REGULATORY OVERSIGHT OF PERCUTANEOUS CORONARY INTERVENTION IN MARYLAND

A Report of the Maryland Health Care Commission

December 22, 2011

Executive Summary

Percutaneous coronary intervention (PCI**)** is the treatment of occlusion or narrowing (also known as stenosis) of coronary arteries, through use of catheter-based techniques. It is the most frequently used invasive method of treating this condition of the coronary arteries and is performed in cardiac catheterization facilities at acute care hospitals. *Primary PCI* is the intervention during a heart attack (acute ST-segment elevation myocardial infarction, or STEMI), performed on an emergency basis. *Elective, or non-primary, PCI* is the planned intervention to relieve narrowing of the artery before an acute heart attack occurs.

PCI services have been regulated by the Maryland Health Care Commission or its predecessor since 1990, which is a period covering the emergence of PCI as a common and widespread service. Primary PCI is currently performed in half of Maryland's 46 general acute care hospitals, which are located in half of Maryland's 24 jurisdictions. In 2010, 87.5% of Maryland's population resided in those twelve jurisdictions. (See Appendix D.)

Ten of the 23 hospitals providing PCI also provide cardiac surgery. MHCC and its predecessor agency, adopted regulations that, with certain exceptions implemented in 1995, require that PCI programs be co-located at hospitals with cardiac surgery programs. In 2004, the American College of Cardiology and the American Heart Association changed its guidelines (in response to the C-PORT research study that was approved by the Commission's predecessor in 1996) changing its co-location requirement to guidance that primary PCI may be performed at hospitals without surgery on site that met certain staffing, institutional, volume, and quality requirements. Hospitals with cardiac surgery on site provide approximately 80 percent of the PCI procedures performed in Maryland.

Beginning in 2006, MHCC began issuing time-limited waivers to primary PCI programs at non-cardiac surgery hospitals, some of which had been providing this service as part of a research project (and, later, under the terms of data reporting to a registry) as the result of an exemption from the co-location requirement that was granted by the Commission's predecessor in 1996. MHCC's 2004 regulatory change did not repeal the PCI/cardiac surgery co-location requirement. Rather, MHCC chose, at that time, to leave this standard in place and created a specialized CON "waiver" status and waiver review process as a path for approval of primary PCI programs in hospitals without cardiac surgery programs. The requirement did not change for non-primary PCI because clinical investigation of the safety of PCI outside of the hospital setting in which cardiac surgery is also available had only been completed for primary PCI. A waiver to provide primary PCI without on-site cardiac surgery is time-limited, requiring formal review and renewal of the approval every two years. A feature similar to this, CON approval conditioned on continuation of specified performance levels, has only been used on a limited basis in Maryland's CON program to date, with program case volume as the performance measure; since the late 1990s for cardiac surgery and organ transplantation and, as noted, since 2006, for CON waivers given to hospitals for primary PCI programs. The primary PCI waiver requirements extend beyond case volume requirements to include other measures of performance, most importantly, volume requirements and door-to-balloon time (the time involved in reperfusion and revascularization after the patient arrives in need of treatment for a heart attack).

In 2009, eight of the thirteen Maryland hospitals with primary PCI programs were authorized by MHCC to participate in a research study that investigated the safety of elective PCI performed in hospitals without open heart surgery programs. A research waiver authorization process was developed by MHCC to assure that the research would be conducted safely and effectively. MHCC also structured the program to limit the number of research sites and provide variety in the hospital service area characteristics of the research hospitals to better fit the research study's needs. In November, 2011, these hospitals, under regulatory requirements established by MHCC, had their CON research waivers to provide elective PCI renewed because the clinical investigation phase of the research had been completed. These hospital programs are now in a registry waiver status, in which they are required to maintain their primary PCI programs in good standing, perform in line with the requirements for elective PCI that they were required to meet as research waiver hospitals, and report data on all of their PCI services to national registries, which will allow MHCC to monitor their performance.

It is anticipated that the research findings with respect to the safety of elective PCI performed in hospitals without open heart surgery programs will be published in 2012 and, based on the results of the Principal Investigator's six-week follow-up of randomized patients, is likely to find that elective PCI was provided safely by the participating hospitals, which were required to meet certain program and practitioner volume standards and other requirements established as part of the clinical investigation. For this reason, an examination of the law establishing the scope of MHCC's regulatory oversight authority with respect to hospital services and the requirements for regulatory oversight is timely. In the 2011 General Assembly Session, House Bill 1182 (Chapter 616) was adopted, mandating that MHCC make that examination and provide recommendations to the Governor and General Assembly. This report responds to that legislation.

MHCC recommends the following changes to Maryland statute:

1. Percutaneous coronary intervention should be identified as a service regulated by MHCC and, when provided in hospitals without cardiac surgical backup, requiring an exemption from Certificate of Need.
2. MHCC should be given statutory authority to oversee PCI and cardiac surgery, including existing cardiac surgery hospitals, on an ongoing basis after issuance of a CON or an exemption from CON. This ongoing regulatory authority will require that PCI and cardiac surgery programs meet minimum performance standards as a condition of continuing to provide PCI and cardiac surgery services.
3. MHCC should be identified in Health-General §§19-218 and 14-411 as a State agency that can receive and share information for the purpose of investigating quality or utilization of care in regulated facilities.
4. The words "open heart surgery" in Health-General §19-120(j)(2)(iii) should be changed to "cardiac surgery" to reflect current usage.

MHCC acknowledges the concern expressed by stakeholders during the development of this report that requirements for peer review in the delivery of PCI should be embodied in Maryland law. We recognize the vital importance for cardiologists performing PCI to engage in effective oversight of the hospital programs in which they work, to assure that PCI is being used

appropriately and to assure that the service, when needed, is competently provided. The development of implementing regulations for the statutory changes outlined above will include careful consideration of the requirements for internal and external peer review of the appropriateness and quality of PCI. We will incorporate expert advice and guidance in the development of regulatory requirements for peer review in PCI.

I. Introduction

During the 2011 regular session, the Maryland General Assembly passed House Bill 1182, *Certificates of Need – Percutaneous Coronary Intervention Services.* Approved by the Governor on May 19, 2011, Chapter 616 of the Acts of 2011 became effective on July 1, 2011, and remains effective until June 30, 2012. During this one-year period, the law prohibits a hospital from establishing a non–primary PCI program or providing non–primary PCI services unless the hospital was operating a PCI program on January 1, 2011, through:

(1) a certificate of need for an open heart surgery program; or

(2) a non–primary waiver in good standing from Certificate of Need and State Health Plan requirements, issued by the Maryland Health Care Commission.

The law requires the Maryland Health Care Commission, on or before December 31, 2011, to:

(1) develop recommendations for statutory changes needed to provide appropriate oversight of PCI services; and

(2) report its recommendations to the Governor and, in accordance with §2–1246 of the State Government Article, the General Assembly.

In May, 2011, after passage of House Bill 1182, Senators Thomas Middleton and Robert Garagiola, Chairmen, respectively, of the Senate Finance Committee and the Health Subcommittee of the Senate Finance Committee, wrote to the Chair and Acting Executive Director of MHCC and requested that House Bill 1182 include a study of:

- Issues relating to the accreditation of PCI programs, including whether a formal accreditation process would provide best practices, encourage more cost-effective methodologies, and better ensure patient safety;
- The use of clinical data to evaluate PCI programs, including whether the collection of clinical data and administrative data should be merged for greater efficiency in the interpretation of data related to PCI services; and
- The form and scope of peer review that should be required for PCI services, including whether innovative options for independent, external peer review of PCI services might provide for higher quality, more cost-effective services.

This report provides recommendations for statutory changes needed to provide appropriate oversight of PCI services. It includes, as an attachment, the report of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services, a group convened by MHCC with broad representation by hospitals, cardiologists, a major payer, consumers, and State agencies to advise MHCC in developing the recommendations for statutory changes required by HB 1182.

PCI is the treatment of occlusion or narrowing (also known as stenosis) of coronary arteries, through use of catheter-based techniques. The object of PCI is reperfusion, or restoring blood

flow to the heart muscle (myocardium), thus minimizing critical damage due to oxygen loss to the muscle. PCI accomplishes reperfusion through revascularization, or restoring blood circulation in the blood vessels. PCI is performed in the cardiac catheterization laboratory by physicians specializing in interventional cardiology, along with a specialized team on RN(s) and technician(s). This procedure involves inflating a balloon in the artery (balloon angioplasty) to compress plaque against the artery wall. PCI may also include placement of a stent, which is a mesh stainless steel tube that can be expanded by a balloon, to prop open the arteries. The stent may be a bare metal stent or a drug-eluting stent, which is designed to prevent re-stenosis and repeat stents. *Primary PCI* is the intervention during a heart attack (acute ST-segment elevation myocardial infarction, or STEMI), performed on an emergency basis. *Elective, or non-primary, PCI* is the planned intervention to relieve narrowing of the artery before an acute heart attack occurs.

Primary PCI is provided at 23 Maryland hospitals. Ten of these hospitals provide on-site cardiac surgery and, as such, are approved, under current MHCC rules, to provide primary and elective PCI, by virtue of their status as cardiac surgery hospitals.[1] Eight other hospitals provide elective PCI through research waivers issued by the Commission and primary PCI through a separate waiver, but do not provide cardiac surgery. The remaining five hospitals provide only primary PCI under waivers issued by the Commission.

II. Current Statutory and Regulatory Authority of Maryland State Agencies with Respect to PCI

Maryland Health Care Commission

The Maryland Health Care Commission (MHCC or the Commission) is the primary State agency that engages in direct oversight of PCI. MHCC regulates the provision of PCI by hospitals through its statutory authority, found in Health-General §19-120(j)(2)(iii), to regulate open heart surgery. This regulation of services provided by health care facilities is called Certificate of Need (CON).

