Dr. Horneffer congratulated Dr. Miller on the proposal and noted that EPR, by eliminating the bias that can plague IPR processes, can effectively address the problems that have been noted with performance even when IPR programs are present. Hospitals have been unwilling to take necessary actions when problems are found for physicians accounting for major case volume and EPR may be the only effective approach for programs with small numbers of active practitioners.

Ms. Fleck asked why the approach that Dr. Miller described cannot largely replace IPR. Dr. Miller responded that the approach is uniquely valuable in examining and assessing appropriateness of use. However, case review for practitioner, team, and facility performance improvement is still a necessary focus of IPR. She also stressed the value of EPR as a process that drives improvements in the quality of data reported and the documentation of key information in case records.

Dr. Williams asked how appropriateness is graded. Dr. Miller said one of three grades is assigned appropriate, uncertain, or inappropriate. These grades are based on consideration of guidelines and also on clinical practice and the angiographic evaluation. Two evaluators are used, with a third brought in when there is disagreement on the review findings. All evaluators are Board certified interventionalists. Ben Steffen asked about the use of the quantitative coronary angiography (QCA) software used by MACPAQ and its availability throughout the State's PCI programs. Dr. Miller said it is not universally available. Richard Pomerantz, M.D. asked if using QCA to reclassify lesions after visual evaluation creates problems? Dr. Miller noted that different thresholds were used in QCA (50%) and visual assessment (70%) of stenosis, based on recognition of the technology's characteristics. QCA is useful in identifying significant discrepancies – gross disparities. She reiterated its value, within the overall process used in EPR,

in assessment of data quality and its benefits with respect to educating physicians about the treatment decision-making process and appropriate use considerations.

Dr. Dehmer noted that angiography is only one of five factors that need to be considered in appropriateness evaluation. He asked, how deep into clinical documentation do reviewers go? Dr. Miller responded that clinical documentation is used and that information is key to effective evaluation of appropriateness of treatment. MACPAQ tries get all of the source documents scanned in, including clinic notes, admission notes, discharge summaries, and stress and nuclear imaging test results. The documentation is blinded by the coordinating center before the EPR is initiated. Dr. Miller noted that MACPAQ has found that many uncertain case grades are due to documentation issues (e.g., insufficient and incomplete records to supplement the angiographic record), reiterating her earlier comments on the value EPR has shown for better record development.

Dr. Williams asked if the blinding really worked in eliminating all potential bias – does recognition by reviewers of hospitals, patients, or doctors ever occur? Dr. Miller said this potential is very limited but can occur. She noted that expansion of a MACPAQ review process statewide would reduce the potential to very small odds because of the larger number of institutions and practitioners participating. Dr. Williams asked if cases are sent back out for review to check for consistency of the process. Dr. Miller indicated that this has not been a standard practice but incorporating such a check method is a good idea.

Dr. Mitchell Schwartz asked if MACPAQ depends on the hospital to evaluate the trend in physician and program performance over time, noting that EPR does not resolve the problem of small institutions where relatively low case volume over long periods of time must be examined to draw reliable conclusions. How do we know if hospitals will handle the information produced by EPR appropriately? Dr. Miller stated that MACPAQ tracks trends in order to assist the institutions and physicians in interpreting the output of the EPR.

The issue of randomness was raised and the ability of the MACPAQ EPR to include cases that arise with contentious issues from the separate and ongoing internal peer review process. A CAG member asked, can such cases be incorporated while maintaining appropriate random selection? Dr. Miller indicated her feeling that such cases can be incorporated while maintaining appropriate random selection as a feature of the process with sufficient case volume reviewed.

Dr. Miller was asked about the rate of reviews per physician. She indicated that MACPAQ seeks to review 10% of cases per physician per hospital per year and a minimum of 10 cases. She was asked if the process has identified differing performance levels by the same practitioner at different hospitals. She said this phenomenon had been observed.

There was more discussion of random selection and Dr. Miller noted that a random algorithm method was employed by MACPAQ. It was noted that “apps” for scoring PCI appropriateness based on selected metrics were available (e.g., a given patient profile could be scored as “appropriate” or “rarely appropriate.”) Dr. Miller stated that MACPAQ does not use an electronic “app.” The EPR is, in that sense, manual.

A comment was made about the importance of measuring fractional flow reserve (FFR) for physiologic assessment and the importance placed by MACPAQ's process on whether an FFR was done. The commenter noted a concern with being overly critical of treatment decisions made without this measurement. Dr. Miller stated that the MACPAQ process appropriately balanced the value and limitations of the pertinent test results in the record.

It was noted that there is a hospital in Maryland doing blinded, random IPR.

Dr. Williams commented that EPR could focus on identifying specific bands of lesion stenosis, such as the more questionable low percentage values, as an approach to addressing more objective problems and putting less emphasis on those (e.g. 50% + stenosis) where the range of interpretation presents less clarity on appropriateness.

Dr. Williams asked Dr. Miller to outline the barriers to expanding the MACPAQ model statewide – why can't we do it tomorrow? Dr. Miller stated that "buy-in" needs to come from hospitals and physicians and they will need to understand and accept the burden it will place on them. She identified the primary burden as providing the data, which can be accomplished electronically, but requires assembling, organizing and scanning the documentation for submission. MACPAQ uses a web-based link for use by physicians. Various people perform these tasks at hospitals, including non-physician or nurse administrative staff.

Redaction to enable blinded review was briefly discussed. Dr. Miller explained that redaction begins at the hospital (patient and physician identifiers) and is completed at the MACPAQ coordinating center (hospital identifiers), providing a good double check for blinding.

Funding the EPR model was discussed. Dr. Miller explained that the sponsoring institutions, so far, are funding this effort "on the side" but, long-term, a more permanent funding arrangement would need to be established. Expanding the program statewide using the infrastructure already in place will hold down costs to the participating hospitals and the NCDR registry data system is already universal, with the EPR program improving the ability to use this data through data validation.

Dr. Williams asked about how the system handles patient choice, e.g., the patient who does not want to undergo surgery even when this is the best treatment option, which is not uncommon. Dr. Miller noted that the EPR process can effectively address this factor when good documentation is present. It will not "score" as inappropriate treatment selection for the practitioners or hospitals and will document the higher risk profile of this person as a PCI patient. An unusual pattern of patients rejecting recommended treatments at one hospital or for one team of practitioners would be concerning.

Dr. Dehmer emphasized the importance of pattern recognition. Most everyone has an inappropriate case at some point. It's all about establishing the pattern. He asked about reviewer qualification, training, and assessment and also asked if MACPAQ's goal would be to use physicians from all over the state as reviewers. Dr. Miller stated that the intent is to involve physicians from all over the state in reviews. This is important to reap the educational benefits

of the process. Reviewers are trained in the guidelines and continually updated on new guidance that emerges. The CORE lab component of the process provides a way to monitor reviewer performance with respect to consistent “over” or “undercalling.” She agreed with Dr. Dehmer that the pattern of performance revealed over time is what the process is designed to look for, not problems arising in an individual case.

Dr. Williams asked about the ultimate scope of MACPAQ - what would be its “charge” if expanded statewide. Dr. Miller viewed its primary mission as meeting institutional needs in Maryland for peer review that effectively functions as a quality assurance and improvement tool. It is a platform that could be expanded over time beyond its primary focus on EPR as needed by hospitals and regulators, if the desire and capability to function in new ways is there.

Two questions were posed. First, if the process tracks a physician with a problematic pattern, the hospital is given the data, but takes no action, then what happens? Second, will MHCC get information from the EPR program on outliers identified by the process, just as they are able to look at outliers now with respect to case volume, DTB times, and cath lab down time? Dr. Miller responded that MACPAQ’s role is to return the information to the physicians and hospitals, and it is up to the institution to decide what it will do with the information. Dr. Williams expressed the view that it should be up to the hospital to solve the problem first, but another body has to check that hospitals are addressing problems.

Dr. Deychak asked about sampling for underuse of PCI or surgery, reviewing cases that did not get PCI or surgery. Dr. Miller said this should be easy to incorporate in the existing EPR model. Dr. Williams asked about adapting the model as an EPR system for cardiac surgery. Dr. Miller stated that the system could be adapted to look at effectiveness of CABG, considering whether the surgery correctly targeted the problems identified and how well the surgery worked based on post-surgery angiograms.

Mr. Steffen asked about liability risk associated with MACPAQ. Dr. Miller responded that the two hospitals’ attorneys looked closely at how the system was structured. Both hospitals recognize, in their bylaws, that it is a quality improvement initiative. Dr. Chambers emphasized that the system must be non-punitive to be accepted and effective.

Current use of the NCDR data by MHCC was discussed. Theresa Lee briefed the CAG on MHCC’s plan to implement an audit of the NCDR data set being provided, based on our review of the data sets submitted over the last two years and the waiver data sets submitted by non-cardiac surgery PCI centers. MHCC has concluded that an audit function is necessary to reach a point where the data sets can be confidently used to support both public reporting and regulatory oversight. The agency’s Cardiac Data Advisory Committee will be deciding on the clinical elements to focus on in the audit.

Dr. Dehmer said that he sees tremendous synergy between the MACPAQ process and the auditing process to improve the self-reported NCDR data sets, which everyone recognizes has errors. He briefly discussed the auditing that NCDR has done internally and its plans for expanded auditing, published about six months ago. He noted that some states using NCDR for reporting independently audit the data.

Dr. Miller expressed her belief that physicians will want to participate in an expanded EPR process as long as it is engaging them appropriately and efficiently in quality improvement and is non-punitive.

The discussion returned to the State's role in assuring that problems identified in EPR are addressed. How does the State adjudicate? Dr. Schwartz stated that hospitals should have every right to take action first, but asked, doesn't the State need to know about egregious problems?

Paul Parker framed the issue in the context of the new regulatory oversight process, which will involve MHCC in periodic decisions on whether or not to issue PCI programs a Certificate of Continuing Performance. One standard requirement to obtain such a certification could be that the hospital must participate in an EPR process that has features such as those developed in the MACPAQ model. However, he noted that MHCC would also need assurance that the hospitals are using the process to effectively address performance problems and this presents a challenge with respect to preserving the non-punitive nature of the process.

Dr. Chambers remarked that EPR cannot be viewed as a substitute for hospitals to examine overall quality of care as part of their quality assurance responsibilities. Requiring accreditation may be the way to go. EPR is just one aspect of the quality assurance effort. He asked about the cost of the MACPAQ model, questioning how realistic the \$8,000 per hospital per year estimate in the presentation is thought to be. Dr. Miller conceded that this was just an estimate and more detailed budget analysis would be required.

Mr. Steffen emphasized that MHCC's regulatory authority is applicable to hospitals and not physicians. MHCC is not the licensure board, but it can share information with the licensing agency. It cannot intervene in individual medical practice or regulate doctors.

Dr. Walford commented that audited data, reviewed over time, will be a way to assess whether hospitals are responding appropriately to EPR findings.

Dr. Williams asked if deaths were examined in the MACPAQ EPR process. Dr. Miller stated that outcome measures are not trended.

Dr. Horneffer asked if a star rating system, similar to that developed for cardiac surgery from the STS data registry, could be developed for PCI and used in regulatory oversight?

Dr. Stafford Warren suggested that MHCC recertification could involve asking the EPR system's Executive Committee for an opinion on whether the hospital has acted responsibly in addressing problems revealed through the EPR process.

Ms. Fleck asked about the amount of physician time required for reviews. Dr. Miller estimated 30-40 minutes per case for reviewers with CORE lab adding additional time. She added that the system tries to get the "biggest bang for the buck" by focusing on npPCI, given that high levels of appropriateness for STEMI-related primary PCI is well documented.

Dr. Deychak expressed his support for going forward with expanding on the MACPAQ structure. He asked if the objective was to have reviewers that work at all the participating hospitals. Dr. Miller answered affirmatively, at least one for each hospital.

Dr. Warren stated that the Maryland Chapter of ACC had looked at the MACPAQ model and supports it.

Dr. Dehmer asked about payment for reviewers. Dr. Miller indicated that MACPAQ wants to reduce the need for compensation but it is an issue that needs to be considered. Providing continuing education credits as one form of non-cash compensation has been discussed. Her cost estimates assumed a modest payment to some reviewers for their time. The hospitals need to take the lead on this issue. It was noted that Massachusetts has voluntary physician participation in a similar effort. Mr. Steffen suggested that some type of cooperative arrangement might be established by hospitals to address the physician compensation issue.

Dr. Chambers praised the effort that has gone into MACPAQ but questioned whether a mandate for EPR by Maryland is needed. He was not aware that any State mandates external review at this time.

At this point, Dr. Williams thanked Dr. Miller and suggested that the CAG return to discussion of the issues as outlined in the Discussion Guide for the balance of the time remaining.

Continued Discussion of Issues from the Discussion Guide

Dr. Williams asked Ms. Fleck to review the bullet points under Continuous Quality Improvement (CQI) Recommended Components. Ms. Fleck noted that she believes all hospitals already have a standing committee with chairman and staff coordinator for handling the CQI process. Dr. Williams was less convinced that all hospitals already had such a committee in place. He noted that there is a person in charge of data at his hospital and there are morbidity and mortality reviews. He noted that there are meetings on CQI at Brigham and Womens, but there is not a committee devoted to it.

A member commented that he believes Maryland currently requires such a committee. Ms. Fleck confirmed that is the case. Dr. Chambers noted it is not a State requirement in Pennsylvania, but his hospital does have a committee that meets monthly. Dr. Walford noted that in New York there is a requirement for such a committee. Other members added similar comments. Dr. Williams asked if St. Joseph Medical Center had such a committee, but its problems arose despite having the committee. Another CAG member commented that the requirement was a recent change.