The Commission is responsible for developing a State Health Plan for health care entities and programs that are required to obtain a CON or a CON exemption. Section 19-120 of the Health-General Article and its implementing regulations, *COMAR 10.24.01: Certificate of Need for Health Care Facilities*, require a health care facility to have a CON issued by the Commission before establishing a new cardiac surgery program. MHCC regulations related to cardiac surgery and PCI are in *COMAR 10.24.17: the State Health Plan for Cardiac Surgery and Percutaneous Coronary Intervention Services* (Chapter). The Chapter includes the methodologies, standards, and criteria for CON review, and provides the regulatory basis for PCI waiver and research waiver programs of the Commission. A Maryland hospital can only provide PCI services if it

[1] These cardiac surgery hospitals are: Johns Hopkins Hospital (Baltimore City); Peninsula Regional Medical Center (Wicomico County); Prince George's Hospital Center (Prince George's County); Sinai Hospital of Baltimore (Baltimore City); St. Joseph Medical Center (Baltimore County); Suburban Hospital (Montgomery County); Union Memorial Hospital (Baltimore City); University of Maryland Medical Center (Baltimore City); Washington Adventist Hospital (Montgomery County); and Western Maryland Regional Medical Center (Allegany County).

has cardiac surgery services or has a Commission-issued waiver from the co-location requirement. (*See Section III for a detailed description of MHCC oversight of PCI services.*)

Office of Health Care Quality, Department of Health and Mental Hygiene

The Office of Health Care Quality (OHCQ), within the Department of Health and Mental Hygiene (DHMH), operates under the statutory authority of Health-General Article §19-319 – §19-324 to provide oversight of Maryland health care facilities, which it exercises through health care facilities' licensure and licensure renewal.

The oversight that OHCQ exercises with respect to PCI is complaint-driven rather than systematic and ongoing. OHCQ has no specific regulatory responsibility related to PCI or cardiac services, nor are there any specific regulations related to procedures. Interventional cardiology care and PCI services could come under investigative oversight by OHCQ, if based on a specific complaint, through review of credentialing for surgeons or anesthesiologists, assessment of appropriate maintenance of equipment and physical environment; and through oversight of quality assurance and performance improvement programs

OHCQ was recently charged by the General Assembly with new oversight responsibilities. House Bill 286 (Chapter 587 of the 2011 Acts**)** requires hospitals, as a condition of licensure, to have a process to objectively evaluate the performance of each member of the medical staff, as part of the reappointment /re-credentialing process. Each hospital's process must include a review of randomly selected cases, for quality and appropriateness of care, and all cases with unexpected adverse outcomes. A hospital's reviews must be performed by trained staff of the same specialty with no competing interests. Since all physicians must be reviewed by the hospital, interventional cardiologists performing procedures at a particular hospital will have some cases evaluated for medical appropriateness, as well as adverse events, by that hospital. The OHCQ regulations are currently in development; the resulting assessment process for practitioner performance review by the hospitals might extend more broadly than the process currently performed by hospitals for the Joint Commission surveys.

Health Services Cost Review Commission

The Health Services Cost Review Commission (HSCRC) is responsible for setting rates for 46 general acute care hospitals in Maryland. Its statutory authority stems from Health-General §19-201, *et seq*. It is the only all-payer hospital rate setting authority of its kind in the United States.

HSCRC can be viewed as engaging indirectly in PCI oversight, primarily through payment incentives for quality, a tool that applies to all hospital services. However, recently HSCRC was asked by the DHMH Inspector General to review hospital-level PCI utilization trends – a request related to concerns about the performance of medically unnecessary PCI procedures. HSCRC, in consultation with an interventional cardiologist, analyzed PCI utilization at Maryland hospitals for the purposes of identifying hospitals that have a greater risk-adjusted PCI to catheterization ratio than might be expected. The HSCRC has done an initial analysis and has shared that analysis with OHCQ; however, HSCRC and OHCQ have stated that the results cannot be assessed for appropriateness of care without an independent clinical chart review of the cases.

Board of Physicians

The Maryland Board of Physicians, with oversight of medical practitioners, has two main areas of jurisdiction – professional licensure and discipline. The statutory authority is the Maryland Health Occupations Article §14-201 – §14-415, and provides powers of subpoenas and administration of oaths. The Board of Physicians' responsibility is complaint-driven, and is involved in investigative processes; in clinical standard of care issues, the initial investigation is performed primarily by independently contracted peer reviewers. In terms of PCI services, a case involving an alleged breach of the standard of care by an interventional cardiologist may be peer reviewed and may result in charges issued by the Board of Physicians. If the case is not resolved, it will proceed to an adjudicatory hearing before an administrative law judge who issues a Recommended Decision that is considered by the Board after hearing argument. The Board then issues appropriate disciplinary action, which can range from a reprimand to revocation of a practitioner's license to practice medicine in Maryland.

Maryland Institute for Emergency Medical Services Systems (MIEMSS)

MIEMSS' statutory authority is found in the Education Article §§ 13-504 and 13-509. MIEMSS is responsible for the Emergency Medical System plan that ensures effective coordination and evaluation of emergency medical services delivered in Maryland. The applicable regulations related to PCI are COMAR 30.08.16 (*Designation of Trauma and Specialty Referral Centers – Cardiac Interventional Center Standards*). MIEMSS is responsible for the designation and ongoing evaluation of Cardiac Interventional Centers, which are acute care hospitals that may receive patients transported by ambulance with acute ST-segment elevation myocardial infarction (STEMI) who need primary PCI. MIEMSS has designated Cardiac Interventional Centers in a regionalized care model based on the trauma care model, so that the EMS provider can take patients to the most appropriate treatment facility based on patient condition. The designated Cardiac Interventional Centers must have a Certificate of Need or CON waiver from MHCC, and the regulatory requirements for MHCC and MIEMSS are aligned. However, since its focus is on emergency services, MIEMSS oversight does not include elective PCI.

III. MHCC's Regulatory Oversight of PCI

Regulating the Availability of PCI Services

PCI services have been regulated by the Maryland Health Care Commission or its predecessor agency since 1990, which is a period covering the emergence of PCI as a common and widespread service. Primary PCI is currently performed in half of Maryland's 46 general acute care hospitals.

The State Health Plan for cardiac services (*COMAR 10.24.17 State Health Plan for Facilities and Services: Specialized Health Care Services - Cardiac Surgery and Percutaneous Coronary Intervention Services)* requires that PCI be co-located with on-site cardiac surgery, following the longstanding recommendation of the American College of Cardiology and the American Heart Association (ACC/AHA).

In 1995, the State Health Plan was modified to exempt certain research projects from the policy requiring co-location of cardiac surgery and angioplasty services. The Maryland Health Resources Planning Commission, a predecessor agency to the MHCC, approved a waiver from the requirement for on-site cardiac surgical backup for a research study that would permit a small number of Maryland hospitals to participate in an investigation to evaluate the safety and efficacy of providing primary angioplasty in hospitals without on-site cardiac surgery. The multi-state Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT), a randomized trial, was conducted from July 1996 through December 1999, to evaluate whether primary PCI is superior to thrombolytic therapy at these non-cardiac-surgery hospitals. The data from the C-PORT clinical trial made an important contribution to the knowledge base concerning primary angioplasty. In its second phase, which began in August 1999, the C-PORT project functioned as a registry, with ongoing data collection and evaluation of quality standards. The C-PORT study findings showed that PCI is superior to thrombolytic therapies in STEMI patients, and that primary PCI can be performed safely in non-cardiac-surgery hospitals. Because the early C-PORT study results so strongly showed that emergency angioplasty performed in hospitals without on-site cardiac surgery was superior to thrombolytic therapy, the research study stopped randomizing patients earlier than had been originally proposed.

Following the publication of C-PORT study results in 2002, the Commission convened an Advisory Committee on Outcome Assessment in Cardiac Care to develop recommendations on systems of on-going outcome assessment for cardiovascular care and to develop a research agenda for evidence-based approaches to policies governing the location of primary and elective PCI. The Advisory Committee was comprised of leading cardiologists and health care experts from Maryland and other states. Its Interventional Cardiology Subcommittee reviewed data from the C-PORT study and other medical research to evaluate the most effective strategies for improving the system of care for STEMI patients.

The Advisory Committee acknowledged C-PORT's findings that PCI is preferable to thrombolytic therapy for patients with acute STEMI at non-cardiac-surgery hospitals, and that extension of primary PCI capability to non-cardiac-surgery hospitals would improve timely access to reperfusion therapy. The Advisory Committee further recommended institutional, physician and program development requirements for PCI at non-cardiac-surgery hospitals.

The Advisory Committee's findings informed the development of the State Health Plan on Cardiac Surgery and PCI Services that was adopted by the Commission in 2004. Noting that the ACC/AHA guidelines published in 2001 reiterated that hospitals performing elective PCI should have cardiac surgery services available on-site, the Interventional Cardiology Subcommittee concluded that "[t]his policy direction, which should continue to be reviewed periodically, should remain in place until clinical evidence confirms the efficacy and safety of elective angioplasty without on-site cardiac surgery back-up." Hence, the State Health Plan maintained the co-location requirement.

In 2004, the Commission also adopted the Advisory Committee's recommendation for two different "waivers" from the policy requiring co-location of cardiac surgery and PCI: a waiver for primary (emergency) angioplasty services and a waiver for participation in specific

Commission-approved PCI research projects. The 2004 State Health Plan amendments permitted a waiver of the co-location requirement for primary PCI program that meeting the requirements recommended by its Advisory Committee, which primarily followed the ACC/AHA guidelines.

The following chart summarizes the primary PCI waiver requirements.

Chart: Requirements for the Primary PCI Program
Source: COMAR 10.24.17, Supplement, Table A-1

- Institutional Resources
  - 24/7 operation of cardiac catheterization lab
  - 24/7 nursing and technical staffing for cardiac cath lab and coronary care unit services
  - Provide primary PCI as soon as possible and not to exceed 90 minutes from patient arrival for 75% of appropriate patients
  - Formal, written agreement for patient transfer with cardiac surgery hospital
  - Formal, written agreement with advanced cardiac life support EMS provider
- Physician Resources
  - ACC/AHA criteria for competency of 75+ total PCI cases per year
  - New physicians (out of fellowship < 3 years) complete a minimum of 50 acute Myocardial Infarction cases or 10 proctored cases before performing primary PCI alone
  - Participation in on-call schedule
- Angioplasty Center Program Standards
  - Development program (standards, staff training, logistics plan, and quality and error management program)
  - Hospital leadership supports the program.
- Volume-Quality Relationship for Primary PCI
  - Minimum of 36 (rural areas) and optimally 49 (metropolitan areas) cases
- On-Going Quality Assessment
  - Develop uniform data set to be collected and analyzed from all hospitals in Maryland offering primary PCI services. Participate in ACC Foundation ACTION Registry and CathPCI Registry.

With respect to research waivers for investigation of the safety of elective PCI in non-cardiac surgery hospital settings, MHCC requires such research waiver hospitals to maintain a volume of 200 PCI cases per year following the start-up year, and to ensure that interventional cardiologists performing PCI under the research waiver maintain an operator volume of at least 75 PCI procedures per year. These requirements are based on research findings linking lower mortality to higher PCI case volume at both the hospital and physician level.