Ms. Myers commented that Table A-1 in COMAR 10.24.17 does not apply to cardiac surgery, so when the Maryland Institute of Emergency Medical Services Systems (MIEMSS) developed regulations for hospitals that provide primary PCI services, it required all sites to have a medical review committee. The notes from medical review committee meetings are reviewed during site visits, so MIEMSS is aware of whether hospitals comply with the standard. Dr. Williams closed discussion of the issue by noting that a committee is much different than just a meeting. He suggested that the idea needs to be fleshed out more for the CAG's consideration.

For the second bullet point on the CQI list, it was noted that data collection is necessary in order to have a functioning medical review committee. Ms. Fleck noted that participation in the NCDR CathPCI data registry is required, so data collection is already required. Dr. Chambers commented that the key is to review and discuss the NCDR data and not just put it on a shelf. Dr. Walford responded that the review of data should happen at least once a month. Dr. Williams agreed, but added that it's important to know what the committee will be doing.

With regard to the incorporation of practice guidelines, another bullet point on the list, Ms. Fleck was not sure if such a requirement was explicitly stated, but believed that it is understood and would make sense to include. She also thought the group had an interest in referencing guidelines in regulations.

With regard to individual quality review, Dr. Williams posed the question, what should be looked at, in broad terms, without drilling down to details? Dr. Pomerantz commented that New York has a standard way to adjust for risk for the evaluation of individual physicians. He asked if the state would be developing a single risk adjustment model for use by all programs.

Dr. Schwartz commented that, at his hospital, they review interesting STEMIs and a random sample of npPCI, as well as other deaths. He noted that there is not a scoring system. There is a focus on trends. He added that sometimes cases are sent out for external review. Dr. Williams suggested that regulations avoid micro-managing and just require hospitals to monitor and take steps to correct problems detected. Dr. Shanahan commented that it is important to avoid overburdening hospitals. Dr. Williams responded by asking, what is the fallback to make sure that patients are safe? Dr. Shanahan responded that the CAG is still trying to answer that question. Dr. Williams suggested looking at just a few key endpoints and having an external body review those. Mr. Steffen commented that Maryland is not going to have a system like New York for individual physicians. There just needs to be individual review occurring. Dr. Walford commented that what to do with the data is a difficult question to answer. The CAG first needs to answer, what are the data elements going to be?

Dr. Williams commented that there will be outcome data from NCDR and for appropriateness there may be a process in place similar to that presented by Dr. Miller. He posed the question, who will get that information? Dr. Walford suggested that hospitals put the data together and review it, and then the state can look at it. He added that the state would get aggregate data to evaluate if hospitals are behaving appropriately, allowing for identification of outliers. New York has that system. Dr. Schwartz commented that having external review helps to make discipline easier, addressing doctors' defensiveness. Dr. Horneffer noted that a board composed of Maryland hospital representatives could play a role in oversight, similar to what is

envisioned on the cardiac surgery side (discussed at prior CAG meetings). Dr. Williams asked Mr. Steffen for his opinion on a standing committee. Mr. Steffen responded that the concept makes sense, but the exact role and financing need to be discussed further.

Dr. Deychak commented that if a committee for reviewing data is set up, it will be very important to have feedback from the cardiac catheterization staff, such as technicians and nurses. He noted that at his hospital there is a way for those staff to provide feedback and feel safe doing so.

Dr. Williams decided to move on to the next issue for discussion, volume requirements. When the issue of volume was first broached, CAG members asked when new guidelines that would speak to volume requirements are expected to be released. Dr. Chambers noted that new guidelines would not be available until May, probably. Dr. Walford reminded the CAG that a certain number of cases is needed to evaluate quality. Dr. Dehmer agreed with this comment and brought up Dr. Aversano's point that years of data could be needed at a lower volume hospital in order to have a sufficient number of cases to be 95 percent certain that a two percent mortality rate is significantly higher than a statewide average of one percent.

Dr. Zimrin asked for clarification on the agreed upon target volume. He thought consensus for 200 cases as the target volume had been reached. Dr. Chambers commented that 200 should be the target because the literature supports using 200. He asked for confirmation from another CAG member, who agreed. Mr. Steffen asked for more thoughts on graduated oversight, and asked what happens when a hospital falls below the target? He added that today in Maryland if a waiver hospital falls below the standard then it loses the authority to perform PCI. Dr. Walford suggested that a focused review take place if a program falls below 200 cases. Dr. Deychak commented that it is possible to perform a superb job below 200 cases, so if a program meets local needs, the state should consider allowing it to continue, instead of just scrapping it based on volume. There was consensus among members on 200 as the target and the need for a focused review if a program falls below 200. It was agreed that 200 should be the projected volume within two years for a new program. It was asked, should new programs should have a focused review no matter what the volume?

Dr. Williams asked whether the term "focused review" had been defined. Dr. Walford commented that it doesn't necessarily mean chart review. It means looking carefully to see if there are outliers in any area. Mr. Parker suggested that the CAG may want to consider a short window for continuing performance review initially for new PCI programs and then a longer period of certification later unless "red flags" were identified in ongoing monitoring of the NCDR data, which could trigger a focused review at any point in the continuing performance certification cycle. Dr. Williams again emphasized the need to define the term focused review, and asked if anyone wanted to volunteer for the task.

Ms. Myers asked if the number of primary PCI cases is going to be stipulated in regulations and whether it would be possible to shut down primary PCI and non-primary PCI separately. Dr. Williams responded that he did not think primary PCI should be performed without elective PCI. Ms. Sanders, commented that at her hospital only primary PCI is done. Mr. Parker suggested that the CAG consider the issue. He explained that the 2012 law that

created the group states that a hospital must do primary PCI before consideration of expanding to non-primary PCI. Dr. Shanahan asked for the logic behind the law. Mr. Parker responded that it was not a change recommended by MHCC.

Dr. Zimrin stated that the rationale for the law is that primary PCI saves lives. Elective PCI can be done anywhere and at anytime. Ms. Myers agreed with this comment adding that Ms. Sanders' program meets a need. Mr. Parker commented that he is not suggesting that dedicated primary PCI programs be eliminated or never considered. He was simply noting that the law does not provide an option for a hospital to propose establishment of a new PCI program that does both primary and non-primary PCI. Dr. Walford commented that the law should be changed. Mr. Steffen noted that there is an exception for hospitals in rural areas.¹

Dr. Walford brought the discussion back to expectations regarding volume. He suggested that there not be a minimum volume requirement and just a focused review for programs below a target volume. The CAG reached consensus that no minimum volume requirement should be included in regulations.

Dr. Williams asked why anyone would want to do only primary PCI. Mr. Steffen responded that it evolved from the C-PORT studies. There are five programs in Maryland that do only primary PCI. Not all of the programs qualified for the C-PORT E study of non-primary PCI without co-located cardiac surgery. Dr. Williams noted that with more practice you get better results, which suggests that the low case volume inherent in primary PCI alone should be discouraged. Mr. Steffen noted that, for practitioners, work at multiple locations is common and they are expected to maintain 75 cases per year.

With regard to individual operator volume requirements, Dr. Deychak suggested that the national recommendations be followed when they are published and the CAG appeared to agree with this approach. There was also agreement that focused review should be triggered when this volume standard is not met.

The view was expressed that focused review should involve a site visit in which a close look at performance through case review, and angiography review can validate if lower volumes are related to poor performance. Mr. Steffen suggested that at the time of waiver renewals physician volume could be checked as part of a focused review. Dr. Williams asked about what literature exists on focused reviews. A CAG member mentioned that Dr. Dehmer had written a great paper on it and suggested looking at New Jersey regulations.

Dr. Walford commented that board certification would be extremely helpful for promoting quality among physicians. His recent experience was that the process was a great educational experience. He suggested that the CAG discuss the issue, but Dr. Williams suggested revisiting at the next meeting.

¹ The law requires that MHCC regulations "require that an acute general hospital, except for an acute general hospital located in a part of the State that does not have sufficient access to emergency PCI services, have provided emergency PCI services in accordance with established standards before seeking a certificate of conformance for elective PCI services.

Adjournment

The meeting was adjourned at 4:00 pm. Mr. Steffen reminded the Group that a final meeting in April would be required and that the meeting date was **April 11, 2013**.

**Maryland Health Care Commission (MHCC)
Cardiac Advisory Group (CAG) on Cardiac Surgery and PCI
Final Summary of Meeting for March 14, 2014**

CAG Members Present

David Williams, M.D., Co-Chair
Thomas Aversano, M.D.
Charles Chambers, M.D.
Sridhar Chatrathi, M.D.
Yuri Deychak, M.D.
George Groman, M.D.
Chris Haas, D.O.
Debra Harper, R.N.
Peter Horneffer, M.D.
Paul Massimiano, M.D.
Lisa Myers, R.N.

Michael Peskin, M.D.
Richard Pomerantz, M.D.
Jeffrey Quartner, M.D.
Sharon Sanders, R.N.
Shahid Saeed, M.D.
Mitchell Schwartz, M.D..
Timothy Shanahan, M.D.
Gary Walford, M.D.
Stafford Warren, M.D.
David Zimrin, M.D.

CAG members present by phone

Greg Dehmer, M.D.

MHCC Staff Present

Paul Parker
Eileen Fleck
Ben Steffen
Suellen Wideman

The meeting convened at 12:35pm. Dr. Williams asked members and MHCC staff present to introduce themselves.

Dr. Williams commented that the CAG has talked about pieces of things, but it is important to try and visualize processes and data flow. He walked the CAG through the process, as he sees it. Starting on the hospital side, he noted that there are procedures/operations (percutaneous coronary intervention (PCI)/cardiac surgery). Data are collected, checked, and reviewed. That data is one source of information for assessing performance at an institution. Another source would be external review, which the CAG talked about at the February meeting, in which blinded angiography film are sent to a facility for review, as described by Dr. Miller at the last CAG meeting. A hospital may also review its own cases on an ongoing basis. Data would then be shared with MHCC, and it would likely have a group of advisors to help with interpretation. There would be flow of information through the system. He asked if everyone has this same understanding. Dr. Walford asked if the group could talk about other schemes and Dr. Williams indicated that would be fine. Dr. Tom Aversano mentioned that he has a slide presentation that is relevant to the discussion.

Review of Meeting Summary

Dr. Williams asked for comments on the meeting summary. He noted that if people want to review and get back to staff later with changes that would be fine. He then suggested that Dr. Aversano give his presentation. He noted the Discussion Guide has material for the meeting, but Dr. Aversano should present first. It took a few minutes to get the presentation loaded and ready.

Before Dr. Aversano began his presentation, Dr. Walford commented that Dr. Greg Dehmer has an excellent paper on site visits and what was learned. It was suggested that it be distributed to the group and added to the MHCC web site.

Presentation by Tom Aversano, M.D. on Measuring and Evaluating Program Quality

Dr. Aversano began by describing data collection and noting that the National Cardiovascular Data Registry (NCDR) data is an appropriate mechanism for it. He noted that achieving a certain level of completeness and accuracy in the Registry is required. He expects that hospitals will do their own internal review of data, but there will also be external review. External review should include peer review and random audits to verify that charts match data entered for NCDR. Dr. Aversano mentioned that audits could be of a few hospitals each year or five percent of the data. Dr. Williams suggested that people ask Dr. Aversano questions as they arise in his presentation, so that it is more of a discussion.

Dr. Williams asked if the random audits have to be done externally. He commented that at the time when angiography images are reviewed, it makes sense to check other data. He does not necessarily see the internal and external review processes as being completely separate. Dr. Williams commented that the hospital may want to have an opportunity to check that NCDR is reporting hospital data accurately. Dr. Aversano commented that the idea is that peer review, data audits, and outliers could trigger a review. For example, if the percentage of patients in shock is eight percent statewide and a hospital is at 20 percent, then it may trigger a review. He sees MHCC reporting summary results from those reviews.

Dr. Williams commented that his concept is a bit different, with MHCC directly getting data from hospitals and an external review group. He would not put MHCC after the external review group. Dr. Aversano explained that he still sees MHCC has the overarching authority, and this is shown on another slide.

Dr. Aversano noted that the data would be the same as what MHCC gets now from NCDR. Ms. Debra Harper added that hospitals transmit what gets sent to NCDR to MHCC too. Dr. Aversano explained that the steering committee will guide the development process. The steering committee will include representatives for all the cardiac surgery and PCI providers in Maryland, MHCC representation, and any other organizations that may want to participate, such as the Maryland Hospital Association. The steering committee will be the cooperative group overseeing quality for the state. He explained that he was discussing the committee as it relates to external peer review, but the committee could have a broader purpose.

Dr. Williams asked for confirmation that the purpose of the committee will be to review data from all the sites and make judgment about whether quality is acceptable or not. Dr. Aversano responded that he expects the committee to guide the process of deciding which data to

collect and examine. He does not expect to decide which data to collect and use for outcome measurement by the end of the CAG process. Dr. Charles Chambers commented that his impression is that the committee process may be onerous. He wanted to confirm that it is just one idea being talked about. Dr. Williams confirmed that and noted that the composition of the committee is something that could be further discussed. Dr. Aversano explained that physicians want a seat at the table. They do not want the regulatory review process to be something completely out of their control. The idea is to be inclusive. Dr. Aversano noted that potentially a hospital could opt out. He noted that the idea is not based on a model in another state.

Dr. Williams commented that he thinks there should be a committee with the functions discussed, but the composition of the committee is something that could be discussed further. Dr. Williams asked if anyone disagreed with his points. No one voiced opposition.

Dr. Aversano noted that he talked with the NCDR staff about use of the data and auditing of the data. There are some problems with the data, but he thinks it is better to have a single source for data instead of multiple forms. He commented that NCDR will likely be very flexible. If a state audits the data, then it saves NCDR money. Right now hospitals get NCDR data back after NCDR has reviewed it, and then hospitals send it to MHCC.

Dr. Aversano explained that he sees MHCC staff as responsible for analyzing the data and putting it together in reports. Staff also oversees reviews that may need to be conducted randomly or on an as-needed basis. Dr. Aversano further explained that MHCC would develop a risk adjustment model and compare hospitals in the state. Although NCDR has its own model of risk adjustment and comparison, he thinks it makes more sense to develop one just for Maryland, the way New York does its own risk adjustment.

With regard to the specific outcomes, Dr. Aversano suggested that the State limit the number reviewed to be sure that we can actually track them. For example, target vessel revascularization can be matched across years in the NCDR data, but there is not information collected in the NCDR data base about whether subsequent revascularizations was planned or just clinically had to be done. With the C PORT study, it had to be declared if staging was planned. It is a reasonable quality indication, but it may be difficult to obtain the information. Mortality is usually easy to capture, but sometimes patients leave and go back to their country of origin, for example, and follow-up information is not available.

Dr. Aversano suggested that the following outcomes be measured and used initially: death, emergency CABG, bleeding, door-to-balloon time, and readmission within 30 days of discharge. With regard to the methodology for evaluating quality, he suggested that Maryland follow the model used in New York. He described this as looking at a 95 percent confidence interval for an outcome at a hospital, as compared to the statewide average for all hospitals providing the same service under review. He emphasized that an adequate volume of cases is required for making timely judgments about whether the differences observed between a particular hospital's outcomes and the statewide average are statistically significant.

Dr. Aversano referred to a slide with mortality information for each hospital in New York with PCI services and the statewide average and confidence interval around the mortality

rate at each site. He pointed to one hospital in particular, Brookdale, and noted that even though the mortality rate is twice the statewide average, the confidence interval overlaps with the statewide average, so it cannot be assumed that Brookdale is actually experiencing twice the mortality rate seen in the State as a whole. Due to the low volume at Brookdale, it will take several more years before it is known whether the quality of PCI services at Brookdale is significantly worse than at the average hospital in New York. Dr. Aversano noted that one solution would be to aggregate years. Dr. Gary Walford noted that in New York, they look at both one year of data and three years of data combined.

Dr. Peter Horneffer commented that on the cardiac surgery side, the CAG talked about using numbers as triggers for a focused review, where experts parse out whether quality is a problem or not. With that approach, you would not have to wait as many years to make a judgment about the quality of a program.

Dr. Walford asked about how MHCC oversees quality concerns. He noted that in New York the same agency that collects and oversees the data also takes complaints from the public. Mr. Steffen responded that with the C PORT trial, if something seemed odd, then there would be follow-up. MHCC does not have responsibility for following up on complaints about hospitals. The Office of Health Care Quality of the Department of Health and Mental Hygiene, which licenses hospitals, or the Board of Physicians follow-up on complaints about hospitals and physicians, respectively.

The CAG returned to the question of what should trigger an audit. Dr. Williams suggested that hospitals start with submitting five years of data at the outset for key variables, such as mortality, as a way to deal with the difficulty of making judgments about the quality of programs with low volumes of PCI services. One CAG member asked if mortality would be defined as cardiac-related. Dr. Walford commented that in New York, all cases are included in the mortality measure, not just deaths that appear cardiac-related. Dr. Williams commented that it is difficult to determine whether a death is cardiac-related, so it makes sense to include all cases. He also noted that all-cause mortality should be close to cardiac mortality.

Mr. Steffen asked, why not use an aspirational goal instead of the statewide average for mortality? Dr. Aversano noted the advantage is that you do not have to be concerned about how the data was gathered or how the average was calculated. Those things are known. Dr. Aversano added that he would expect the mortality rate to be similar to the national average.

Dr. Sridhar Chatrathi asked, what about accounting for appropriateness? Dr. Aversano responded that peer review is the best way to evaluate it. He does not think it can be evaluated based on the NCDR data because the judgment of appropriateness is based on what information is entered. Dr. Chatrathi expressed skepticism about the peer review process, noting that for the director of a cardiac catheterization lab, peer review may just be a political process. Dr. Aversano agreed with this comment. Other members voiced support for external peer review. Dr. Chambers also agreed with the need for external review to do good peer review. However, he also wanted to emphasize that internal review is very important, and hospitals should not be relieved of the pressure to do good internal review.

Dr. Aversano commented that Dr. Miller's presentation (at the February CAG meeting) focused on angiography review, but it could also be used to check the accuracy of the NCDR data. Dr. Williams agreed that both functions could be done. However, Dr. Chambers cautioned that there is an extra cost if hospitals are relying on external review for data quality verification. Dr. George Groman commented that having two tiers of review (internal and external) makes sense. Dr. Walford commented that external review is about creating a level playing field for hospitals. He noted that making sure everyone knows definitions and consistently reports information is key. It may take years to get people on the same page, but over time the data becomes more consistent.

Ms. Harper asked about how the review processes being discussed by the CAG fit in with the review conducted by MIEMSS of cardiac intervention centers (CICs). Lisa Myers responded that MIEMSS' focus is only on primary PCI. The review processes being discussed would be more comprehensive.

Dr. Aversano stated that everyone probably agrees that just looking at mortality is not enough and posed the question, how do we express to the public a judgment about the quality of a program that will be meaningful? He suggested that one way is through the use of a star rating system. He noted that the Society of Thoracic Surgeons (STS) has a star system for cardiac surgery programs, based on registry data collected. He explained his proposed definitions for each star rating, as is described in the paper distributed prior to the CAG meeting. For four stars, he noted that a program must meet all the criteria for three stars and follow long term patient outcomes. He noted that NCDR does not currently look at long term outcomes, but he believes that it will be available as an option next year through NCDR. Hospitals would not be required to follow long term outcomes.

Dr. Williams expressed concern about the star rating system described by Dr. Aversano. He commented that mortality is very important, and the star assignments described seem a bit arbitrary. He expressed concern that a hospital that has a very low mortality rate could be labeled inappropriately as inferior. He later clarified that not just mortality should be considered for ratings, but it should be dominant. Dr. Horneffer also expressed reservations about the star rating model proposed by Dr. Aversano. He suggested that a similar paradigm be adopted for cardiac surgery and PCI services. The star rating system for cardiac surgery developed by STS, which the CAG expressed support for adopting, is oriented differently than the model proposed by Dr. Aversano. Mortality is a dominant factor in the star rating system. He also noted that it is a three-star scale, rather than a four-star scale as described by Dr. Aversano. He noted that basically there is a normative rating and then two outliers (the bottom and top 10-15 percent of hospitals).

In response to Dr. Horneffer's comments, Dr. Chatrathi noted that even though mortality is important, it is a rare event. He thinks that it is important not to overstate its importance. He also added that a program should not be given any stars, if it does not have a peer review process. For example, he noted that if a physician performs PCI on lots of patients with 20 percent lesions, then the program is going to have a low mortality rate. Dr. Williams agreed that looking at appropriateness is very important. He commented that the star rating system

described does not encompass appropriateness of treatment. Dr. Williams added that if there is a rating system, then both appropriateness and “safety” should be part of it.

Paul Massimiano commented that the STS system does help people to know what the data means, and he thinks there should be a star rating system. As he recalls, Dr. Horvath said that about 70 percent of the STS star rating is based on mortality rates. He added that it will be very important to look at the weight given to different outcomes, in setting up a star system for PCI services.

Dr. Aversano continued with his presentation. He discussed the criteria used in the C PORT study for patient selection. He mentioned that exclusion criteria were unprotected left main coronary disease and very low ejection fraction. He mentioned that there was a minimum of 200 cases for each site, by the end of the second year. Dr. Williams asked why 200 cases is the right cut off point. Dr. Aversano explained that 30-day mortality is higher at sites without on-site cardiac surgery, with a big drop off around a volume of 200 cases. He also noted that a certain amount of volume is necessary to evaluate the quality of a program within a reasonable time frame.

Dr. David Zimrin commented that the reason the CAG decided a cutoff of 200 cases is not needed is that volume below that level will trigger a focused review, which should then uncover if there is a problem with the quality of the program. Dr. Williams commented that in the last ten years volumes are down at many locations. He asked whether a minimum case volume of 200 cases is still the right cutoff point. Dr. Aversano again expressed support for a minimum case volume of 200 cases, noting that quality measurement is an issue.

Dr. Stafford Warren brought up that focused reviews had been discussed for sites with volumes below 200 cases. Dr. Mitchell Schwartz commented that focused reviews are expensive, so decisions as to when to conduct them and how many cases to review are critical questions to answer. Dr. Aversano commented that potentially focused reviews are more biased than statistics. He also added that if there are concerns about falling volumes, then the problem could become worse by lowering the volume threshold for programs.

Dr. Aversano continued his presentation. Dr. Aversano mentioned that triggers for review could be outliers identified in MHCC’s review of data or concerns raised through the peer review process. He later added that a complaint from a patient or colleague could also be a trigger. He then described a proposed regulatory process that would be followed. He noted that after data is reviewed and deficiencies have been identified, a site would have 30 days to submit a plan of correction with a timeline. The Commission would then review the plan and either approve it or require modifications. At the end of the timeline for corrections, the Commission would evaluate if acceptable progress had been made, or if further actions should be taken, such as shutting down a program.

Ben Steffen commented that it is clear that there is support for a standing committee, but there is a hesitancy to pass off certain responsibilities to operators. Dr. Aversano commented that MHCC would still be in charge. It would be similar to the current work group which MHCC convened.

Dr. Aversano continued his presentation again noting that the data collection instrument could be the NCDR data, which should then be audited by the State. He mentioned some limitations with the NCDR. For example, there is a check box in the NCDR data set to indicate that a procedure was staged. However, is it known whether that is really the case? Another issue is inter-hospital transfer outcomes. Dr. Aversano estimated that 12 percent of cases are inter-hospital transfers, on average, and those cases will not necessarily appear in the NCDR database. Dr. Aversano regards this as an important issue, even though transfer of a patient does not necessarily mean a patient died or had complications. He explained that the way to capture it is through long term follow-up. Dr. Williams suggested that the burden of follow-up be placed on the initial site for the patient. The site could be responsible for answering just a couple of key questions that are relevant to monitoring and evaluating the quality of care provided. Dr. Walford suggested that linking to another database is another approach, such as the national death index or vital statistics records.

Mr. Steffen asked about the feedback loop if the State audits the NCDR data. Dr. Aversano responded that NCDR would not use the audited data because it wants the data in the registry to be of consistent quality. He noted that Maryland could hire NCDR auditors. The way it works is that the hospital sends charts to the auditors. The auditors refill out the data and compare it with the actual data entry.

Dr. Walford expressed concern that once hospitals in Maryland get better at data entry and get it right the first time, Maryland hospitals could look worse, in national comparisons. He suggested that MHCC needs to be supportive of hospitals, if hospitals wind up looking worse in this way. Mr. Steffen and another CAG member agreed with the concern raised by Dr. Walford.

Dr. Aversano noted that the State could use the NCDR auditors to train its own auditors. He thought the training might even be provided for free. Dr. Walford asked if angiographic review would be part of the review, and Dr. Aversano noted that it would not. Dr. Aversano concluded his presentation.

Dr. Dehmer commented that Dr. Aversano's presentation is an elegant way to look at the data. However, he suggested that the CAG think about what led to the formation of the CAG. It was not high mortality rates or concerns about door-to-balloon time, it was the appropriateness of PCI cases by certain operators. He shares Dr. Aversano's concerns about the appropriateness measure available in the NCDR data set. The information is basically self-reported, and currently 98.6 percent of cases are judged appropriate by NCDR. He thinks more peer review than planned may be needed.

Dr. Williams noted that both internal and external review should occur, and there may be both types of review in some cases. He noted that with a rating system, looking at appropriateness is important, not just complications, as he mentioned earlier. He thanked Dr. Dehmer for raising the point and reminding the group of those issues.

Discussion of Issues Noted in Discussion Guide

Dr. Williams next suggested that the CAG turn its attention to the discussion guide. He asked Eileen Fleck to review the issues in the document that still require further discussion. With regard to quality assurance, Ms. Fleck commented that it seemed like the CAG has not yet closed out the discussion. She thought it might be useful to identify what percentage of cases should be reviewed or what number of cases. She asked if the group had suggestions. She also asked whether the CAG thinks there should be a standard specified. Dr. Walford responded that his suggestion is five percent of cases.

Dr. Schwartz suggested that there be a minimum number of cases reviewed per interventionalist and site. Ms. Fleck responded that the CAG seemed to favor that idea at a previous meeting, but numbers were not chosen. Dr. Aversano suggested that flexibility be built in so that regulations would not have to be revisited to change the standard. The process of updating regulations could be onerous. Mr. Steffen added that with public reporting MHCC has always given hospitals an opportunity to see the results before publically reporting.

Dr. Williams suggested that it might be a good idea to find out what the experience is for providers. Dr. Chambers responded that review of five to 10 percent of cases is typical and a minimum of 10 per year. Dr. Williams proposed that 10 percent of cases be reviewed in house, five percent be reviewed externally and a minimum of 10 per operator. One CAG member asked if the external review of cases should overlap with the internal review of cases. Dr. Chambers responded that there is no precedent for that. The review should be random. He added that often reviewers do not know how random has been defined. Cases have already been pulled for their review, and they are told the cases were chosen randomly. Dr. Williams suggested moving to the next topic.

Ms. Fleck asked the CAG whether certain aspects of care need to be specifically evaluated or whether it is fine to leave that open-ended and just specify the number or percentage of cases to be reviewed. Dr. Williams suggested that appropriateness and safety be reviewed. He asked if anyone objected to that approach, and no one disagreed. Ms. Harper later commented that the Joint Commission requires a robust process be in place for review of morbidity and mortality, so she thinks the issue of which aspects of care to review should be taken care of.