A hospital that desires to provide primary PCI must meet requirements in the State Health Plan before the Commission will grant a waiver. First, a hospital must document that it sees a minimum number of acute ST-segment elevation myocardial infarctions annually in order to show that it is likely to be able to meet the required minimum institutional primary PCI volume. Also, the hospital must satisfy the following major components: implementation of the SHP requirements for care of patients with acute myocardial infarction and patients undergoing primary PCI; training of nursing and technical staff in both the cardiac catheterization laboratory

and coronary care unit; logistical planning and the institution of management systems for quality assurance.

As a result of these changes in the State Health Plan, the C-PORT Registry was transitioned into a program where non-cardiac-surgery hospitals could apply for a waiver to provide primary PCI. In 2005, MHCC took initial waiver applications from hospitals, and in 2006, MHCC granted the initial pPCI waivers that allowed approved hospitals without on-site cardiac surgery programs to provide emergency angioplasty to STEMI patients. Thirteen hospitals currently participate in this primary PCI waiver program:

- Anne Arundel Medical Center (Anne Arundel County);
- Baltimore Washington Medical Center (Anne Arundel County);
- Carroll Hospital Center (Carroll County);
- Franklin Square Hospital Center (Baltimore County);
- Frederick Memorial Hospital (Frederick County);
- Holy Cross Hospital (Montgomery County);
- Howard County General Hospital (Howard County);
- Johns Hopkins Bayview Medical Center (Baltimore City);
- Meritus Medical Center (Washington County);
- Saint Agnes Hospital (Baltimore City);
- Shady Grove Adventist Hospital (Montgomery County);
- Southern Maryland Hospital Center (Prince George's County); and
- Upper Chesapeake Medical Center (Harford County).

As discussed earlier, the 2004 State Health Plan provided that the Commission could grant a research waiver to a hospital that participated in a approved research study that would assess the safety and efficacy of providing non-primary PCI services for certain patient groups without on-site cardiac surgery. The resulting research proposals that were submitted by the C-PORT E Team, were reviewed by the MHCC's Research Proposal Review Committee, and culminated in the multi-state C-PORT E (elective angioplasty) study. Between September 2008 and June 2009, the Commission awarded time-limited research waivers to nine primary PCI waiver hospitals that permitted them to participate in the C-PORT E study to determine whether or not elective PCI provided in hospital without on-site cardiac surgery was inferior to elective angioplasty provided in hospitals with on-site cardiac surgery services. One hospital voluntarily relinquished its research waiver after receiving notice from the Commission that it should close its program as a result of its failure to meet the Commission's research waiver requirements. The eight hospitals that currently provide elective PCI without on-site cardiac surgery as part of the follow-on registry to the C-PORT E research study are:

- Anne Arundel Medical Center;
- Baltimore Washington Medical Center;
- Frederick Memorial Hospital;
- Johns Hopkins Bayview Medical Center;
- Meritus Medical Center;
- Saint Agnes Hospital;

- Shady Grove Adventist Hospital; and
- Southern Maryland Hospital Center.

C-PORT E study enrollment of patients ended on March 31, 2011, and the 9-month follow-up of patients in the study will conclude at the end of 2011. Anticipating the end of the patient enrollment into C-PORT E, the Commission, in February 2011, adopted regulations to establish a Follow-On Registry of non-primary PCI that would continue the research waivers of hospitals participating in the C-PORT E research study until the results of the Study were calculated and published in a peer-reviewed journal. The eight non-primary PCI research waiver hospitals were approved by the Commission to participate in the Follow-On Registry, and will continue to submit quarterly reports to the Commission regarding enrolled C-PORT E patients for nine months post-procedure. These hospitals will participate in the Follow-On Registry unless they fail to meet the on-going requirements, which include maintaining a primary PCI waiver in good standing, or until the results of the C-PORT E study are published and can be considered by the Commission in an update to its State Health Plan Chapter on Cardiac Surgery and PCI Services. The study results from C-PORT E are expected to be published in 2012 and the findings from this research will inform the Commission with respect to appropriate policies and regulatory processes regarding PCI going forward.

Ongoing Oversight of Performance – Monitoring and Assuring Compliance

PCI in Hospitals without On-Site Cardiac Surgery

The State Health Plan requires that both primary PCI waiver hospitals and non-primary research waiver hospitals, as a condition of maintaining their waivers, satisfy on-going performance standards and other requirements. A primary PCI waiver must be renewed every two years. Moreover, a hospital with a research waiver permitting it to provide non-primary PCI must maintain compliance with all of the requirements of its primary PCI waiver. The terms of non-primary research waivers in good standing under the Commission's limitations and requirements are extended while the hospital participates in the C-PORT E Registry, until such time as the Commission has the information from the research study that is needed to guide State policy about the regulation of non-primary PCI.

PCI in Hospitals with On-Site Cardiac Surgery

The Commission amended its Cardiac Surgery and Therapeutic Catheterization Services Chapter of the State Health Plan in 1997, requiring, for the first time, that a new cardiac surgery program meet and maintain a minimum annual case volume in order continue to have a cardiac surgery program. This requirement only applies to the two cardiac surgery programs established since that date. If the Commission finds that hospital failed to attain the required volume, the hospital must close its cardiac surgery program. These requirements are a departure from most Certificates of Need granted by the Commission, which seldom contain conditions related to on-going compliance with quality-related performance standards.

Under the existing State Health Plan chapter, the ten hospitals that have cardiac surgery/PCI programs are not required to comply with on-going performance or other standards regarding

PCI; however, the two hospitals whose CONs contain volume requirements for cardiac surgery procedures would lose their ability to provide PCI if they were required to close their cardiac surgery/PCI programs.

Requirements for Hospital Participation in Cardiac Data Registries

As part of hospital performance evaluation through public reporting, MHCC requires, as of July 1, 2010, all hospitals to participate in two National Cardiovascular Data Registry (NCDR) hospital-based cardiovascular registries: ACTION Registry-Get With The Guidelines (GWTG) and CathPCI Registry. MHCC has also convened the Cardiac Data Advisory Committee to provide recommendations on data collection, risk adjustment, and ways to leverage existing registries for further quality improvement purposes, and will advise on ways to review, interpret and adjudicate data.

Gaps and Limitations in PCI Oversight

One legacy of the evolution of MHCC's regulatory oversight of PCI, as outlined above, is inequity in the application of ongoing monitoring of PCI program performance across Maryland hospitals, based on the presence or absence of a co-located cardiac surgery program, and mechanisms for assuring compliance with performance standards. MHCC's regulatory authority with respect to PCI, stems from its CON regulation of cardiac surgery, through the cardiac surgery/PCI co-location requirement. There are thirteen primary PCI waiver hospitals, eight of which have participated in the elective PCI research waiver program (and, now, the follow-on registry waiver program); these hospitals' PCI programs have close evaluation for on-going compliance, based on their waiver status, but no similar on-going performance requirements are in place for PCI at the cardiac surgery hospitals, where most PCI is provided. A PCI waiver hospital is at risk of losing its authority to provide PCI if it does not meet well-established standards, while a cardiac surgery hospital has no such risk to its ability to provide PCI. The following table illustrates the uneven application of oversight in PCI.

Cardiac Surgery (CS) and PCI Waiver Hospitals in Maryland
Conditions to Maintain Services

Hospital Program	Services Provided	Hospitals	Performance Requirements for	
			Cardiac Surgery	PCI
Pre-1997 CS	OHS/PCI	8	NO	NO
Post-1997 CS	OHS/PCI	2	YES	NO
Primary PCI	Primary PCI Only	5	NA	YES
Primary/Elective PCI	Primary/Elective PCI	8	NA	YES

Source: MHCC governing statutes and State Health Plan regulations

A hospital that has a CON to perform cardiac surgery is also approved and required to provide the full range of PCI services. Although the State Health Plan includes requirements for primary PCI programs at hospitals with on-site cardiac surgery, the Commission has not established a process to review the ongoing compliance of those programs. Currently, the statute does not give

MHCC authority to oversee the quality of PCI services at a hospital with an existing cardiac surgery program.

As previously noted, beginning in the late 1990s, a CON issued by MHCC for establishment of a cardiac heart surgery program has included a condition that the hospital achieve and maintain a minimum case volume, specified in the State Health Plan, in order to continue to provide the service. The Commission does not have the statutory authority to impose this condition retrospectively upon a hospital that was granted a CON to provide cardiac surgery prior to the Commission's adoption of this regulatory requirement in the1997 Chapter of its State Health Plan, even if the pre-1997 cardiac surgery hospital does not meet minimum utilization levels. Hence, there is a gap in MHCC oversight of cardiac surgery, as well as PCI.

IV. The Current Clinical Environment for PCI

Recent clinical research findings as well as data from cardiovascular-related registries are influencing patterns of PCI utilization and decision-making at the physician and hospital levels. Concerns about quality in PCI services have moved from questions of safety at non-cardiac-surgery hospitals to doubts about appropriateness of some elective PCI procedures, whether or not they the services are provided at a cardiac surgery hospital.

Declines in PCI Utilization

In the most recent decade, PCI case volumes expanded and then significantly contracted. The number of cardiac surgery cases has also declined in recent years. A recently published national study of Medicare patients indicated that, between 2004 and 2009, PCI procedures declined 2.5% annually, following annual decline in CABG of 5% between 2001 and 2004.[2] Meanwhile, the results also indicated that use of intravascular ultrasound and fractional flow reserve (diagnostic tests to assess degree of stenosis, often used in uncertain cases) increased. Maryland hospital data indicates that the number of PCI procedures in Maryland declined from over 14,000 in Fiscal Years 2005 and 2006, to just below 10,000 in Fiscal Year 2010.[3] The decline in PCI procedures may be due to multiple factors:

- Concern about inappropriate procedures;
- Changes in the practice of using revascularization for stable angina patients (following the COURAGE trial results);
- Changes in clinical guidelines for appropriateness of elective stent placement (e.g., the clinical threshold changed from 50% to 70% stenosis in 2009);
- The publication of clinical research results on outcomes which may better help practitioners better identify which treatment approaches are most effective with particular types of patients;
- Refinements in guidelines from ACC/AHA/SCAI on appropriate use criteria;

[2] Riley RF, Don CW, Powell W, Maynard C, Dean LS. Trends in coronary revascularization in the United States from 2001 to 2009: Recent declines in percutaneous coronary intervention volumes. *Circulation: Cardiovascular Quality and Outcomes* 2011; 4(2): 193-197.

[3] Health Services Cost Review Commission analysis of hospital data (unpublished), completed in 2011.

- Increased use of drug-eluting stents, which has resulted in lower rates of re-stenosis and thus fewer repeat PCIs; and
- Increased use of medical, rather than invasive, therapeutic approaches to heart disease, influenced by perceived improvements in available therapies.