Ms. Fleck next asked whether angiography images should be required for review of all elective PCI cases. Dr. Williams commented that both elective and primary PCI cases should be reviewed, and he does not see a reason to treat elective cases differently for the review of imaging. Other CAG members commented that elective cases are more likely to be inappropriate. One stated that over 90 percent of primary PCI cases are appropriate. Someone suggested that primary PCI cases could be a small percentage of cases reviewed relative to the elective cases, such as an 80/20 split. Dr. Williams stated that would be fine and suggested moving to the next discussion question.

Ms. Fleck asked whether hospitals should be required to calculate and evaluate risk adjusted mortality rates for physicians. She noted that this issue was discussed at the last meeting, and a question was raised about whether the State will come up with a model or hospitals will be on their own to develop their own approaches. Dr. Williams responded that it

should not be done on an individual basis by each hospital. Ms. Fleck agreed that it makes sense for the State to have a model. Dr. Williams asked if anyone disagreed with his answer. Dr. Walford commented that MHCC regulates at the hospital level. Ms. Fleck agreed. She further explained that MHCC is regulating sites not individual operators, but hospitals are expected to review individual operators and make a judgment about whether they are providing quality care. The question is should the State come up with a model for risk adjustment of cases or should each hospital figure out how it is going to evaluate operators given the risk levels of patients who they treated. Dr. Walford responded that the information can be obtained from the NCDR records.

One CAG member asked if there are any plans for publically reporting data on individual physicians. Mr. Steffen stated that no such reporting is planned.

Someone asked for clarification on who would be reviewing data for external reviews. Dr. Williams responded that the plan described by Dr. Aversano was being referenced. Dr. Aversano added that the reviewers would be those on the committee he described, with representation from all hospitals. Another CAG member asked if an outside group (not associated with any Maryland hospitals), like ACE, might be contracted to do a focused review. Dr. Walford proposed that alternatively the committee members could be asked if they know people outside the state who would be willing to do the reviews. Dr. Williams suggested that the group move on to the next topic, the Heart Team approach.

Ms. Fleck explained that the Heart Team approach had been discussed briefly at the previous meeting, and then Dr. Dehmer suggested that there was an article that it might be helpful for the CAG to review before continuing the discussion. Ms. Fleck sent a copy of the article to the group, in case anyone did not already receive it from Dr. Dehmer directly. Ms. Fleck stated that the main question is whether the CAG wants to reference the Heart Team approach in regulations or not. Dr. Williams asked about who had used the approach. He noted that it is used in his hospital, but it is very informal. He does not think every patient requires a Heart Team approach, but in some cases it may not be clear.

Dr. Zimrin responded that trying to regulate at what level to get involved is not possible. It will depend on geography, the type of hospital, and other factors. The process is still evolving, and his preference is not to limit people to a specific approach because it will hinder innovation and development of best practices. He noted that requiring the Heart Team approach is important, but trying to spell out the details would be counterproductive.

Dr. Williams noted that his viewpoint on the Heart Team approach is probably at the other end of the spectrum as compared to Dr. Zimrin. Dr. Timothy Shanahan commented that it could be part of a quality metric that is part of case reviews. If a case was borderline and surgery may have been appropriate instead, that question could be evaluated as part of the external review process. Dr. Horneffer agreed noting that it could be the responsibility of the steering committee. He noted that a surgeon is always available and could be called to request an opinion, even if a surgeon could not be physically present.

Dr. Yuri Deychak commented that the Heart Team approach is already embedded in current guidelines. He anticipates that regulations are going to follow current guidelines, but it is just a guideline. He does not think MHCC can regulate sound clinical judgment. He thinks the Heart Team approach should be encouraged, but it is not possible to go further than that. Dr. Deychak also noted that a surgeon may have an entirely different picture of a case through face-to-face contact as compared to an assessment over the phone. Dr. Williams suggested that the group move on to the next topic, external peer review.

Ms. Fleck stated that the group had already spent a fair amount of time discussing external peer review, and she was not sure if the CAG should continue the discussion. She mentioned that it might be useful to talk about how biases would be handled if the committee with representation from all Maryland hospitals is established as the vehicle for external reviews. She asked Dr. Williams whether he preferred to spend time discussing this issue or move on to another topic. Dr. Williams responded that Dr. Aversano had described one approach, and he did not think the CAG should spend time discussing in detail the composition of the group. However, the role of the group and the general composition may be worth discussing further.

Dr. Chambers asked about whether the CAG was planning to mandate a particular approach to external review. Dr. Williams responded that maybe the CAG can agree on the broad concepts of internal and external review and having a committee that would receive data and make judgments about programs.

Dr. Schwartz asked whether the CAG needs to make sure that the committee concept is inclusive of the type of review described by Dr. Miller. He noted that he favors using a committee with Maryland representatives from all hospitals. Dr. Aversano noted that hospitals could be given the option of using the committee for external review or using an outside group approved by the Commission. Mr. Parker commented that his understanding is the CAG wants to mandate external review, but how that is accomplished can vary among hospitals. Dr. Walford added that it is important to specify that the external review process includes angiographic review.

Dr. Chambers asked for confirmation that the CAG is proposing that Maryland mandate external review. He also expressed reservations as to whether such a mandate was necessary. One CAG member thought the mandate already exists. However, Mr. Steffen stated that it is not currently mandated. The legislation passed last year mandates internal or independent review. External review is not mandated. Dr. Williams confirmed that the CAG is proposing that external review be mandated, and he suggested moving on to the next topic for discussion.

Ms. Fleck brought up the issue of door-to-balloon time and asked the CAG how it should be measured. She noted that the NCDR reports exclude some cases from the benchmark for door-to-balloon time, such as transfer cases, but MHCC does not exclude those cases for its review of waiver renewals. Dr. Zimrin asked for clarification on how MHCC defines “door” for the transfer cases. Before Commission staff responded to this question, the CAG discussed which cases to include and decided that transfer cases should be excluded.

Dr. Shanahan made the point that the idea is to use NCDR and not have different systems and definitions for things like door-to-balloon time. Ms. Myers responded by noting that NCDR collects information that allows for looking at the arrival time of patients who are later transferred to another hospital. She commented that MIEMSS feels strongly that the transfer times should be reviewed, but hospitals cannot be held accountable for delays outside their control. Dr. Williams agreed that it may be worth keeping track of the door-to-balloon times of transfer patients.

Dr. Zimrin explained that he asked the question about which door is used for door-to-balloon time because with transfer cases, a hospital has an advantage if its door is used (rather than the transferring hospital's door). Similar to field activation cases, there is time for the hospital to get ready for the patient, once it is known a patient is expected. Following the meeting, Dr. Haas offered the following clarification of the definitions of door-to-balloon (DTB) time and first-medical-contact-to-device (FMCD) time. The door to balloon time interval starts with the patient's arrival at the PCI facility and concludes at the time of delivery of definitive therapy in the cath lab. FMCD time begins with the initial presentation of the patient, either in the field with EMS or at a non-PCI facility, and concludes with delivery of definitive therapy at the PCI facility. The goal for FMCD time for patients who are transported directly to a PCI facility is 90 minutes. The FMCD time for patients who are first transported/present to a non-PCI facility and are then subsequently transferred to a PCI facility is 120 minutes. The D2B is always 90 minutes at the PCI facility, regardless if the patient first presents to the PCI facility, or is transferred from a non-PCI facility. These changes were agreed upon by the CAG when the March meeting summary was reviewed at the beginning of the April CAG meeting.

Dr. Williams suggested moving to the next issue for discussion. Ms. Fleck commented that she thought it would be a good idea to discuss what time standard should be used for the transfer cases. Dr. Zimrin commented that he thought MIEMSS looks at those cases and has standards. Ms. Myers explained that for transfer patients, according to the ACC/AHA Guidelines for care of STEMI patients, the goal is to have the patient out the door within 30 minutes (for transfer to the next hospital). She added that the door-to-balloon time goal is still 90 minutes, but up to 120 minutes is considered acceptable for primary PCI according to the AHA/ACC Guidelines.

Dr. Williams suggested the CAG move on to the next issue. First though, Dr. Aversano wanted to know if there are any plans to hold the hospitals without primary PCI services accountable for the 30 minute standard mentioned by Ms. Myers. Mr. Steffen responded that the plan is to hold hospitals with primary PCI services accountable, both those with cardiac surgery on-site and those without. He noted that MHCC does not know the door-to-balloon times for hospitals with cardiac surgery. MHCC has only been tracking it for the hospitals without cardiac surgery on-site. Dr. Williams noted that Dr. Aversano was asking about hospitals without PCI services, which Mr. Steffen did not address. Dr. Williams added that it seems like a good idea to hold those hospitals accountable. Ms. Myers commented that MIEMSS would support that idea. Dr. Shanahan asked for clarification on whether 30 minutes refers to out the door or ready for transport. He noted that getting a patient out the door in 30 minutes is very difficult because of all the layers involved. He mentioned that his hospital has worked very hard on getting transfers out. Dr. Williams commented that tracking could be done without being punitive. It would be a

way to highlight an area for improvement, without labeling a hospital as bad. Another CAG member suggested looking at the data to see if trends can be identified. Mr. Steffen suggested that the CAG move on to the next issue.

Ms. Fleck suggested the CAG next address patient selection criteria for primary PCI services. She mentioned that at the last meeting the CAG suggested just referencing existing guidelines to identify those patients appropriate for primary PCI, and then someone expressed concern that patients who are in cardiogenic shock could not be treated with PCI services, as they currently may be, at hospitals without cardiac surgery on-site. The CAG regarded the existing language in Maryland regulations as adequate to address the concern. Ms. Fleck tried to explain that she thought the CAG previously decided to replace the language with reference to current guidelines for patient selection. She noted that the intent of the CAG was clear, and staff would work out how to change the language to match those intentions.

Dr. Warren asked, if a patient with unprotected left main in cardiogenic shock came in, would it be appropriate to treat that patient? Dr. Williams commented that usually those patients die, and in his view it would be appropriate to treat that patient. Dr. Aversano expressed concern about how cardiogenic shock would be defined. He noted that there are lots of different ways it could be defined. Dr. Walford responded by stating that the NCDR definitions should be accepted. He noted that the definition of cardiogenic shock for the NCDR registry is very clear. It needs to have lasted a minimum of 30 minutes. He added that New York has taken those patients out of public reporting, but it does not make much difference in ratings.

Ms. Fleck moved on to the next discussion question, at the top of page 11 of the discussion document. Mr. Parker suggested the group look at the bottom of page 10 of the discussion document for a summary of the issue. He explained that the Maryland EMS Protocol for post cardiac arrest patients with return of spontaneous circulation (ROSC) calls for transport to a Cardiac Interventional Center. MHCC staff's understanding is that hospitals are concerned about performance of primary PCI on such patients under our current definition of "suitability."

Dr. Williams commented that he is not clear on the concern raised. Dr. Groman explained that if a patient has a cardiac event outside the hospital, comes to a hospital with primary PCI services but no on-site surgery, and does not have an ECG that shows a STEMI, the question is, can the patient be brought into the cardiac catheterization lab to evaluate lesions and then potentially be treated? Dr. Aversano added that the question needs to be answered for hospitals with only primary PCI. (Note: Commission staff reviewed the regulations following the meeting and disagree that the question is only applicable to hospitals that only provide primary PCI; all hospitals without cardiac surgery on-site are subject to the same requirements.) Dr. Williams asked for feedback from the CAG on this issue.

In response to Dr. Williams' request, Dr. Zimrin explained that MIEMSS has an EMS protocol for post-cardiac arrest patients with ROSC to begin therapeutic hypothermia ("cooling") and then transport to the nearest CIC because all CICs have indicated they can continue therapeutic hypothermia and they all have a cardiac catheterization lab. Dr. Aversano commented that this protocol seems acceptable. If you can cool the patient, then it is not unreasonable. Dr. Williams commented that the situation does not seem that different as

compared to a shock patient. Mr. Parker wrapped up the discussion by asking the CAG whether it wanted to add to the definition of suitable patients for primary PCI to address the concern raised. The CAG affirmed that it wants to modify the definition.

Ms. Fleck brought up the next issue for discussion, whether to reference existing guidelines regarding non-primary PCI patients. She noted that there are two different guidelines that could be used, which are described in the discussion document and included in Appendix 3. Dr. Pomerantz strongly recommended that the CAG not reference the guidelines and suggested that micromanaging of decisions in the cardiac catheterization lab should be avoided. He felt that a good quality assurance program should be able to pick up whether there is a problem. Dr. Williams agreed with Dr. Pomerantz that internal and external review should be adequate to address the issue. Dr. Williams further commented that physicians are not going to want to get into trouble, so they have an incentive to show good judgment with regard to patient selection. Dr. Aversano brought up that device selection for performing procedures is a related issue. Dr. Williams commented that in that area too, he thinks it should be assumed that physicians know how to do procedures. He noted that outcomes can be used to evaluate whether the right decisions were made. However, he did think it would be acceptable to say that a rotoblade should not be used at locations without cardiac surgery on-site. He asked if anyone else wanted to offer opinions. One CAG member suggested that it makes more sense to say that a lesion that requires a rotoblade should not be done at a site without cardiac surgery on-site. There were no other comments. Dr. Williams suggested moving to the next issue.

Ms. Fleck stated that the CAG expressed an interest in further defining the term “focused review” at the previous meeting. She copied regulatory language pertaining to focused reviews in New Jersey and New York and included it in Appendix 4, highlighting the relevant text. She noted that the regulatory language covers both cardiac surgery and PCI services. Dr. Walford suggested that it is better to be more general. He noted that New York tried to be specific and that created problems, so it revised its regulations to be more general. Ms. Fleck commented that for both states the standards seemed general and not overly specific. She noted that in New Jersey a focused review is triggered by a volume threshold and a corrective plan must be submitted within 30 days of the review. She thought the language was similar to the language presented by Dr. Aversano earlier in the meeting.

Dr. Aversano noted that the regulations of New Jersey have several volume thresholds and below a certain volume a program is shut down. Ms. Fleck responded that the CAG had discussed and decided on a threshold of 200 cases and no minimum volume that would result in automatically shutting down a program. Ms. Fleck explained that her understanding is the CAG wanted to define the term focused review and what it means, since not everyone is sure what that term means. Dr. Williams suggested that staff work on the issue further and get back to the CAG. Dr. Chambers offered to provide some assistance on the issue.

Ms. Fleck moved on to the next issue, requirements for interventionalists. She thought the CAG agreed on a requirement for board certification, but that it may want to consider allowing exceptions to the requirement. She included examples of language from two other states, New York and Massachusetts, in the discussion document on page 12. She asked CAG members for feedback on those examples. Dr. Williams read the regulatory language for New

York to the CAG. He asked if anyone favored that language, and no one expressed support for it. Dr. Williams next read the regulatory language for Massachusetts. Dr. Zimrin proposed rather than referring to 'seeking board certification' instead the language should refer to 'obtaining board certification.' No one disagreed with this point.

A question was raised about whether fellows are comfortable performing cases on their own at the conclusion of a fellowship. Dr. Zimrin commented that it depends on the fellow. He also noted that what is meant by supervision is unclear. He added that to be consistent with other specialties, he believes that passing a board exam within three years should be the requirement. Dr. Deychak noted that when he completed his fellowship about 20 years ago, he was able to operate independently right away. He expressed reservations about limiting the practice of new fellows. Dr. Williams commented that Dr. Zimrin's description of supervision seemed fair, slightly more surveillance. Dr. Zimrin commented that using the term loosely is probably fine. He added that the supervisor should be anyone who is qualified without specifying a minimum level of case experience. Dr. Williams suggested the CAG move on to the next issue.

Ms. Fleck asked the CAG about whether interventionalists should be allowed to have on-call coverage at multiple locations. She mentioned that some hospitals allow this and others do not. She mentioned that MHCC received feedback on the issue by email. Comments received included concerns about having enough coverage to go around if physicians were not allowed to cover multiple locations. It was suggested that hospitals should be allowed to make whatever is the best decision for them. Dr. Williams suggested that it may be possible to just evaluate outcomes instead of addressing. Ms. Fleck mentioned that idea had been suggested by someone through email. Dr. Zimrin explained that this issue came up because of the current regulations. The CAG agreed that allowing on-call coverage at multiple locations is fine.

Dr. Chambers asked about interventionalists with foreign certification, for example Canadian certification, and whether that would be an issue for practicing. Dr. Deychak commented that the guidelines expected in May will probably address that issue. Dr. Williams suggested moving to the next issue.

Ms. Fleck asked the CAG whether there should be volume requirements for cardiac catheterization lab medical directors, and if there are volume requirements, then should there be exceptions? She noted that she had received feedback expressing concern about a potential negative impact on some Maryland providers. Dr. Williams commented that at Massachusetts General Hospital, the lab director does not do PCI and never has, but he is a good director, so he is not sure that there should be a requirement. Other CAG members were in agreement with Dr. Williams.

Dr. Williams thanked Dr. Aversano for his presentation and asked Mr. Steffen if he wanted to add anything. Mr. Steffen noted that there is one more meeting. Mr. Parker further explained that staff will put together a document that summarizes the final recommendations of the CAG for both cardiac surgery and PCI services for the final meeting. At the final meeting, he would also like to discuss the regulatory review process for certificates of performance and certificates of ongoing performance. Mr. Parker noted that he provided an outline of the issues to be discussed in a document handed out to CAG members at the meeting. He noted that the

last two pages of the document are just for context and describe the conventional certificate of need review process. He noted that most of the regulatory review process will be monitoring programs on an ongoing basis and identifying problems. He explained that he is looking for feedback on how the committee discussed will fit in with the regulatory review process. Dr. Williams noted that he is interested in a comparison of the quality monitoring for PCI services and surgery. He added that it would make sense to have a similar approach for both services.

Dr. Aversano asked Mr. Steffen if MHCC has the ability to develop summary statistics from the NCDR data and do regression analysis. Mr. Steffen noted those can be done by MHCC staff. He added that the NCDR data are currently used in a limited way. Mr. Steffen noted that STS data is not available to MHCC staff currently. Dr. Walford asked about the need for funding. Mr. Steffen noted that MHCC is user fee funded but it can seek grants for projects. The meeting adjourned at 4:00pm.

Maryland Health Care Commission (MHCC)
Cardiac Advisory Group (CAG) on Cardiac Surgery and PCI
Final Summary of Meeting: April 11, 2014

CAG Members Present

Loren Hiratzka, M.D., Co-Chair
David Williams, M.D., Co-Chair
Yuri Deychak, M.D.
James Gammie, M.D.
George Groman, M.D.
Chris Haas, D.O.
Debra Harper, R.N.
Peter Horneffer, M.D.
Keith Horvath, M.D.

Lisa Myers, R.N.
Michael Peskin, M.D.
Richard Pomerantz, M.D.
Jeffrey Quartner, M.D.
Shahid Saeed, M.D.
Sharon Sanders, R.N.
Mitchell Schwartz, M.D.
Gary Walford, M.D.
Stafford Warren, M.D.

CAG Members Present by Phone

Thomas Aversano, M.D.
Greg Dehmer, M.D.

MHCC Staff Present

Eileen Fleck
Paul Parker
Ben Steffen
Suellen Wideman

The meeting was convened at 12:35pm. Dr. Loren Hiratzka, Co-Chair asked that everyone introduce themselves. After introductions, the March meeting summary was discussed. Eileen Fleck noted that Lisa Myers had proposed some changes which were distributed to the CAG. She proposed clarifying the description of door-to-balloon time goals and the Maryland EMS protocol for post cardiac arrest patients with return of spontaneous circulation. These changes and a request from Dr. Chris Haas to clarify how the time of first medical contact relates to the measurement of door to balloon time were agreed upon by the CAG. The meeting summary was approved with those changes. The CAG then moved on to the first agenda item, the role of the standing committee.

Role of the Standing Advisory/Oversight Committee

Ms. Fleck presented a diagram prepared by MHCC staff for discussion that outlined reporting and communication relationships between MHCC, a standing advisory committee, the existing Cardiac Data Advisory Committee, and an external peer review organization, such as MACPAQ. The diagram also provided summaries of the advisory roles played by these entities and the relationship of the entities to a body formed by MHCC to undertake “focused” or “triggered” review of potential program performance issues or problems. The diagram portrayed a single oversight committee that could be structured to primarily function as two subcommittees, one for percutaneous coronary intervention (PCI) and one for cardiac surgery. She noted that the composition of the group would include representatives from many, if not all,

Maryland providers. The committee(s) would provide advice on updating the State Health Plan chapter for cardiac services with respect to regulations developed pursuant to the CAG recommendations. It would also address issues that arise in the implementation of the new regulatory oversight process. It would also review and advise the Commission on plans of correction developed for hospitals after focused or comprehensive reviews. Lastly, it could also provide some advice on performance measurement, but the primary responsibility for developing performance measures would be with the Cardiac Data Advisory Committee (CDAC), which is an existing group responsible for public reporting on quality measures. The CDAC would also be responsible for reviewing proposed risk adjustment models and providing advice on the auditing of the NCDR data and possibly the STS registry data.) The CAG would communicate its findings and advice to the oversight committee and MHCC.

Ms. Fleck continued her explanation of the oversight committee and its relationship to other committees. She noted that the focused review/triggered review team would be composed primarily or exclusively of external (out-of-state) experts to minimize conflict of interest concerns inherent in use of in-state expert reviewers. The triggered review team's role would be to investigate concerns in program performance, report its findings, and make recommendations to the program under review and to MHCC. For routine external review, Ms. Fleck explained that it could be performed by either a statewide or state-based hospital consortium, such as MACPAQ (an organization currently used for blinded external review by Johns Hopkins Health System and the University of Maryland Medical System, or another external review body. She explained that MHCC would receive a confidential detailed report, but the oversight committee would only receive summary level information without identification of hospitals.

Dr. Stafford Warren commented that the standing committee should have representation from ACC. No objections to this idea were raised.

Ms. Debra Harper asked for clarification on how the MHCC diagram related to the materials sent out for the meeting. Ms. Fleck explained that Drs. Thomas Aversano and Peter Horneffer also diagrammed schemes for functional, advisory and consultative structures related to MHCC regulatory oversight of PCI and cardiac surgery for consideration by the CAG. Their slides were distributed prior to the meeting, and both members would have an opportunity to outline their ideas to further the CAG's discussion and consideration.

Dr. David Williams asked for an explanation of the Cardiac Data Advisory Committee. Paul Parker explained that the CDAC is an existing committee and noted that six members of that group are part of the CAG. There are 17 members. Most are physicians, and the remaining members are primarily hospital staff involved with cardiac services delivery. Ms. Myers from MIEMSS is also part of the CDAC and there is also a representative from the Office of Health Care Quality, the hospital licensing division of the Maryland Department of Health and Mental Hygiene. It was formed with the function of advising MHCC's Hospital Quality Initiatives division, which is responsible for public reporting on hospital performance. The diagram shows its role as advisory on performance measurement, risk adjustment models, and data auditing, to be undertaken by MHCC as necessary, to allow for effective use of data bases such as NCDR. Public reporting of performance measures would continue to be a primary advisory role of CDAC. Advising MHCC on issues directed related to regulatory oversight would be the primary

responsibility of the standing committee, which would be the first line advisor on the drafting of implementing regulations and, over time, adjustments and changes that might be needed to improved regulatory oversight.

Dr. Hiratzka asked if cardiac surgery would be under the CDAC or separate. Mr. Parker responded that he thought it made sense to include this service under the heading of “cardiac data” considered by this committee. He noted that, up till now, PCI is the service that has been the chief concern. With the recommendation to use the STS registry data as the foundation for considering cardiac surgery program performance, it would seem logical for CDAC to also add this data stream to its oversight. Dr. Williams asked if the CDAC would compete with the standing advisory committee. Mr. Parker responded that the CDAC is an existing group, and he thinks it should provide advice on both public reporting and the use of data for regulatory oversight. However, he noted that the standing committee was expected to provide an institutional perspective on the regulatory oversight issues and that unconstructive duplication of effort could be minimized with good communication between the groups and an understanding of their respective areas of responsibility. For example, the standing oversight committee would be a source of review and comment to CDAC on risk adjustment models.

Ms. Harper, who has been involved in both the CDAC and the CAG, commented that she sees the data work as very intensive. She sees the CDAC as a technical work group. Dr. Horvath commented on the proposed structure of oversight, noting that it would be unwieldy to have one big group. He proposed having separate groups for cardiac surgery and PCI. In addition, he commented that he did not understand why the CDAC would be involved in the risk adjustment modeling because, for cardiac surgery, that risk adjusting is already done. He expects that the CDAC would be more interested in auditing, which also seems more important.

Ms. Fleck responded to Dr. Horvath’s comments by explaining that for PCI, the CAG talked about developing a risk adjustment model for Maryland only. NCDR does risk adjustment based on the national data that it collects, but the CAG seemed to strongly endorse the need for Maryland to create its own risk adjustment model.

Dr. Greg Dehmer commented that, on request, NCDR will create a state- specific risk-adjusted data set for Maryland and it has done so for other states. Dr. Williams asked for confirmation that the risk adjustment to the data would be based on the national experience. Dr. Dehmer confirmed that is the case; the assumption is that the patient base is basically similar to the national patient base reflected in the data submitted to NCDR. He noted that the greater statistical power available through using national data is helpful; the confidence intervals would be larger if just Maryland data was used.

Dr. Gary Walford commented that most states that do their own risk adjustment models come up with similar models. However, he suggested that Maryland may want to look at 30-day follow-up through use of the HSCRC data, so having a technical advisory committee will be helpful. He noted that Maryland has an opportunity to do something that other states have not done because of the NCDR CathPCI data linking to the NCDR Action Registry and possibly other data sets as well.

Mr. Parker commented that Maryland is not necessarily trying to reinvent the wheel in creating a risk adjustment model. It can look at models developed by other organizations, but the idea is that the CDAC will provide input on the model to use for both the NCDR data and the STS registry data, which could involve adopting a national model. Dr. Keith Horvath commented that the risk adjusted results are put together for STS. He also noted that the STS registry data is audited but that Maryland could perform its own auditing as well. He also noted that there is a lot of detailed reporting in the STS registry data; it's not just mortality and a couple other measures. Dr. Walford commented that it would make sense for the CDAC to look at measures in the STS registry and consider them for inclusion in the evaluation of a hospital's program. It will be an ongoing process. Dr. Walford asked if STS would give MHCC the raw patient level data in Excel spreadsheets, for instance. Dr. Horvath said that he would have to check on it.

Ms. Fleck suggested that the CAG talk about other regulatory oversight models that had been proposed. She noted that Dr. Horneffer has some ideas, and his slides were distributed to the CAG prior to the meeting. However, Mr. Steffen asked that Ms. Fleck first talk about external review and focused reviews. She explained that a requirement for external review of at least five percent of cases was previously agreed upon by the CAG. She explained that in the MHCC proposed model, the external reviewer could be MACPAQ or some other independent organization. Reports from the external reviewer would come directly to MHCC. She also noted that some summary level information could go to the standing committee for their consideration. It could be used to inform whether changes in regulations are needed.

Ms. Fleck then went on to explain the concept of focused reviews. She explained that these are triggered by review of the data being collected from hospitals, when the data suggests there may be a problem with program performance and/or patient safety. MHCC would put together a team to investigate, which she suggests should be primarily people with appropriate expertise from outside of Maryland. She noted that these reviews and teams could vary; it could just be an MHCC staff review if the problem appears to be more related to missing information and data collection and reporting practices. The focused review team would come up with recommendations, which would be given to both the hospital and MHCC. In some cases, a hospital could be expected to propose a plan of correction which would then be subject to review and comment.