Peer Review and Appropriate Use of PCI

Over the last few years, there has been increasing public concern about the appropriateness of elective PCI procedures. In Maryland, this concern has been driven by two widely reported cases in which cardiologists practicing at two Maryland hospitals, St. Joseph Medical Center (SJMC) and Peninsula Regional Medical Center (PRMC), were alleged or accused of placing stents in the coronary arteries of patients who did not have heart disease conditions warranting this intervention. In the PRMC case, the physician was indicted and found guilty of insurance fraud, and the hospital agreed to pay a settlement to resolve allegations that it failed to prevent medically unnecessary stent procedures. In the SJMC case, the physician's medical license was revoked by the Board of Physicians.. SJMC settled claims by the Center for Medicare and Medicaid Services related to billings for medically unwarranted stents. SJMC and PRMC are hospitals that operate cardiac surgery programs and, as such, provide the full range of PCI services.

As concerns with respect to medical appropriateness of PCI have heightened, there have been more calls for strengthening of peer review in interventional cardiology. Peer review of medical procedures, the examination of medical charts by a practitioner of the same specialty, is performed to assess quality of care and appropriateness of procedures, as well as to determine factors involved in adverse events. Regular peer review is now common within hospital staffs as part of quality assurance, re-credentialing, and accreditation reviews. External peer review, when records are reviewed by someone not affiliated with the physician's medical group or with a hospital where the physician has privileges, may also be incorporated in peer review program. External peer review is viewed as more likely to have an objective evaluation of the clinical record. The adequacy of internal and external review of practitioner performance related to PCI has been called into question. Obviously, the matters described regarding the two physicians in the preceding paragraph suggest that peer review processes were probably inadequate at these hospitals.

Definition and measurement of the clinical appropriateness of PCI procedures have become useful tools in evaluating quality of care as well as informing clinical decision making. In 2009, six professional organizations jointly published the most recent criteria for appropriate utilization of coronary revascularization.[4] The criteria were developed by a 17-member expert panel that adjudicated 198 different clinical scenarios representing various combinations of clinical

[4] Patel MR, Dehmer GJ, Hirshfeld JW, Smith PK, Spertus JA; American College of Cardiology Foundation Appropriateness Criteria Task Force, et al. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a report by the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. *Journal of the American College of Cardiology* 2009; 53(6): 530-553.

presentation: severity of symptoms; ischemia severity based on functional testing; high-risk clinical features; intensity of medical therapy; and extent of coronary anatomical findings on diagnostic angiography.[5] These criteria are now included as data elements in American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) CathPCI Registry, so that evaluation of appropriateness can be broadly utilized in the clinical setting.

The American College of Cardiology Foundation notes that it is important to distinguish between clinical practice guidelines, appropriate use criteria, and performance measures[6]. *Guidelines* are syntheses of available research evidence and provide recommendations for a range of acceptable clinical approaches; guidelines "still require clinical judgment to be adapted to the care of individual patients." *Appropriate use criteria* provide options based on different clinical presentations (i.e., the clinical scenarios mentioned above), and communicate findings about relative risks and benefits of particular procedures. They are also practical tools for measuring variability, determining whether an indication is "appropriate," "uncertain" or "inappropriate," and for evaluating utilization patterns. *Performance measures* are specific measures that indicate high-quality, evidence-based clinical care. Although the focus is on performance, they are intended to help practitioners evaluate quality and identify areas for improvement (rather than labeling "good" or "bad" practice).

A recent data analysis of CathPCI registry data, using the appropriate use criteria estimated the percentage of PCIs classified as appropriate, inappropriate, or uncertain.[7] The findings suggested that for elective PCI, 50.4% were classified as appropriate, 38% as uncertain, and 11.6% as inappropriate; in emergency PCI, 98.6% were judged appropriate, while only 0.3% were classified as uncertain and 1.1% as inappropriate. The researchers also observed notable hospital-level variation in the proportion of elective procedures that were inappropriate. The use of these criteria, and this key study, promote clearer feedback to physicians, and more-informed and deliberate decision-making at the provider level. The criteria will likely be employed, to some extent, in internal and external peer review. Of importance to performance-based regulation, they may also add another tool for ongoing evaluation of PCI programs.

The C-PORT Studies

The initial C-PORT study indicated that primary PCI can be performed safely and effectively in hospitals without on-site cardiac surgery, and that primary PCI had superior results compared to the thrombolytic therapy that was used at that time for certain heart attack patients when treated at non-cardiac surgery hospitals. The C-PORT E study is a non-inferiority randomized clinical trial, which is testing the hypothesis that the outcomes of elective PCI at hospitals without cardiac surgery on-site, as measured by both mortality at 6-weeks and MACE (mortality, myocardial infarction, or target vessel revascularization) at 9-month follow-up, are not inferior to the outcomes of elective PCI performed in hospitals with cardiac surgery on-site. In order for the non-inferiority hypothesis to be

[5] The defined threshold for significant obstructive coronary artery disease was $\geq$ 50% stenosis of the left main coronary artery or $\geq$70% stenosis of a major epicardial or branch vessel 2.0 mm or greater in diameter.
[6] ACCF, ACCF Guidelines, Appropriate Use Criteria and Performance Measures: What You Need to Know" Cardiosource.org. Accessed September, 2011.
[7] Chan PS, Patel MR, Klein LW, Krone RJ, Dehmer GJ, et al. Appropriateness of Percutaneous Coronary Intervention. *JAMA* 2011; 306(1): 53-61.

accepted, non-inferiority would need to be demonstrated for both endpoints, 6-week mortality and 9-month MACE.

In November, 2011, the C-PORT E Principal Investigator, Dr. Thomas Aversano, presented preliminary study results at the American Heart Association Scientific Sessions.[8] The primary finding presented was that, in non-cardiac-surgery hospitals where a complete formal PCI development program has occurred, patient inclusion and exclusion criteria are met, and whose outcomes are monitored, at 6-week follow-up, non-primary PCI is safe and associated with similar rates of adverse events including mortality, rates of emergency CABG, and rates of adverse events, as at cardiac surgery hospitals. The collection of outcome data on study subjects is currently being completed and publication of the study findings in a peer-reviewed journal is expected in 2012.

Because the preliminary C-PORT E findings indicate that non-primary PCI is safe at hospitals without on-site cardiac surgery, re-evaluation of the cardiac surgery/PCI co-location standard will be necessary, in the same way in which this standard was re-evaluated following completion of the initial C-PORT study. At that time, the standard was maintained and a waiver approval process for primary PCI was established and implemented. If C-PORT E's conclusions are in line with the preliminary results released, discontinuation of the standard is appropriate. This potential change in State policy has provided the impetus for this report.

V. OPTIONS FOR REGULATING THE PROVISION OF PCI

The Law and Regulations

This report, in order to be responsive to the direction provided in HB 1182, limits itself to discussion and recommendations regarding the question of statutory changes that will improve the ability of the Commission to oversee the delivery of PCI services at Maryland hospitals, consistent with the most recent research findings in this field. As an appropriate and related consideration, the report also addresses the oversight of cardiac surgery in the current law. The Commission recommends specific additions of language to the statute that are consistent both with the historic and current program needs and with the Commission's legislative mandate, found at Health-General §19-103(c)(2), to "[p]romote the development of a health care regulatory system that provides for all Marylanders, financial and geographic access to quality health care services at a reasonable cost …." The Commission's requested statutory changes are consistent with the General Assembly's finding, in Health-General §102(a), that "the health care regulatory system in this State is a highly complex structure that needs to be constantly reevaluated and modified in order to better reflect and be more responsive to the ever changing health care environment and the needs of the citizens of this State."

[8] Aversano Thomas, MD, Outcomes of Non-Primary PCI at Hospitals with and Without On-Site Cardiac Surgery: A Randomized Study, presented at American Heart Association Scientific Sessions, November 14, 2011, accessed at http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/@scon/documents/downloadable/ucm_433712.pdf.

Consequently, this report does not discuss, at any length, or include recommendations concerning the specific rules or review processes that might be adopted by MHCC in regulations to guide its future decision-making in the area of specialized cardiac services. The General Assembly has acknowledged, the "ever changing health care environment"; this is particularly true in the areas of PCI and cardiac surgery. The Commission believes that it should meet its legislatively directed purpose and objectives though the adoption of regulations that reflect the current best science, and that are the result of a broadly inclusive and deliberative public process. The Commission has a long history of using its adoption of regulations that serve public purposes and achieve important care improvements, reflecting changes in knowledge about the delivery of health care services. The delivery of PCI services is a prime example of this adaptive ability. (See *Regulating the Availability of PCI Services* in Part III of this report.) Over the last 20 years, the Commission has used the General Assembly's grant of authority requiring a Certificate of Need for open heart surgery, without major changes in the statute, to:

- Promote and approve the engagement by Maryland hospitals in research on the safety of providing primary PCI in hospitals without back-up cardiac surgery on site;
- Create and implement a review process to authorize primary PCI in such hospitals, more than doubling the number of sites at which primary PCI is available and increasing the proportion of Maryland's population living in a jurisdiction with primary PCI availability from approximately 60 to almost 90 percent;
- Approve and structure the engagement by Maryland hospitals in research on the safety of providing elective PCI in hospitals without back-up cardiac surgery on site;
- Approve the transition of the research waiver hospitals from research status to the interim status of registry hospitals (interim with respect to publication of the research findings and the Commission's adoption of resulting needed changes in the State Health Plan);
- Establishing these new sites for primary and elective PCI using a regulatory oversight model requiring monitored performance and closure of the service if performance is substandard; and
- Require reporting by hospitals of data on their delivery of PCI to national registries, so that standardized and audited information necessary for evaluating performance under this regulatory model is readily available.

Certificate of Need and Alternatives

The General Assembly, in HB 1182, recognized the need to consider appropriate oversight of PCI services, particularly in the light of the on-going C-PORT E research study that may result in the removal of the cardiac surgery/PCI co-location requirement that serves as the foundation supporting the Commission's historic use of CON to regulate PCI. Two basic options are available to regulate the establishment of PCI services going forward and to deal with quality concerns regarding this service in hospitals with and without cardiac surgery on site. The first approach would be to leave MHCC's law alone and repeal the CON regulations addressing PCI, effectively decoupling PCI from cardiac surgery and from regulatory oversight. This deregulation of PCI is not recommended by the Commission, and was not recommended by the Technical Advisory Group in its report to the MHCC or, explicitly, by any organizations or individuals who have provided comments on that report. This option would not mean the

complete absence of State regulatory oversight that could touch on provision of PCI, as can be seen in the overview of State regulation, Part II of this report. However, it would eliminate current oversight over the establishment of PCI services and would also eliminate the most direct approach available to enforce performance requirements in the delivery of PCI services.