Dr. Hiratzka noted that the CAG had talked about other triggers, such as institutions that have some concerns or questions. Dr. Williams agreed that piece is missing. Dr. Williams also added that internal reviews were also discussed and should be folded into the diagram. Dr. George Groman commented that Dr. Williams point is an important one.

Dr. Walford commented that it may be possible to use in-state people from a different part of Maryland to avoid conflicts of interest. Dr. Aversano agreed with Dr. Walford.

Dr. Williams requested clarification on whether the MACPAQ reviews are only procedural reviews that do not touch on whether a patient should have had the procedure in the first place. Dr. Aversano stated that the MACPAQ reviews would cover the angiographic review, appropriateness review, and outcomes review, and clinical data from medical records

could be used to assess the accuracy of the NCDR data. Dr. Hiratzka asked if there were any other comments. There were none, so Dr. Hiratzka suggested moving on to the other proposals. Dr. Hiratzka asked Dr. Horneffer to talk about his proposal for the regulatory oversight structure, and Dr. Williams suggested that Dr. Horneffer also compare it to the MHCC proposal.

Dr. Horneffer explained that his idea was based on other efforts that he is aware of in New England and Virginia, and a similar effort that he is aware of that is currently underway, the Maryland Cardiac Surgery Quality Initiative (MCSQI). He noted that he sees it as a rebirth of an effort that was attempted 15 years ago that failed. He thinks that the problems that gave rise to law changes in Maryland and the creation of the CAG could potentially have been avoided, if there had been sufficient transparency and oversight. The main theme of the proposal is to create a structure on both the PCI and cardiac surgery side, which is why he has two separate boxes, one for each. All providers of those services and other experts would have representation. There would be data transparency while also blinding data, as necessary, for specific functions. He noted that similar systems have been set up in other states and a lot of the details have been worked out by those efforts. For example, in Virginia, where there are 17 cardiac surgery programs, it does not make sense for everyone to be on the board, but they all can elect people to the board for rotating terms. The oversight committee would have representation from cardiology and cardiac surgery as well as organizations like the American College of Cardiology.

Dr. Horneffer explained that MCSQI will be forming regardless of what comes out of the Commission, but he thinks having a state connection provides an impetus to move forward. Its primary responsibility will be process improvement. To do that, the group needs to have a good handle on the data, so there will need to be a subcommittee to handle those issues. He believes hospitals will pull together and work collaboratively to bring up the level of performance of weaker programs. The emphasis will be on improving, not punishing programs. In his view, the proposal is similar to that of MHCC.

Dr. Hiratzka asked for comments on Dr. Horneffer's proposal. Dr. Aversano commented that he is concerned about the data analysis, gathering, and auditing being done outside MHCC and fed to an oversight committee. With doctors assessing their own outcomes, the appearance and the integrity of the outcomes in public reporting would be questionable. To him, MHCC along with the experts should be gathering and analyzing the data independently. Otherwise, he thinks the concepts are pretty similar. Dr. Hiratzka asked for feedback on that issue. Dr. Horvath commented that he thought it would be addressed through an audit. He also expressed concern that another layer of oversight is being added that will create confusion. He anticipates that if you get numbers that do not exactly match, then a lot of time may be spent on resolving those issues, rather than actually improving quality.

Dr. Aversano commented that the kind of patient-level information from NCDR that MHCC is getting can be audited and analyzed within the State. Neither STS nor NCDR can do the level of auditing that has been discussed; only a very small percentage of cases are audited in the STS registry and NCDR. Dr. Aversano stated that auditing will be useful for training people who enter the data, and data entry will improve. He sees it as a fundamentally different effort, not as a duplication of effort. Dr. Horvath responded that it seems like there is an auditing problem, so there should be an auditing solution. As part of that, he agreed there could be

education for those who do the data entry. Dr. Aversano responded that the NCDR will not take audited data and put it back in the data set; he is not sure if the STS will or not.

In response to Dr. Aversano's comments, Dr. Horneffer noted that MHCC can do whatever it wants with the data, but the MCSQI needs accurate data too because process improvement will only work if data is accurate. He sees getting data managers together will be an important early step. He also noted that there will be blinding of information so it will be hard to game the system. Dr. Williams asked Dr. Horneffer how an evaluation of appropriateness of care is handled. Dr. Horneffer responded that it would be based on established criteria. He is proposing mechanisms for answering that question. The experts will be in the room and will be responding to changes in practice/technology over time. Dr. Williams noted MACPAQ is doing that now, right? Dr. Horneffer confirmed that is the case. The idea is to put the structure in place for answering those questions. Dr. Walford commented that surgeons are dragged along due to problems regarding PCI, so it is not surprising that they like their system. However, he thinks getting the data from STS and verifying its accuracy is important. It may turn out the data is very accurate. Both Dr. Horneffer and Dr. Walford asked whether MHCC can get the raw data from STS. Dr. Hiratzka responded that institutions could send the data to MHCC individually because they each have their own data.

Dr. Horneffer commented that he sees the review of data as a separate issue. His focus is on the structure. He could see MHCC getting the data too, and if, after five years, it is apparent that the data are very similar then it may make sense to not have both review the data. Dr. Hiratzka commented that he sees MHCC as essential to the whole process. He is not sure about creating another committee for the data handling. Dr. Horneffer noted that he is proposing an advisory structure to address unforeseen issues, that's all. Dr. Hiratzka commented that the focus should be on developing the primary elements without getting into too much detail.

Dr. Hiratzka asked Dr. Aversano to talk about his proposal for the oversight structure. It's just a refinement based on the last meeting and feedback from the CAG. He tried to strip out some of the details to make it clearer. Dr. Williams noted that MHCC's proposal looks reasonable and requested input from Dr. Aversano on it. Dr. Hiratzka commented that he thinks most of the elements are the same. The tricky part is how to judge appropriateness. Dr. Aversano commented that there is pretty good guidance for angioplasty. Dr. Williams commented that the external reviewer will be looking at angioplasty and for the internal hospital level reviews; he would hope that it is looked at for the focused reviews too.

Dr. Hiratzka asked for comments on the diagram put together by Dr. Aversano, included as a meeting handout. Mr. Steffen commented that a big difference appears to exist in the connection of the peer review and triggered review committees and the oversight committee. Under Dr. Aversano's diagram those are linked to the oversight committee. MHCC thinks those should come directly from MHCC. Dr. Aversano explained that it is important to read the descriptions that go along with the diagram. He sees each group as not being independent. Each is created and empowered by MHCC. No group is independent of MHCC.

Ms. Fleck elaborated on the key differences between the MHCC staff diagram and ideas that were previously discussed by the CAG. She noted that the external review process

previously had been discussed as something more closely tied to the standing committee, and MHCC is proposing that the process be more separate, with some flexibility for hospitals in how they meet the external review requirements. It could be MACPAQ or someone else. Dr. Horvath commented on the third paragraph on page 1 of the discussion guide, which states that the Commission prefers that people outside the state perform reviews that may ultimately lead to closure. Dr. Horvath noted that there is really a direct connection between the group performing reviews and MHCC.

Mr. Parker agreed with Dr. Horvath's comment. He added that Dr. Aversano's point is that all the groups are MHCC groups that originate with MHCC and provide feedback to MHCC. MHCC would like to have more disaggregation. He noted that staff made a point of listing the functions of the groups. Groups are not taking a direct role in regulatory actions. They are not doing external review as an official MHCC body. MHCC is more comfortable with this type of structure, as outlined on the chart. MHCC has not typically put out staff recommendations for the CAG to consider, so he wants to make it clear that the goal of putting together the diagram is not consensus on a staff proposal. The idea was to facilitate getting the best advice from the CAG.

The other proposals show a much more integrated approach with MHCC. MHCC's proposal shows that MACPAQ is an option, but not mandatory. An alternative body can be used. MHCC gets a report directly to make sure hospitals are looking at appropriateness and dealing with it appropriately. When you look at Dr. Miller's proposal for expanding MACPAQ statewide, there is an emphasis on being non-punitive, and staff's diagram is structured in a way that preserves that perception of MACPAQ. For the standing oversight committee, it will give advice to MHCC on specific hospital questions, but only when MHCC is concerned about program performance, has initiated a focused review, and has findings and recommendations that the oversight committee can comment on. The oversight committee will not be used for focused reviews. MHCC thinks it makes sense for MHCC to form its own focused review team without trying to pick Maryland providers who may be disinterested or from other parts of the state. There are not 23 independent hospitals providing PCI and ten independent hospitals providing cardiac surgery; development of multi-hospital systems has advanced to a point where clear "disinterest" will often be difficult to achieve with Maryland experts. MHCC wants the focused reviews to be unquestionably independent.

Mr. Parker further explained that the focused review team will make findings and recommendations, and a hospital may need to put together a plan of correction, based on those findings and recommendations. The plan of correction would be sent to the oversight committee, which could provide advice on whether the plan is acceptable, before the Commission takes action. Those are the main differences. The diagram is informed by the ideas of Dr. Aversano and Dr. Horneffer, but different in that its emphasis is on avoiding conflicts of interest.

Dr. Walford asked what would happen when an individual complains. Ms. Fleck responded that, as she recalls, Dr. Aversano noted that an individual complaint could be a possible trigger for a focused review. The MHCC proposal focuses more on the structure for oversight, but if the CAG wanted to make a recommendation on that issue, it could be added.

Dr. Walford asked who gets patient complaints. Ms. Fleck responded that she thinks it would be the Board of Physicians and/or the Office of Health Care Quality. However, if a complaint related specifically to regulatory oversight, like peer review, MHCC would get involved.

Dr. Hiratzka asked the CAG for feedback on the composition of the standing committee. Ms. Fleck also added that members should comment on the models themselves too because a lot of time has been spent describing the different models and not much opportunity has been given for feedback on the models.

Dr. Horvath noted that the grassroots effort for the CSQI is designed to have a hospital representative and an administrator representative. He thinks rather than having another committee, it makes sense to use that structure. He added that it is important to have administrators included, so they understand the issues and how to address them. He also wanted to reiterate that there should be two committees; one for PCI and one for cardiac surgery. Dr. Yuri Deychak suggested including cardiac catheterization lab staff for PCI because they have a different perspective than physicians.

Dr. Warren asked about having subcommittees for PCI and cardiac surgery. Dr. Hiratzka suggested that each hospital could nominate people to be part of the oversight committee in order to keep the number of members more manageable. Dr. Warren also added that he likes the proposal described by Mr. Parker. He agrees that it may be important to have outside reviewers for focused reviews, if a program may potentially be shut down.

Dr. Hiratzka asked Ms. Fleck if she had everything she needed. Ms. Fleck responded that it seems like a lot of people have not really weighed in on which model is preferred. She asked whether it is difficult to figure out the differences between them.

Dr. Aversano commented that the fundamental issue is the boxes outside of MHCC, and the idea that the external review team is independent of MHCC but reports to MHCC. Dr. Aversano sees it as semantics, although he understands from a regulatory standpoint it is important. He asked, why would those organizations outside of MHCC exist unless there was a need to report to MHCC? There's a certain need that MHCC has for the data from external reports. Mr. Steffen agreed with Dr. Aversano's comments.

Dr. Aversano next asked for clarification on where the NCDR data is sent and who analyzes it. Ms. Fleck responded that MHCC currently receives that data and reviews it, and she expects that to continue. Dr. Aversano agreed, but commented that he did not see that noted on the MHCC's diagram of its proposed oversight structure. He noted the CDAC has responsibility for providing advice on the data and asked why two committees are needed for that task (oversight committee and CDAC). Ms. Fleck responded that she thought what had been discussed is that the data work is very technical and labor intensive, so it would have primary responsibility for the data, but the oversight committee would have lots of communication with the CDAC. The oversight committee would have a different set of primary responsibilities related to revising and implementing the State Health Plan.

Mr. Steffen noted that the relationship of CDAC to the standing committee could be discussed, but it is a group that already exists and is currently working. He does not want to take CDAC apart and start all over again. Dr. Aversano suggested that it could become part of the oversight committee. Dr. Walford suggested that it could be part of subcommittees for PCI and cardiac surgery. He also suggested that there be rotating representation on the oversight committee, so the number of members can be around 20, with representation from surgery and PCI programs, as well as other organizations. He also suggested that there could be multiple specialized subcommittees that feed into the CDAC.

Dr. Hiratzka agreed with the potential need for multiple subcommittees that feed into the CDAC because there will be a lot of tasks that have to be completed, such as reviewing the NCDR data. Dr. Aversano was surprised by that idea, and said that he has not heard that before. Dr. Aversano noted that a key element of monitoring the NCDR data is angiographic review, so he thinks the peer review process would be the place for it. Ms. Fleck agreed.

Dr. Aversano asked for clarification on who would be auditing the data, noting that he finds the arrows on the MHCC diagram confusing. Ms. Fleck responded that CDAC will provide advice on auditing of the NCDR data. It will not be doing the auditing of data itself. The evaluation of the appropriateness of care will be done through peer review, which may be an external review body.

Dr. Horneffer commented that the proposals are all very close, but he would like to know whether it is acceptable to MHCC to have an independent incorporated oversight committee that provides advice to MHCC or whether that oversight committee will have to be part of MHCC. Dr. Aversano commented that he sees MHCC welcoming the external review groups like MACPAQ and MCSQI. His concern is the appearance of integrity for data analysis. As he understands it, MHCC is going to continue to receive NCDR data, will audit the data in some way, and will develop a risk adjustment model for the quality measures chosen. Dr. Horneffer agreed, but added that it would not preclude another group from doing data analysis.

Dr. Horneffer commented that he does not see much difference between the proposals. Dr. Walford commented that there is a big difference. The staff diagram does not have an independent organization for oversight; depending on an external group to validate the data is very different. Dr. Horneffer commented that is not what he is proposing. The group would have an advisory role to MHCC. He believes MHCC is seeking advisory input, more so than data collection.