The second option is to continue to regulate PCI and bring the law in line with the emerging scientific conclusion that elective PCI should not be limited to hospitals that also provide cardiac surgery. As can be seen in the report of the Technical Advisory Group on Oversight of PCI Services (Appendix B), there is broad agreement among the many organizations represented that Maryland should continue to regulate the establishment of PCI services through MHCC. This Group expressed a consensus on three aspects of this regulation that have implications for Maryland's statute:

1. The authority of a hospital to provide PCI services should not be granted for an indefinite period. Rather, there should be continuing evaluation of performance based on established performance standards, with renewal of authority to provide PCI services based on ongoing compliance with the standards;
2. Performance requirements should be aligned across all PCI program settings: hospitals with cardiac surgery programs and hospitals without cardiac surgery programs; and
3. MHCC should be added to the State agencies listed in Maryland law that can share information for the purpose of investigating quality or utilization of care in regulated facilities.

The primary point of debate or contention with regard to moving forward with regulation of PCI, and comments submitted by some Maryland hospitals in response to the Technical Advisory Group's report, is the form which regulatory oversight, as framed in the statute, should take. Should the law mandate keeping regulation of PCI within the regulatory program that MHCC has used to regulate hospital facilities and services, the Certificate of Need program, or, alternatively, should the law mandate that MHCC use a separate regulatory program to provide regulatory oversight to PCI?

MHCC believes that an examination of the views expressed by those supporting the latter alternative suggests that those views can be grouped under two broad themes:

- CON regulation as a regulatory oversight model for PCI will not focus appropriately on performance and will focus on inappropriate or less important considerations (e.g., need, cost effectiveness, viability, and impact) which historically may have involved lengthy financial and legal analyses; and
- CON regulation of PCI may result in fewer PCI programs in Maryland and/or will inappropriately hinder the ability to expand PCI to more hospitals. Specifically, in this regard, seven of the eight hospitals with waivers to provide elective PCI, or their parent health systems, have commented that they oppose any use of CON to provide regulatory oversight and/or support what is commonly referred to as "grandfathering" the elective PCI research waiver hospitals.[9] We interpret this to involve the deeming, by MHCC,

[9] The non-primary PCI research waiver accepted by these hospitals states that they are permitted to perform non-primary PCI for either two years or until the end of C-PORT E patient study accrual.

that these programs, by virtue of having received research waivers, now have fully approved status as providers of elective PCI.

It appears that most, if not all, of these commenters support the idea that regulatory oversight of PCI should include the requirement that the Commission approve new PCI programs. This regulatory power is the primary, and in many cases, the only regulatory power of consequence wielded by the CON program. This power would also appear to be intricately related to another regulatory power that these commenters also appear to support, the power to enforce termination of programs for substandard performance, i.e., it would be hard to imagine regulatory oversight authority that would allow MHCC to enforce a minimum level of performance by PCI hospitals on an ongoing basis unless MHCC granted authority to these hospitals to provide PCI in the first place. Therefore, these commenters appear to be recommending that the statute create a new regulatory oversight process, exclusively for PCI, that, in its basic design, mirrors the CON review and approval process but assures that MHCC will not incorporate any criteria into this process, that do not relate directly to examining capacity to perform PCI at an established level of performance and quality of care.

With respect to the first concern referenced above, that CON regulation is an inappropriate regulatory oversight model for PCI, it appears that a chief concern, as reflected by some of the comments, is that regulatory oversight of PCI within the framework of CON may be expensive, slow, and litigious, if it incorporates consideration of the criteria currently established in regulation as general review criteria for all CON reviews. Proponents of this view can point to CON project reviews, primarily those that have involved contests between competing applicants or between applicants and opposing interested parties, that have been lengthy and expensive, because of the extensive legal record developed and the extensive review process and judicial appeals that may follow.

With respect to the second theme, that CON regulation of PCI may result in fewer elective PCI programs in Maryland and/or will inappropriately hinder the ability to expand elective PCI to more hospitals, the Commission believes that this is a concern that arises because a new regulatory form, CON regulation of PCI as an explicitly-regulated service, was proposed by Commission staff. While the substance of CON regulation of PCI, as practiced by MHCC, need not change as a result of this change in form, any change is naturally concerning to the hospitals now providing elective PCI under research waivers.

The Case for Regulation of PCI Through Exemption from CON

Having considered the comments and concerns expressed, the Commission concludes that appropriate oversight of the establishment and continuing performance of PCI services can be accomplished through a process by which the Commission grants an exemption from CON. This review process exists in statute and has been employed by the Commission in its review of certain changes by merged asset systems. The advantage to the applicants in this form of review and approval is that there is no provision for interested party status in the review, and thus, no contested case reviews, and, likely, fewer judicial appeals. Some statutory and regulatory changes would be needed to adapt this process to the regulatory oversight of PCI, but this option also has the advantage of being one in which the basic framework has been used by the

Commission. Thus, it is a process that meets the clear desire for MHCC to regulate the availability of PCI in Maryland but utilizes a process that limits some of the key features of standard CON regulation that can create delay and expense. This is an apt alternative in the case of PCI, because of the transitional nature of the regulatory process that must proceed for this service; transitioning a system of services that has evolved through research and waivers to a system that is more conventionally established on the basis of advancing objectives for service availability and performance.

The particulars of how PCI is regulated within the CON exemption process will need to be tailored to fit the needs and interest of the public through the development of implementing regulations: (1) the State Health Plan for the criteria and standards that will be used in reviewing requests for exemption from CON approval and the performance levels required for maintenance of approval; and (2) COMAR 10.24.01.04, for the process that will be used in exemption from CON regulation. If the General Assembly enacts changes to the Commission's statute (and following the release of the results of the C-PORT E study), the MHCC staff will begin the process of updating the Cardiac Surgery and PCI Services Chapter of the State Health Plan. As with earlier Chapter updates, the Commission anticipates that its staff will convene a work group consisting of in-State and out-of-State experts who will give guidance to Commission on clinical and technical issues related to cardiovascular practice guidelines, standards of care, and research findings, that will be considered in revising the Chapter.

That the Commission can properly regulate the establishment and continuation of quality services is seen in its regulation of primary (emergency) PCI. (See *Regulating the Availability of PCI Services* in Part III of this report.) Changing the law to make PCI a regulated service requiring an exemption from CON will result in a process that is likely to be very similar to the process used by MHCC that dramatically increased the number of quality primary PCI programs in Maryland that provide this life-saving treatment to heart attack patients.

VI. Recommendations for Statutory Changes

Salient Issues Considered

This report is intended to place regulatory oversight of PCI by MHCC on a firm legal footing that is not dependent on co-location of cardiac surgery and PCI. It also seeks to assure that Maryland law establishes a model of regulatory oversight that will allow for MHCC to assure, on an on-going basis, that high quality performance is maintained. However, other salient issues were considered.

The Technical Advisory Group examined current issues related to potential accreditation for PCI programs, the use of clinical data in combination with administrative data for evaluation of care, and internal and external peer review. Through presentations by TAG members representing the Maryland Chapter of the American College of Cardiology and the Society for Cardiovascular Angiography and Intervention, as well as by the member representing the Maryland Hospital Association, the group learned about and discussed the specific merits of robust internal and external peer review programs,[10] and learned about the current options for

[10] Recommendations from SCAI are also stated in Klein LW, Uretsky BF, Chambers C, et al, Quality Assessment and Improvement in Interventional Cardiology: A Position Statement of the Society of

accreditation of PCI programs. The TAG also discussed how the NCDR and other clinical data can inform quality improvement and monitoring at the hospital and physician levels, as well as their potential for use in reporting and regulatory functions at the state level.

The group concurred with the suggestion from the ACC and SCAI representatives (Appendix C), that accreditation not be mandated in Maryland law but remain optional for the present time.

Regarding peer review, it seems prudent at this time to await the implementation by the Department of Health and Mental Hygiene of HB 286 (practitioner performance evaluation to be undertaken by hospitals, with OHCQ review of hospitals' evaluation procedures) which was just mandated in 2011. MHCC will evaluate the implementation of this law, with particular attention to the issue of appropriate use of PCI, in its consideration of regulatory requirements for peer review in the State Health Plan. MHCC will also review the extent and reach of the voluntary internal and external review programs across Maryland hospitals (as suggested by the MHA Necessary Care Work Group) as an initial step in development of implementing regulations.

MHCC does not support inclusion of peer review standards in any statute that could result from this report. Peer review standards will evolve over time and a regulatory approach provides more flexibility in adapting to changes in the science of peer review. MHCC incorporates ACCF/AHA/SCAI Guidelines for PCI as those guidelines are revised periodically.[11] MHCC expects that peer review standards would undergo similar changes, suggesting that regulations offer more flexibility to respond to improvement in the science. This position is consistent with the recommendation from the TAG.

Regarding the use of clinical data, the TAG noted that the Cardiac Data Advisory Group of MHCC is addressing this and related issues in its forum. MHCC believes the work of this body should be allowed to go forward in 2012 prior to the consideration of any statutory changes needed with respect to data availability and use.

Recommended Changes

With respect to the availability and performance oversight of PCI, it is now time to align MHCC's statute to with the framework for regulatory oversight that the Commission has developed over the last five years. Going forward, the law should assure that PCI can be regulated independently of cardiac surgery, because the results of the C-PORT E research, expected to be published in 2012, are likely to indicate that elective PCI services can be delivered at a level of safety that is not inferior to that achieved by hospitals providing both cardiac surgery and PCI, under certain conditions. **This requires that percutaneous coronary intervention be identified in the statute as a service regulated by MHCC, in the same manner that the law now specifically identifies open heart surgery, organ transplant surgery, and other services as categorically regulated.** The Commission believes that it is appropriate to "grandfather" existing primary PCI programs that meet and continue to meet requirements established or to be established in the State Health Plan.

Cardiovascular Angiography and Interventions: Part 1: Standards for Quality Assessment and Improvement in Interventional Cardiology. *Catheterization and Cardiovascular Interventions* 2011; 77-927-935.

[11] The ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention were updated in 2009 and 2011.

Second, in order for regulatory oversight of PCI to be comprehensive and equitable, statutory changes are needed to apply the same regulatory requirements uniformly across all settings in which PCI services are provided. Currently, approximately 80% of PCI cases provided in Maryland are provided at the ten hospitals that operate cardiac surgery programs. Only two of these programs, the newest ones established in 1999 and 2004, are operating under Certificates of Need that are conditioned upon meeting certain volume requirements that only apply to cardiac surgery. **Thus, the statute should provide MHCC with the authority to incorporate these existing cardiac surgery hospitals into a system of regulatory oversight that will require their PCI programs, as well as all existing or new PCI programs located in non-cardiac surgery hospitals, to meet minimum standards as a condition of continuing to provide PCI services.** A uniform set of standards can then be applied across all hospital PCI program settings.