Dr. Hiratzka asked members for their thoughts on having an external oversight committee (independent organization) versus an 'internal' one under MHCC's control. Mr. Steffen commented that the model proposed by Dr. Horneffer would be difficult to adopt. He noted that those organizations could be represented as part of the standing committee though. Diverse representation is necessary in his view. Dr. Hiratzka asked members to vote on which model for the oversight committee they support (an external independent organization or an internal one under MHCC's control).

The vote strongly favored a committee empowered by MHCC. Dr. Deychak asked if members of committee would be volunteers. Ms. Fleck explained that generally committee members would be volunteers. She noted that the external review process is something hospitals would need to pay for, and she expects that the focused review teams would need to be compensated, but otherwise members would likely not be compensated. She noted that for this group some compensation would be necessary for people traveling from out of state.

Regulatory Oversight Process

The next discussion question focused on whether MHCC's proposal for the regulatory oversight process was acceptable, which Dr. Hiratzka posed to the CAG. Ms. Fleck explained that the discussion guide includes a description of the timing of the process for certificates of conformance and certificates of ongoing performance. She noted, as key considerations, the timing of the renewals, specifically the number of years between renewals, and the process for when a plan of correction is needed.

Dr. Aversano asked about the lack of opportunity for interested party status by an entity that thinks it will be harmed. Ms. Fleck explained that the CAG previously talked about the opportunity for appeal, but with the way the law is written there would not be an opportunity to appeal. Mr. Steffen noted that allowing interested parties tends to lengthen the regulatory process considerably. Ms. Fleck suggested that, in the interest of time, the CAG move on to other issues.. She suggested that members email comments with respect to the regulatory oversight process, following the meeting, so that there would be sufficient time to consider the remaining important issues.

Outcome Measures

Ms. Fleck suggested that the CAG discuss outcome measures again, with respect to PCI and cardiac surgery. She noted that for cardiac surgery, it was suggested that the star rating system be used and other outcome measures considered. Dr. Williams asked about the outcome measures previously discussed, and Ms. Fleck mentioned the star rating system created by STS. Dr. Williams asked if the star rating system was currently in use. Ms. Fleck explained that it is not currently in use because the cardiac surgery programs are not subject to ongoing review by MHCC, but she thought there was consensus on use of the star rating system, going forward with the new regulatory oversight process, that would involve periodic recertification of cardiac surgery (Certificates of On-Going Performance).

Dr. Williams disagreed that consensus had been achieved. He commented that the star rating system seems arbitrary and could be misinterpreted. He would rather give the data for specific outcomes. Dr. Horvath responded that the goal is to come up with a system for determining whether a program has satisfactory outcomes, and the star rating system meets that need. Dr. Williams commented that from the perspective of a patient, it is important to know that a program is meeting certain minimum standards.

Dr. Walford asked for clarification on whether the question pertained to public reporting. Ms. Fleck responded that it is about evaluating the quality of a program for purposes of regulatory oversight but that public reporting would, of necessity, also be an issue with any rating system adopted for use in regulation.

Dr. Walford suggested that risk-adjusted mortality makes sense for PCI and surgery. For process outcomes, for surgery, he suggested use of the risk-adjusted rate of myocardial infarction following CABG with left interior mammary artery to the left anterior descending artery (LIMA to LAD). This measure was proposed because when making bypass grafts, surgeons have learned that an artery works better than a vein in the particular situation when the graft is needed to restore blood flow to a very important part over the front of the heart. This is true even though it is technically more difficult and requires more time to use the artery than the vein.

For process measures, for PCI, Dr. Walford suggested door-to-balloon time. Dr. Horvath commented that the star rating system incorporates 11 different aspects that relate to process, mortality, morbidity, demographic information. He added that the STS star rating system has already addressed how to evaluate the quality of a program, and consumers appreciate having a simple way to evaluate programs.

Dr. Horneffer suggested having only two ratings instead of three: good program and troubled program. He commented that a lot of thought went into creating the STS star rating system and some clinical information may not make much sense to the average consumer, so the star rating system makes it easy to understand where the quality of a program ranks. Dr. Hiratzka agreed that the star rating system really simplifies the evaluation process for everyone. Ms. Harper asked for clarification on the issue being discussed. She thought the issue was looking at outcomes to use to evaluate the quality of a program, not public reporting. Her understanding is that the star rating is supposed to be a trigger for review. Others agreed. Mr. Steffen suggested public reporting be taken off the table for discussion, and the CAG focus instead on measuring quality.

Dr. Richard Pomerantz asked if elective and emergency PCI can be separated, as is done in New York. He thinks there is a big difference and elective PCI is a true measure of whether there is something wrong with a program. Dr. Walford noted that usually a program that has problems with elective cases also has problems with emergency cases. Dr. Deychak asked if salvage cases are included for the risk-adjusted mortality calculations. Dr. Walford commented that New York does not include it, but Massachusetts includes it. He added that Maryland needs to decide what it wants to do and can draw on the experiences of other programs. Dr. Aversano commented that you have to have clear definitions because there is a lot of mucking up you can do in terms of categorizing. In response, Ms. Fleck agreed that Dr. Aversano makes a good point, but she suggested that the CAG focus more on the outcomes to use and less on the details, which can be worked out through the CDAC.

Dr. Walford noted that the NCDR data is being used and will be audited. Dr. Groman commented that he agrees with Dr. Pomerantz's point that emergency and elective PCI cases should be separated. A patient in the midst of a STEMI is not going to be asking about whether

the ambulance is going to a two star or a three star program. Dr. Walford commented that that issue relates to public reporting, which is already off the table for discussion at this meeting. Dr. Williams added that he is not sure about how much detail the CAG needs to get into. He suggested that putting the structure together is very important, and once groups are created, they can wrestle with some of the issues.

Ms. Fleck commented that she wanted to discuss appropriateness review for cardiac surgery. Dr. Williams asked if MACPAQ would look at the surgery cases, or if not, would there be a similar entity. Ms. Fleck responded that it could be MACPAQ or a similar body for external review. Ms. Fleck stated that it would be helpful to have more direction from the CAG on how appropriateness review of cardiac surgery cases should be accomplished. For PCI, her understanding is that review of the angiography will be key. In response to this request, Dr. Horvath commented that he assumes Ms. Fleck is referring to evaluating the appropriateness of CABG. He noted that the cardiologist is a filter for cases, and you would look at the same angiogram that is reviewed for PCI cases. From a practical standpoint, the way to resolve the issue is through auditing that includes a review of the angiogram.

Dr. Horneffer commented that he sees the review of appropriateness of heart valve surgery as a more significant problem, even though those cases are a much smaller percentage of cardiac surgery cases than CABG procedures. He thinks appropriateness review in these services comes down to oversight bodies. There may be many surgical techniques that may be inappropriate now, but completely appropriate five years from now. He asked which group (in the MHCC diagram) would be responsible for reviewing appropriateness of cardiac surgery on an ongoing basis, as the definition changes. Dr. Horvath responded by suggesting that a cardiac surgeon be added to the MACPAQ to address the issue. The angiograms for cardiac surgery cases could also then be reviewed by that body.

Mr. Steffen commented that he thought Dr. Aversano indicated that Dr. Horvath's idea was feasible. He asked if Dr. Aversano was still on the phone, but he was not. Dr. Walford commented that the patients that are appropriate for surgery fall out of the CathPCI data. He added that the appropriateness for surgery is amazingly good, based on the literature. He also commented that the data elements are already gathered, but it makes sense to audit the data. It was noted that the data needed to evaluate appropriateness is also in the STS registry data set.

Dr. Hiratzka commented that a new database and review structure does not appear to be needed, for looking at appropriateness. Dr. Warren added that he has not been involved in MACPAQ, but he is confident with the redacting mechanism that it could be done. He suggested leaving it up to the standing oversight committee and not making a decision now. He noted that for cardiac surgery you have two opinions for everyone that has surgery, and the value of the additional costly review should be considered. He asked other CAG members whether they agreed. Dr. Williams responded that it would be robust to have the system in place to do it. For completeness, he would do it, even if the review is not done at the same frequency. He would not wait to see what the oversight committee thinks. Ms. Harper agreed with Dr. Williams and added that it helps to model the Heart Team approach.

Heart Team Approach

Ms. Fleck commented that the Heart Team approach had been discussed at the last meeting, and as she recalls, the CAG emphasized avoidance of micro-managing. She then asked the CAG for feedback on having a requirement to have a protocol for when to use it. Dr. Pomerantz opposed this idea. He commented that most programs have a relationship with a provider of cardiac surgery, even if those services are not available on site. Ms. Fleck clarified that she was asking about whether a standard should be developed requiring policies with respect to use of the heart team approach. Dr. Williams suggested that the CAG can be identified as endorsing the approach. Dr. Deychak commented that, from a regulatory standpoint, he would endorse the Heart Team approach, but if he had to write out specific regulations describing which patients must get it to determine the proper course of treatment, it would be very difficult. He does not think that writing it down at that level of specificity is possible. Ms. Fleck clarified again, that her idea is to require hospitals to have a policy. Detailed requirements would not necessarily need to be written into regulations. The CAG's consensus was to not require hospitals to have a policy on when to use the Heart Team approach.

Pediatric Cardiac Surgery

It was decided that outcome measures had already been covered adequately, so Dr. Hiratzka brought up the issue of pediatric cardiac surgery and the approach to evaluating the quality of those programs. He questioned whether the CAG is in a position to tackle the issue. Dr. Horvath responded that in the STS registry, there is a pediatric data set. The database is not as large or longstanding, but he believes both programs in Maryland participate in it. He suggested asking for both pediatric and adult data from those hospitals. He noted that there is not a star rating system yet because of the low volume of cases for most types of procedures. Dr. Williams asked Dr. Horvath if there had been contentious pediatric cases or questions about appropriateness. Dr. Horvath was not able to provide any examples of such cases. Dr. Horneffer commented that it is probably too much to tackle for the CAG.

Dr. Williams asked if there should be any kind of reporting at all for pediatric cases. Dr. Hiratzka commented that getting the reports is one thing, but figuring out what they really mean is another issue. Dr. Horneffer agreed, adding that the field is one that is very rapidly evolving. Dr. Walford commented that there are certain groups with high mortality. He commented that adding someone with a specialization in pediatric cardiac surgery to the regulatory oversight structure could be done.

Ms. Fleck asked if anyone else wanted to comment before moving on. Dr. Walford commented that a big issue is what happens with the pediatric patients once they reach adult age, but added that it could be an issue for future discussion instead of tackling now. Ms. Fleck commented that putting off making recommendations on pediatric services could be done, and asked for feedback from the CAG. The CAG agreed with that idea. Dr. Horneffer added that in the future it would make sense to look at both pediatric cardiac surgery and pediatric cardiology and its invasive procedures.

Focused Reviews

Ms. Fleck noted that what is meant by focused review is fairly straight forward; a specific programmatic investigation into an area of concern based on a review of the data. Dr. Hiratzka noted that it would not just be based on a review of the data. It could also be the result of an outside entity expressing concerns or an institution requesting it. Dr. Williams commented that a definition should be included. Dr. Aversano asked if the term focused review is synonymous with triggered review. Ms. Fleck stated the terms are being used interchangeably.

Ms. Fleck commented that she also has introduced the term comprehensive review, which would be every five years at the time of renewal of a certificate of ongoing performance, which would be an opportunity to take a detailed look at a program, especially if there have not been any focused reviews. Dr. Aversano commented that a comprehensive review seems unnecessary, given that there will be ongoing peer review, both external and internal, and the opportunity to do focused reviews.

Dr. Hiratzka asked for clarification on the scope and purpose of the comprehensive review. It was noted that the review would happen as part of the legally required authorization renewal process. Ms. Harper suggested that the review be a review of the data already collected with the addition of checking on Joint Commission reports and whether any complaints had been filed. Ms. Fleck commented that the idea is to primarily rely on the ongoing review, but she thought it might also be helpful to have an on-site review. Ms. Harper commented that comprehensive reviews seem unnecessary given the ongoing review process.

Dr. Hiratzka asked what would be reviewed, and Dr. Williams proposed that there would be a review of random charts. Dr. Aversano commented that a random review of charts is already being done anyway through the peer review process. It was noted that the CAG had agreed that five percent of cases be reviewed externally and 10 percent internally, with a minimum of ten cases reviewed per physician.

Dr. Williams asked if anyone on the CAG thinks comprehensive reviews are necessary. Dr. Horvath commented that it would only be needed if there had been triggered reviews. Dr. Aversano agreed that would be a reasonable approach. Someone else suggested that it be left to the discretion of MHCC staff, and it appeared that the consensus of the CAG was that comprehensive reviews should take place only if there had been a focused review in the prior five years since the last renewal and left to the discretion of MHCC staff. There would not automatically be a comprehensive review.

Triggers for Review

The CAG has previously talked about volume and quality concerns as triggers for reviews. Ms. Fleck noted that she thought the CAG had not discussed a volume trigger for programs that only have primary PCI. Ms. Myers thought it had been chosen, based on the current State Health Plan (SHP) standard: 36 for rural hospitals and 49 for urban/suburban hospitals. (The SHP, COMAR 10.24.17, currently states that a primary PCI program “should perform a minimum of 36 and optimally 49 primary PCI procedures annually” and also states “The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available.”) Other CAG members agreed with Ms. Myers.

PCI Programs Limited to Primary PCI

Dr. Williams, in previous meetings, had questioned the validity of regulatory policies supporting maintenance of PCI programs that only perform primary PCI and suggested that the CAG should have a recommendation on that issue. Dr. Groman commented that, in the case of Howard County General Hospital, a non-cardiac surgery hospital in the Johns Hopkins Health System that is currently authorized to only provide primary PCI, it did not make sense to add elective PCI because most of the physicians who would be performing elective PCI are on staff at The Johns Hopkins Hospital. It did not seem to make sense from the perspective of the patient. Dr. Williams asked whether the team would be providing better care because of the greater level of experience gained by performing more PCI procedures. Dr. Groman commented that he does not have data on that issue, but it makes logical sense to him that a team with more experience would do better. However, he was still uncertain as to whether the difference would be clinically relevant for patient outcomes.