Third, while it is not strictly necessary to assuring a more effective regulatory model for PCI service oversight, it would be logical for the General Assembly to undertake this second change in MHCC's statute so that it applies to both PCI and cardiac surgery. Cardiac surgery hospitals will continue to be the dominant sites for delivery of PCI services in the foreseeable future and the cardiac catheterization facilities and staff at these hospitals comprise a core platform for both the diagnostic patient services preceding cardiac surgery and the diagnostic and treatment services involved in PCI. As noted above, in the late 1990s, Maryland's CON program established rules requiring a mandatory performance condition for a new cardiac surgery program but, prior to the adoption of this policy in the State Health Plan, eight out of the state's ten programs were granted Certificate of Need approval to provide cardiac surgery that did not contain this condition. From 2003 to 2010, the number of coronary artery bypass graft cases performed at Maryland's cardiac surgery hospitals declined nearly 20%. Case volume increased at only one of the nine cardiac surgery programs that operated throughout this period and half of the remaining eight hospitals saw large declines in cardiac surgical case volume, ranging from 36% to 71%. Changes in the medical science of cardiac surgery or PCI (which address the same disease condition) and changes in the practitioner communities practicing in these fields at particular hospitals or in particular hospital markets, can clearly influence how each service is used or can influence the overall stability of the institutional structure of cardiovascular services in which both services are provided. Coupling both cardiac surgery and PCI into the same mode of regulatory oversight, one in which ongoing performance monitoring assuring maintenance of an acceptable standard of quality care in both services, is the most effective approach to regulation, given the relationship of these cardiovascular services. **The statute should provide MHCC with the authority to incorporate all of the existing cardiac surgery hospitals in the State into a system of regulatory oversight that will require their cardiac surgery programs to meet minimum standards as a condition of continuing to provide cardiac surgery.**

Fourth, in order to assure that MHCC has the information needed to provide appropriate regulatory oversight to assure quality of PCI services, **Maryland statute should identify MHCC, at Health-General §§19-218 and 14-411, as a State agency that can share information for the purpose of investigating quality or utilization of care in regulated facilities.**

Finally, **the words "open heart surgery" in Health-General §19-120(j)(2)(iii) should be changed to "cardiac surgery" to reflect current usage**,

Appendix A contains recommended changes in statutory text which will implement these recommendations.

Appendices

Appendix A: Specific Recommended Changes in the Text of Maryland Statute

Appendix B: Report of the Technical Advisory Group on Oversight of PCI Services

Appendix C: Comments Received on the Report of the Technical Advisory Group on Oversight of PCI Services

Appendix D: Maryland Hospitals Providing Cardiac Surgery and/or PCI

Appendix A:

Specific Recommended Changes in the Text of Maryland Statute

AN ACT concerning

Certificates of Need, Exemptions from Certificate of Need, and Assurance of Continuing Quality – Open Heart Surgery and Percutaneous Coronary Intervention Services

FOR the purpose of requiring an Exemption from Certificate of Need to establish a percutaneous coronary intervention (PCI) service or provide PCI services, unless the hospital was operating a PCI program on a certain date through a certain certificate of need; requiring the Maryland Health Care Commission, to develop regulations assuring that cardiac surgery and PCI services to meet and maintain certain quality standards established by the Commission in the State Health Plan; to change the terminology from "open heart surgery" to the more current term "cardiac surgery"; requiring the Commission to "grandfather" under certain conditions certain existing primary PCI programs in community hospitals that meet and requirements established in the State Health Plan; and generally relating to cardiac surgery, percutaneous coronary intervention, and certificates of need.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 19–120(j)(2)(iii)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, without amendments,
Article – Health – General
Section 19-120 (a) through (j)(2)(ii)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY enacting
Article – Health – General
Section 19-126.1

BY repealing and reenacting, with amendments,
Article – Health – General
Section 19–134(e)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, without amendments,
Article – Health – General
Section 19-134 (a) through (d)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, THAT, NOTWITHSTANDING ANY OTHER PROVISION OF LAW, A HOSPITAL MAY NOT ESTABLISH A NON–PRIMARY PERCUTANEOUS CORONARY INTERVENTION (PCI) PROGRAM OR PROVIDE NON–PRIMARY PCI SERVICES UNLESS THE HOSPITAL WAS OPERATING A PCI PROGRAM ON JANUARY 1, 2011, THROUGH:

(1) A CERTIFICATE OF NEED FOR AN OPEN HEART SURGERY PROGRAM; OR

(2) A NON–PRIMARY WAIVER IN GOOD STANDING FROM CERTIFICATE OF NEED AND STATE HEALTH PLAN REQUIREMENTS, ISSUED BY THE MARYLAND HEALTH CARE COMMISSION.

Article – Health – General

§ 19-120.

(a) Definitions. --

(1) In this section the following words have the meanings indicated.

(2) "Consolidation" and "merger" include increases and decreases in bed capacity or services among the components of an organization that:

(i) Operates more than one health care facility; or

(ii) Operates one or more health care facilities and holds an outstanding certificate of need to construct a health care facility.

(3) (i) "Health care service" means any clinically related patient service.

(ii) "Health care service" includes a medical service.

(4) "Limited service hospital" means a health care facility that:

(i) Is licensed as a hospital on or after January 1, 1999;

(ii) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;

(iii) Retains an emergency or urgent care center; and

(iv) Complies with the regulations adopted by the Secretary under § 19-307.1 of this title.

(5) "Medical service" means:

(i) Any of the following categories of health care services:

1. Medicine, surgery, gynecology, addictions;

2. Obstetrics;

3. Pediatrics;

4. Psychiatry;

5. Rehabilitation;

6. Chronic care;

7. Comprehensive care;

8. Extended care;

9. Intermediate care; or

10. Residential treatment; or

(ii) Any subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of health care services for which need is projected in the State health plan.

(b) Application fee. -- The Commission may set an application fee for a certificate of need for health care facilities not assessed a user fee under this subtitle.

(c) Rules and regulations. -- The Commission shall adopt rules and regulations for applying for and issuing certificates of need.

(d) Determination of circumstances under which application required. -- The Commission may adopt, after October 1, 1983, new thresholds or methods for determining the circumstances or minimum cost requirements under which a certificate of need application must be filed.

(e) Required. --

(1) A person shall have a certificate of need issued by the Commission before the person develops, operates, or participates in any of the health care projects for which a certificate of need is required under this section.

(2) A certificate of need issued before January 13, 1987, may not be rendered wholly or partially invalid solely because certain conditions have been imposed, if an appeal concerning the certificate of need, challenging the power of the Commission to impose certain conditions on a certificate of need, has not been noted by an aggrieved party before January 13, 1987.

(f) New health care facility. -- Except as provided in subsection (g)(2)(iii) of this section, a certificate of need is required before a new health care facility is built, developed, or established.

(g) Relocation. --

(1) A certificate of need is required before an existing or previously approved, but unbuilt, health care facility is moved to another site.

(2) This subsection does not apply if:

(i) The Commission adopts limits for relocations and the proposed relocation does not exceed those limits;

(ii) The relocation is the result of a partial or complete replacement of an existing hospital or related institution, as defined in § 19-301 of this title, and the relocation is to another part of the site or immediately adjacent to the site of the existing hospital or related institution;

(iii) Subject to the provisions of subsections (i) and (j) of this section, the relocation is of an existing health care facility owned or controlled by a merged asset system and is to:

1. A site within the primary service area of the health care facility to be relocated if:

A. The proposed relocation is not across county boundaries; and

B. At least 45 days prior to the proposed relocation, notice is filed with the Commission;

2. A site outside the primary service area of the health care facility to be relocated but within the primary service area of the merged asset system if:

A. At least 45 days prior to the proposed relocation, notice is filed with the Commission; and

B. The Commission in its sole discretion, and in accordance with the criteria adopted by regulation, finds that the relocation is in the public interest, is not inconsistent with the State health plan, and will result in the more efficient and effective delivery of health care services; or

3. For a limited service hospital, a site within the immediate area as defined in regulation by the Commission; or

(iv) The relocation involves moving a portion of a complement of comprehensive care beds previously approved by the Commission after January 1, 1995, for use in a proposed new related institution, as defined in § 19-301 of this title, but unbuilt on October 1, 1998, if:

1. The comprehensive care beds that were originally approved by the Commission in a prior certificate of need review were approved for use in a proposed new related institution to be located in a municipal corporation within Carroll County in which a related institution is not located;

2. The comprehensive care beds being relocated will be used to establish an additional new related institution that is located in another municipal corporation within Carroll County in which a related institution is not located;

3. The comprehensive care beds not being relocated are intended to be used to establish a related institution on the original site; and

4. Both the previously approved comprehensive care beds for use on the original site and the relocated comprehensive care beds for use on the new site will be used as components of single buildings on each site that also offer independent or assisted living residential units.

(3) Notwithstanding any other provision of this subtitle, a certificate of need is not required for a relocation described under paragraph (2)(iv) of this subsection.

(h) Bed capacity. --

(1) A certificate of need is required before the bed capacity of a health care facility is changed.

(2) This subsection does not apply to any increase or decrease in bed capacity if:

(i) For a health care facility that is not a hospital, during a 2-year period the increase or decrease would not exceed the lesser of 10 percent of the total bed capacity or 10 beds;

(ii) 1. The increase or decrease would change the bed capacity for an existing medical service; and

2. A. The change would not increase total bed capacity;

B. The change is maintained for at least a 1-year period; and

C. At least 45 days prior to the change, the hospital provides written notice to the Commission describing the change and providing an updated inventory of the hospital's licensed bed complement;

(iii) 1. At least 45 days before increasing or decreasing bed capacity, written notice of intent to change bed capacity 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, or conversion of a health care facility or part of a facility to a nonhealth-related use;

B. Is not inconsistent with the State health plan or the institution-specific plan developed 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, the Commission notifies the health care facility of its finding; or

(iv) The increase or decrease in bed capacity is the result of the annual licensed bed recalculation provided under § 19-307 of this title.

(i) Bed capacity of hospitals located in counties with three or more hospitals. --

(1) Except as provided in paragraph (2) of this subsection, for a hospital located in a county with three or more hospitals, a certificate of need is not required before the bed capacity is increased or decreased if the change:

(i) Occurs on or after July 1, 2000;

(ii) Is between hospitals in a merged asset system located within the same health service area;

(iii) Does not involve comprehensive or extended care beds; and

(iv) Does not occur earlier than 45 days after a notice of intent to reallocate bed capacity is filed with the Commission.

(2) A hospital may not create a new health care service through the relocation of beds from one county to another county pursuant to this subsection.

(j) Change in services. --

(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;

(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. **ESTABLISHMENT OF A PERCUTANEOUS CORONARY INTERVENTION SERVICE IN A HOSPITAL THAT DOES NOT HAVE ON-SITE CARDIAC SURGERY, UNLESS THE HOSPITAL OBTAINS [WITHOUT] AN EXEMPTION FROM CERTIFICATE OF NEED IN WHICH THE COMMISSION SPECIFICALLY FINDS THAT THE SERVICE:**

A. IS CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES;

B. WILL RESULT IN THE DELIVERY OF MORE EFFICIENT AND EFFECTIVE HEALTH CARE SERVICES; AND

C. IS IN THE PUBLIC INTEREST.

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

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.

SECTION 2. AND BE IT FURTHER ENACTED, THAT THE COMMISSION SHALL "GRANDFATHER" CERTAIN EXISTING PRIMARY PCI PROGRAMS IN COMMUNITY HOSPITALS THAT MEET AND CONTINUE TO MEET REQUIREMENTS ESTABLISHED IN THE STATE HEALTH PLAN, PROVIDED THAT EACH SUCH PRIMARY PCI PROGRAM CONTINUE TO MEET REQUIREMENTS ESTABLISHED OR TO BE ESTABLISHED IN THE STATE HEALTH PLAN.

19-126.1 CERTIFICATION OF CONTINUING PERFORMANCE

(A) A VALID CERTIFICATION OF CONTINUING PERFORMANCE ISSUED BY THE COMMISSION MUST BE MAINTAINED BY AN ACUTE GENERAL HOSPITAL IN ORDER TO CONTINUE TO PROVIDE CARDIAC SURGERY SERVICES OR PERCUTANEOUS CORONARY INTERVENTION SERVICES IN THE STATE OF MARYLAND.

(B) THE COMMISSION SHALL ADOPT RULES AND REGULATIONS FOR ISSUANCE OF A CERTIFICATION OF CONTINUING PERFORMANCE THAT:

(1) ADDRESS QUALITY, ACCESS, AND COST;

(2) SET MINIMUM STANDARDS TO OBTAIN AND MAINTAIN A CERTIFICATION OF CONTINUING PERFORMANCE;

(3) SET AN APPROPRIATE TIME PERIOD FOR THE EXPIRATION OF A CERTIFICATION OF CONTINUING PERFORMANCE; AND

(4) REQUIRE, AS A CONDITION OF THE ISSUANCE OF A CERTIFICATION OF CONTINUING PERFORMANCE, THAT AN ACUTE GENERAL HOSPITAL AGREE THAT IT WILL VOLUNTARILY RELINQUISH ITS AUTHORITY TO OFFER EACH APPLICABLE SERVICE IF IT FAILS TO MEET THE MINIMUM QUALITY STANDARDS SET BY THE COMMISSION FOR THAT SERVICE.

(C) AN ACUTE GENERAL HOSPITAL ISSUED A NON-PRIMARY PERCUTANEOUS CORONARY INTERVENTION RESEARCH WAIVER BY THE COMMISSION IS NOT ELIGIBLE FOR A CERTIFICATION OF CONTINUING PERFORMANCE UNTIL IT OBTAINS AN EXEMPTION FROM CERTIFICATE OF NEED ISSUED BY THE COMMISSION.

19-134

(a) Established; regulations; limitations; licensing fee; electronic transmissions. --

(1) In order to more efficiently establish a medical care data base under § 19-133 of this subtitle, the Commission shall establish standards for the operation of one or more medical care electronic claims clearinghouses in Maryland and may license those clearinghouses meeting those standards.

(2) In adopting regulations under this subsection, the Commission shall consider appropriate national standards.

(3) The Commission may limit the number of licensed claims clearinghouses to assure maximum efficiency and cost effectiveness.

(4) The Commission, by regulation, may charge a reasonable licensing fee to operate a licensed claims clearinghouse.

(5) Health care practitioners in Maryland, as designated by the Commission, shall submit, and payors of health care services in Maryland as designated by the Commission shall receive claims for payment and any other information reasonably related to the medical care data base electronically in a standard format as required by the Commission whether by means of a claims clearinghouse or other method approved by the Commission.

(6) The Commission shall establish reasonable deadlines for the phasing in of electronic transmittal of claims from those health care practitioners designated under paragraph (5) of this subsection.

(7) As designated by the Commission, payors of health care services in Maryland and Medicaid and Medicare shall transmit explanations of benefits and any other information reasonably related to the medical care data base electronically in a standard format as required by the Commission whether by means of a claims clearinghouse or other method approved by the Commission.

(b) Medical care claims information. -- The Commission may collect the medical care claims information submitted to any licensed claims clearinghouse for use in the data base established under § 19-133 of this subtitle.

(c) Comparative evaluation of quality of care and performance of categories of health benefit plans determined by Commission. --

(1) The Commission shall:

(i) Establish and implement a system to comparatively evaluate the quality of care and performance of categories of health benefit plans as determined by the Commission on an objective basis; and

(ii) Annually publish the summary findings of the evaluation.

(2) The purpose of the evaluation system established under this subsection is to assist carriers to improve care by establishing a common set of quality and performance measurements and disseminating the findings to carriers and other

interested parties.

(3) The system, where appropriate, shall:

(i) Solicit performance information from enrollees of health benefit plans; and

(ii) On or before October 1, 2007, to the extent feasible, incorporate racial and ethnic variations.

(4) (i) The Commission shall adopt regulations to establish the system of evaluation provided under this subsection.

(ii) Before adopting regulations to implement an evaluation system under this subsection, the Commission shall consider recommendations of nationally recognized organizations that are involved in quality of care and performance measurement.

(5) The Commission may contract with a private, nonprofit entity to implement the system required under this subsection provided that the entity is not an insurer.

(6) The annual evaluation summary required under paragraph (1) of this subsection shall include to the extent feasible information on racial and ethnic variations.

(d) Comparative evaluation of quality of care and performance of nursing facilities. --

(1) The Commission, in consultation with the Department of Health and Mental Hygiene and the Department of Aging, shall:

(i) On or before July 1, 2001, develop and implement a system to comparatively evaluate the quality of care and performance of nursing facilities on an objective basis; and

(ii) Annually publish the summary findings of the evaluation.

(2) (i) The purpose of the comparative evaluation system established under this subsection is to improve the quality of care provided by nursing facilities by establishing a common set of performance measures and disseminating the findings of the comparative evaluation to nursing facilities, consumers, and other interested parties.

(ii) In developing the comparative evaluation system, the Commission shall

consider the health status of the population served.

(3) (i) The system, as appropriate, shall solicit performance information from consumers and their families.

(ii) On or before October 1, 2007, to the extent feasible, the system shall incorporate racial and ethnic variations.

(4) The Commission may adopt regulations to establish the comparative evaluation system provided under this subsection.

(e) Comparative evaluation of quality of care outcomes and performance measurements of hospitals and ambulatory surgical facilities. --

(1) The Commission may:

(i) On or before July 1, 2001, develop and implement a system to comparatively evaluate the quality of care outcomes and performance measurements of hospitals and ambulatory surgical facilities on an objective basis; and

(ii) Annually publish the summary findings of the evaluation.

(2) (i) The purpose of a comparable performance measurement system established under this subsection is to improve the quality of care provided by hospitals and ambulatory surgical facilities by establishing a common set of performance measurements and disseminating the findings of the performance measurements to hospitals, ambulatory surgical facilities, consumers, and interested parties.

(ii) In developing the performance measurement system, the Commission shall consider the geographic location, urban or rural orientation, and teaching or nonteaching status of the hospital and the ambulatory surgical facilities, and the health status of the population served.

(3) (i) The system, where appropriate, shall solicit performance information from consumers.

(ii) On or before October 1, 2007, to the extent feasible, the system shall incorporate racial and ethnic variations.

(4) (i) The Commission may adopt regulations to establish the system of evaluation provided under this subsection.

(ii) Before adopting regulations to implement an evaluation system under this subsection, the Commission shall:

1. Consider the performance measurements of appropriate accreditation organizations, State licensure regulations, Medicare certification regulations, the quality indicator project of the Association of Maryland Hospitals and Health Systems, and any other relevant performance measurements;

2. Evaluate the desirability and feasibility of developing a consumer clearinghouse on health care information using existing available data; and

3. On or before January 1, 2001, report to the General Assembly, subject to § 2-1246 of the State Government Article, on any performance evaluation developed under this subsection.

(5) The Commission may contract with a private entity to implement the system required under this subsection provided that the entity is not a hospital or an ambulatory surgical facility.

(6) (i) The comparable evaluation system established under this subsection shall include health care-associated infection information from hospitals.

(ii) The comparable evaluation system shall adhere, to the extent possible, to the current recommendations of the federal Centers for Disease Control and Prevention (CDC) and the CDC Healthcare Infection Control Practices Advisory Committee regarding public reporting of health care-associated infections.

(7) THE COMPARABLE EVALUATION SYSTEM ESTABLISHED UNDER THIS SUBSECTION SHALL INCLUDE INFORMATION ON THE QUALITY, OUTCOMES, AND OTHER RELEVANT DATA REGARDING CARDIAC SURGERY AND PERCUTANEOUS CORONARY INTERVENTION PROCEDURES.

SECTION 3. AND BE IT FURTHER ENACTED, THAT THIS ACT SHALL TAKE EFFECT JULY 1, 2012.

Appendix B:

Report of the Technical Advisory Group on Oversight of PCI Services

Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services

A Summary Report of Advisory Group Activities and Recommendations to the Maryland Health Care Commission July – November, 2011

Prepared December, 2011

Introduction

During the 2011 regular session, the Maryland General Assembly passed House Bill 1182, *Certificates of Need – Percutaneous Coronary Interventions Services.* Approved by the Governor on May 19, 2011, Chapter 616 of the Acts of 2011 became effective on July 1, 2011, and remains effective until June 30, 2012. During this one-year period, the law prohibits a hospital from establishing a non–primary percutaneous coronary intervention (PCI) program or providing non–primary PCI services unless the hospital was operating a PCI program on January 1, 2011, through:

(1) A certificate of need for an open heart surgery program; or

(2) A non–primary waiver in good standing from certificate of need and State Health Plan requirements, issued by the Maryland Health Care Commission.