It was noted that some sites may want to do just primary PCI, and those programs are meeting a critical need. Dr. Groman inquired about whether data from the CPORT-E study would answer Dr. Williams' question. Dr. Aversano suggested that the difference may be more in post-procedure care, not in the procedure itself. He also agreed with the point made about patient care being better by having a primary PCI program compared to having no program at all. With primary PCI, when it first started, the problem was transportation, which has improved a lot. Dr. Warren suggested that individual hospitals decide on whether to do just primary PCI or both primary and elective PCI, and the former option should not be foreclosed.

Potential Decrease in Elective PCI Volumes for Existing Providers

Mr. Steffen asked if there is any concern about spreading the volume of elective cases among more providers and potentially having more low volume programs. Dr. Groman commented that if Howard County General Hospital requested assistance from The Johns Hopkins Hospital in setting up an elective PCI program, it would probably be simply shifting cases from one location to another. Dr. Aversano commented that the CAG had decided that volume does not matter, so it would be hypocritical to take a position that lowering the volume of elective PCI cases is a concern. There should be internal consistency. Dr. Horvath agreed.

Dr. Groman clarified that he is not sure what the impact of adding 100 to 300 elective PCI cases at Howard Community General Hospital might be, but he does not expect that The Johns Hopkins Hospital would see that change as financially advantageous. Dr. Williams suggested looking at the outcome data for sites that only do primary PCI compared to others and returning to the issue in the future. He suggested that the CAG move on to another issue. Ms. Fleck stated that the topic ties to another issue that she wanted the CAG to address, which is the acceptable level of impact on existing programs, when a new program is proposed.

Impact of New Programs on Existing Programs

Ms. Fleck read the relevant standard in the current SHP, which is shown below.

Policy 1.5 The establishment of a new adult cardiac surgery program should permit existing programs operating at volumes of at least 350 cases or more annually to maintain patient volumes of at least 350 cases annually.

Dr. Warren asked where the 350 case volume in the standard came from, but no one was able to speak to the history of its origin. Dr. Warren suggested that the number 200 be used or whatever number the CAG had agreed upon as triggering concerns about quality. Ms. Fleck asked if anyone else wanted to comment on the issue. Dr. Williams commented that having symmetry is good, as proposed by Dr. Warren. Ms. Fleck responded by asking, what if a hospital is doing 500-600 cases and another program is proposed that will pull away 300 of those cases, is that acceptable? The consensus of the CAG was on using 200 cases for both cardiac surgery and PCI.

Mr. Steffen commented that he also likes the symmetry of the approach. He added that the economic issues raised by a large drop in volume could also be considered separately. Dr. Hiratzka asked if anyone else wanted to comment, but there were no additional comments. Dr. Hiratzka spoke about his experience living in a city with eight cardiac surgery programs, about to increase to nine programs, with two hospitals doing less than 100 cases per year. Although he was not able to propose what the level of acceptable impact should be, he expressed concern about how things will play out over the next several years, if volumes keep dropping due to the addition of new providers. He asked Dr. Horvath for his thoughts on it.

Dr. Horvath noted that the discussion guide, on page 5, states that consensus was not reached, but he thought it had been reached. Dr. Horneffer and others agreed. Ms. Fleck explained that while her understanding is that consensus had been reached on the triggers listed, the idea was to revisit the issue in the context of impact after seeing what decisions were made with regard to PCI and to consider whether any additional triggers should be considered. There was no further discussion of the issue.

Volume Requirements for Pediatric Programs

Ms. Fleck asked about volume requirements related to pediatric programs and whether the CAG wanted to change the current policies. She noted these are included on page 7 of the discussion guide. She read the two relevant policies shown below.

Policy 1.1 There should be a minimum of 130 cardiac surgery procedures annually in any institution in which cardiac surgery is performed for only pediatric patients.

Policy 1.2 There should be a minimum of 200 adult open heart surgery procedures and a minimum of 50 pediatric cardiac surgery procedures annually in any institution in which both adult and pediatric cardiac surgery is performed.

Dr. Warren asked about the source of the numbers in the current policies. Ms. Fleck did not know the history of their origin. However, she speculated that the numbers could have come from guidelines of one of the professional cardiology societies' that were current at the time the policy was written. Dr. Horvath commented that the problem is that there is no pediatric

cardiologist included in the CAG, so it would be inappropriate for the CAG to make a recommendation. Ms. Fleck asked if other people agreed. The CAG agreed, so Ms. Fleck suggested moving on.

Dr. Aversano asked why the CAG was talking about volume requirements for cardiac surgery, but not angioplasty. Dr. Aversano noted that new cardiac surgery programs need to meet a volume of 200 cases, but there is no requirement for angioplasty. He thought only a review is triggered by a volume of less than 200 cases. He wanted to know why the programs were not handled similarly. Dr. Warren agreed with Dr. Aversano's point and suggested that 200 be the volume requirement for a new PCI program. Ms. Fleck commented that she thought that requirement had already been endorsed by the CAG. Dr. Walford commented that he thought the CAG was waiting for the ACC to update its guidelines.

Dr. Williams asked Dr. Dehmer if he wanted to comment. Dr. Dehmer noted that it will be addressed in ACC competency guidelines, and it is fairly well documented that there is a cut point for PCI programs of 200 cases. Below that level, generally there may be less favorable outcomes. If a number is included, 200 is the right number in his opinion. Dr. Aversano asked why the same argument does not apply to cardiac surgery. Dr. Dehmer commented that he can only address the PCI side of it.

Mr. Parker commented that his understanding of the CAG discussions to date is that 200 cases is the expected target annual volume for establishing a new cardiac surgery program or a new PCI program. The annual volume level considered low enough to raise concerns and trigger a review would also be 200 cases for PCI programs performing both primary and non-primary PCI. For cardiac surgery, an annual volume of 100 cases would trigger a focused review.

Utilization Projection

Ms. Fleck brought up utilization projections, outlined on page 8 of the discussion guide. She asked if having the utilization projections is helpful for evaluating proposed programs or if a different approach is needed. Ms. Fleck further explained the methodology. The use rates can be put together for cardiac services based on Maryland discharge abstract data and discharge data from hospitals located in the District of Columbia. Three years of historic data are reviewed, and the trend in use rates is then projected forward three years. The information is then used to provide some context for evaluating proposed projects.

One CAG member asked about the historic basis for development of the health planning regions. Mr. Steffen commented that health planning regions take into account patient migration into and out of regions. He noted that historically the regions have been static, but sometimes vary a bit depending on the service. He explained which counties are included in the regions.

Dr. Horvath noted that in the discussion guide, it states that patients cross the regions to obtain services and asked what that meant in terms of the projections. Ms. Fleck explained that migration is taken into account in the utilization projections. For example, it is not assumed that all residents of Anne Arundel County go to hospitals in the Metropolitan Baltimore Health

Planning Region. If many of them go to hospitals in the District of Columbia instead, that will be reflected in the projected utilization for the regions.

Dr. Williams asked about whether rates are assumed to be constant and if rates are calculated for specific procedures, such as TAVR (Transcatheter Aortic Valve Replacement), CABG, and PCI. He noted that TAVR is used more now and CABG is used less. Ms. Fleck explained that the projection is based on the historic three-year trend, so if case volume is declining, that trend would be reflected in the projection. She noted that she has not actually used the utilization projection, and all cardiac surgeries are aggregated in using the methodology. She asked if Dr. Williams was suggesting that breaking down utilization rates for specific types of procedures should be done. Dr. Williams commented that he is not sure what MHCC is trying to do with the utilization projections. He asked if MHCC is trying to project need. Ms. Fleck responded that the projection can be most accurately characterized as a utilization forecast rather than a need projection, because it relies exclusively on observations of previous utilization.

Dr. Hiratzka commented that he sees two scenarios for using the projection; one is a proposed new program in a region. The second use he sees is looking for outliers, if a hospital has very high utilization of a procedure compared to their population. He sees that as a possible trigger for a focused review, looking particularly at appropriateness. Dr. Groman commented that the proposed approach does not take into account the fluidity with respect to appropriate care. Ms. Fleck responded that she thought by looking at the three year trend, to some extent, the utilization methodology takes changes in care into account.

Dr. Hiratzka commented that the basic question is whether the utilization projection should be continued in the future. Mr. Steffen commented that he would prefer not to get bogged down too much in details. He noted that the idea is basically to use the projection to inform the Commission as to whether a program is likely to be viable. Dr. Aversano expressed concern about the details and the lack of granularity. The regions are very large, and things have changed quite a bit since the regions were instituted. He also noted that the need will depend a lot on how the region is defined. Dr. Horneffer commented that he agreed with Dr. Hiratzka's point about the potential to use the data to identify outliers and potential overutilization. He added that the standing advisory body (discussed earlier in the meeting) could evaluate whether overutilization was occurring or not. Mr. Steffen commented that the basic question is whether the utilization projection is useful going forward. He noted that using a normative standard instead is not a question that can be addressed today.

Ms. Harper commented that it is important to look at changes in utilization both when new programs are set up and when program closure is being considered. In the future, she thinks it is important to consider access to services. Mr. Parker asked the CAG whether the inclusion of a quantitative utilization projection should be included in the future for cardiac surgery and for developing a method for PCI services too. He added that it makes a big difference if it is included in the SHP because it establishes expectations upfront. Without it, it gives institutions more flexibility. Either way, a hospital will have to justify a case volume of 200 cases or more within the first two years.

Mr. Parker asked the CAG for feedback on the basic question of whether to have a utilization projection or not. Dr. Aversano commented that there is not a downside to allowing a program to present its own case, and he prefers not to have a utilization projection. Ms. Fleck explained that she sees the utilization projection as setting some parameters, but not necessarily limiting a hospital's own approach to demonstrating the need for a program. She noted that with CON reviews, an applicant often has his or her own methodology for justifying a project, and MHCC staff evaluates the reasonableness of the methodology used, even if the Commission also has its own approach.

Impact on Non-Maryland Providers

Dr. Horvath asked a question about a recommendation on page 8 of the discussion guide. He noted that it is different than what the CAG discussed previously at the December CAG meeting. He read the recommendation, which is shown below.

A new primary PCI, elective PCI, or cardiac surgery program will only be considered when the volume of PCI services at other providers in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will compromise the financial viability of other hospital providers.

He believes that the text should just refer to Maryland hospitals, not hospitals generally. Ms. Fleck asked for feedback from the CAG. Dr. Aversano asked how any hospitals other than Maryland could be considered. Ms. Fleck responded that she felt providers in the District of Columbia should not be ignored, if many Maryland residents utilize those hospitals. Dr. Horvath commented that he understood Ms. Fleck's point, but the quality parameters for Maryland hospitals cannot be imposed on District of Columbia hospitals. The CAG consensus was for the policy to refer to only Maryland hospitals.

Comparative Review Policies

Ms. Fleck brought up comparative review policies as an issue for discussion, noting these policies are described on page 10 of the discussion guide. She read the second listed proposed standard, which is shown below.

In the case of a comparative review of applications in which all policies and standards have been met by all applicants, the Commission will give preference to the applicant that is already providing primary PCI services and elective PCI services over a hospital that is not providing any PCI services.

Mr. Parker asked the CAG if it supported the proposed policy. Dr. Williams commented that it sounded reasonable, but there is no need to make it a law. A vote was taken, and Dr. Walford commented that the proposed policy is reasonable, which was the consensus of the CAG.

The CAG moved on to consider the third policy listed. Ms. Fleck read this policy, which is shown below.

The Commission will approve only one new adult or pediatric cardiac surgery program at a time in each Regional Service Area. After a new program has been approved the Commission will not consider an additional program in that Regional Service Area until the new program has been in operation for at least three years.

The CAG agreed that the third policy is reasonable. The fourth policy listed is new. However, Ms. Fleck commented that it was based on a CAG recommendation, so she does not see a need to discuss it again. No one objected.

Ms. Fleck read the next policy, which is an existing one. It is as follows:

In the case of a comparative review of applications in which all policies and standards have been met by all applicants, the Commission will give preference to the applicant with an established cardiovascular disease prevention and early diagnosis program with particular outreach to minority and indigent patients in the hospital's Regional Service Area. In evaluating the applicant's implemented program, the Commission will take into consideration:

(a) The applicant's demonstrated record of serving minority and indigent patients with cardiovascular diseases; and

(b) The applicant's demonstrated record of establishing a program for outreach to the minority and indigent populations with cardiovascular disease.

Dr. Williams asked if anyone wanted to modify the policy. No one proposed changes. However, Dr. Walford asked for a definition of "minority." Ms. Fleck responded that she is not sure if it is defined in regulations. Dr. Walford specifically mentioned language barriers as being relevant.

Next Steps

Ms. Fleck asked Mr. Parker and Mr. Steffen if there was anything they felt should be discussed in the last few minutes of the meeting. Neither brought issues for further discussion. Mr. Parker discussed the next steps of the process. A draft report with the final recommendations of the CAG will be circulated for comment by members. A final report will be put together based on input from the CAG. The CAG recommendations and Commission guidance will be used to write regulations. He mentioned that a group similar to the proposed standing committee could potentially be used to provide input as MHCC is putting together the draft regulations. Ms. Fleck stated that her goal will be to circulate a draft report in mid-May, and a couple of weeks for review will be given. Dr. Deychak asked about the timing of the anticipated ACC competency guidelines. Mr. Parker commented that he hopes the CAG's recommendations align with those guidelines, but there is still an opportunity for additional input on the regulations. Mr. Steffen thanked the CAG members for their service and the meeting adjourned at 4:00pm.

Appendix 3: General Proposed Oversight Structure

General Proposed Oversight Structure