The law requires the Maryland Health Care Commission, on or before December 31, 2011, to:

(1) Develop recommendations for statutory changes needed to provide appropriate oversight of PCI services; and

(2) Report its recommendations to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly.

Purpose of the Technical Advisory Group

Pursuant to the legislation, the Maryland Health Care Commission appointed a Technical Advisory Group (TAG) in June 2011. To begin the process, the Commission staff solicited nominations from a broad range of stakeholder organizations with expertise in cardiac care and expertise in the administration and regulation of health care facilities and services.

Key Stakeholders:

- Maryland Hospital Association
- Health Consumers
- American College of Cardiology, Maryland Chapter
- American Heart and Stroke Association, Mid-Atlantic Affiliate
- Society for Cardiovascular Angiography and Interventions
- MedChi – The Maryland State Medical Society
- CareFirst BlueCross BlueShield
- Maryland Department of Health and Mental Hygiene
  - Office of Health Care Quality
  - Board of Physicians
- Maryland Health Services Cost Review Commission
- Maryland Institute for Emergency Medical Services Systems

The Technical Advisory Group members are provided in Figure 1**.**

Figure 1.
Members, Technical Advisory Group on Oversight of PCI Services

Neri Cohen, MD
Chief, Division of Thoracic Surgery
Greater Baltimore Medical Center
(Nominated by MedChi, The Maryland Medical Society)

Blair Eig, MD, Senior Vice President, Medical Affairs & Chief Medical Officer
Holy Cross Hospital
(Nominated by Maryland Hospital Association)

Paul T. Elder, MD
Board Chairman
Maryland Board of Physicians

Gray Ellrodt, MD
Chief of Medicine, Berkshire Medical Center
Pittsfield, MA
Vice-Chair, Mission: Lifeline Advisory Work Group
(July 2010 – June 2012)
(Nominated by American Heart and Stroke Association, Mid-Atlantic Affiliate)

Barbara Epke
Vice President
Sinai Hospital of Baltimore / MHA

Dianne Feeney
Associate Director, Quality Initiatives
Maryland Health Services Cost Review Commission

R.C. Stewart Finney, Jr., MD
Chief, Division of Cardiac Surgery
St. Joseph Medical Center/ MedChi

Anne Flood
Director, Risk & Quality Management
Union Memorial Hospital/ MHA

Sonny Klaff
Consumer Representative
(Nominated by American Heart and Stroke Association, Mid-Atlantic Affiliate)

Joe Moser, MD
Senior Vice President, Medical Affairs
Anne Arundel Health System/ MHA

Lisa Myers, RN, MS
Director, Special Programs
Maryland Institute for Emergency Medical Services Systems

Kerry Prewitt, MD, Interventional Cardiologist
Chesapeake CardioVascular Associates
(Nominated by Society for Cardiovascular Angiography and Interventions)

Glenn Robbins, MD, Senior Vice President & System Chief Medical Officer
University of Maryland Medical System/ MHA

Charles Silvia, MD[1]
Vice-President, Medical Affairs
Peninsula Regional Health System, Inc./ MHA

Kevin Smothers, MD, Chief Medical Officer & Senior Vice President, Medical Affairs
Carroll Hospital Center/ MHA

Michael Steiner, AIA
Consumer Representative
(Nominated by American Heart and Stroke Association, Mid-Atlantic Affiliate)

John Chung-Yee Wang, MD
Chief, Cardiac Catheterization Lab
Union Memorial Hospital
(Nominated by American College of Cardiology, Maryland Chapter)

Renee Webster, RS [2]
Assistant Director
Office of Health Care Quality
Maryland Department of Health and Mental Hygiene

Daniel Winn, MD
Vice-President & Senior Medical Director
CareFirst BlueCross BlueShield

[1] Dr. Silvia replaced Thomas Lawrence, MD as Representative on September 9, 2011.
[2] Ms. Webster replaced William Vaughn, RN, as Representative on September 28, 2011.

Scope of the TAG's Activities

The TAG was charged with advising and assisting the Commission to make recommendations on possible legislative changes related to oversight of PCI services. The following activities and discussion questions describe the scope of the advisory group's work:

Activities:

- Discuss current statutory authority regarding PCI services.
- Identify limitations in PCI oversight.
- Consider recommendations for external peer review of PCI cases.
- Make recommendations to the Maryland Health Care Commission for possible legislative changes.

Questions:

- How can the oversight of PCI services provided at cardiac-surgery hospitals be aligned with oversight of PCI services at hospitals without on-site cardiac surgery?
- How can PCI data-sharing across State agencies be strengthened?
- How can hospital quality initiatives be modified and enhanced through the use of existing data that PCI programs collect and report systematically?

Summary of Advice and Other Input Provided to Maryland Health Care Commission by the TAG

The TAG convened for four meetings on July 26, September 13, October 11, and November 8, 2011. Meetings of the TAG were open to the public, and materials considered at each meeting were posted to and made available on the Commission's website at the following address: http://mhcc.maryland.gov/pci/index.html.

1. First Meeting - July 26, 2011

Focus of the Meeting: Background of current statutory authority of the Maryland Health Care Commission over PCI Services

At this meeting, the Commission's Charge under HB 1182 and the charge, structure, and timetable for the TAG were reviewed. MHCC staff presented an overview of current MHCC oversight of PCI services and its limitations. There was a general discussion of the three questions outlined in the preceding section of this report concerning alignment of PCI oversight at cardiac surgery and non-cardiac surgery hospitals, PCI data sharing across State agencies, and enhancement of hospital quality initiatives through use of data reported by PCI programs.

Advice Generated by the TAG: Four consensus positions with respect to statutory authority over PCI services, were established by the TAG at this meeting:

(1) PCI should be added to the section of the Commission's statute that identifies the establishment of an open heart surgery service as requiring a Certificate of Need;

(2) The oversight of PCI by MHCC should be aligned across all hospitals, including those with cardiac surgery on-site, requiring all programs to meet a set of minimum standards;

(3) Oversight and quality measurement should utilize available clinical data, including that collected through the American College of Cardiology Foundation National Cardiovascular Data Registry (NCDR) programs, which is now required in Maryland hospitals.

(4) MHCC should be added to the list of State agencies in legislation regarding the sharing of information for the purpose of investigating quality or utilization of care in regulated facilities.

2. <u>Second Meeting - September 13, 2011</u>

Focus of the Meeting: Oversight of PCI Services by other Maryland State agencies.

At this meeting, State agencies other than MHCC outlined their oversight responsibilities. Representatives of the Health Services Cost Review Commission, the Board of Physicians, the Maryland Institute for Emergency Medical Services Systems, and the Office of Health Care Quality described the statutory and regulatory authority that each could apply to oversight of PCI services.

It was noted that House Bill 286 (Chapter 587 of the 2011 Acts***),*** which places some new oversight responsibilities under the OHCQ, requires hospitals, as a condition of licensure to have a process to objectively evaluate the performance of each member of the medical staff, as part of the physician reappointment process. This process must include "a review of the appropriateness of the plan of care for the patient, particularly any medical procedures performed ion the patients, in relation to the patient's condition." Since all physicians must be reviewed, clearly interventional cardiologists will have cases evaluated for medical appropriateness as well as adverse events. The regulations are being finalized at the end of 2011.

The respective speakers also discussed whether there were current gaps or limitations in agency oversight.

Advice Generated by the TAG: No specific recommendations with respect to other State agencies' oversight of PCI services were produced at this meeting. The Maryland Board of Physicians noted that, although oversight is complaint-driven rather than systematic, there are no limitations *per se*. At OHCQ, the oversight process is also complaint-driven, which limits regular, ongoing, frequent oversight; providing such oversight would require additional staff. MIEMSS noted that its specific authority is to address emergency care, so it could not monitor elective care. At HSCRC, no specific limitations were identified.

In response to the presentation by the Health Services Cost Review Commission ("HSCRC"), there was concern expressed by members of the TAG with respect to use of administrative data by HSCRC to assess quality of care and appropriateness of care in the delivery of PCI services. Members expressed their view that such data could not be used to produce valid conclusions on these issues. Several members of the TAG also expressed discomfort that the referral, by HSCRC, of its findings on issues with respect to appropriateness of PCI services to the Office of Health Care Quality ("OHCQ") of the Department of Health and Mental Hygiene was being handled by OHCQ as a "complaint." Renee Webster of OHCQ noted that, while the term "complaint" may arouse concern, OHCQ cannot legally investigate a matter unless there has been a complaint. She stated that OHCQ would work directly with hospitals on issues raised by the HSCRC referral.

3. Third Meeting - October 11, 2011

Focus of the Meeting: Internal and external peer review of quality of PCI care

At this meeting, TAG members made presentations on the recommendations of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions concerning peer review for PCI services, and the recommendations of the Maryland Hospital Association's Necessary Care Work Group. There was also a description of the review processes used in the PCI program at Union Memorial Hospital.

Advice Generated by the TAG: No specific positions with respect to oversight of PCI services were produced at this meeting.

4. Fourth Meeting - November 8, 2011

Focus of Meeting: A discussion of Commission staff recommendations with respect to oversight of PCI services and alternative approaches.

MHCC staff provided the TAG with the following recommendations:

- Require a Certificate of Need ("CON") for the establishment of PCI services. This would clarify the Commission's oversight of PCI services, putting it on a par with cardiac surgery, and is particularly timely, given the Commission-approved C-PORT E research study involving non-primary PCI in hospitals without on-site cardiac surgery that is expected to be completed in 2012. The Commission's issuance of a research waiver to hospitals currently participating in that study does not constitute an entitlement to provide non-primary PCI beyond the specified time period of the study.

- Require the Commission to adopt regulations for overseeing PCI and cardiac surgery services at all Maryland hospitals. This change will give the Commission authority to assure that all acute general hospitals that provide PCI or cardiac surgery services in the State of Maryland: meet minimum standards; maintain compliance with

requirements for PCI and cardiac surgery services; and periodically renew approval to continue providing these services, in a manner similar to current waiver renewals.

- Add the MHCC to the State agencies (in HB600, 2011 regular session) that may share data or information for the purpose of investigating quality or utilization of care in any entity regulated by the agencies. For instance, the MHCC collects physician-level clinical data as a result of its requirements that PCI waiver hospitals report catheterization/PCI data to the Commission. This statutory change will permit the MHCC and other State agencies to share data, and may lessen duplication of data collection.

- Change the wording in the Commission's statute from "open heart surgery" to "cardiac surgery". This is a technical correction to reflect current usage.

Advice Generated by the TAG: With respect to the third and fourth recommendations listed above, concerning the addition of MHCC as an agency that may share data or information and the replacement of the term "open heart surgery" with "cardiac surgery," no objections or concerns were raised by the TAG.

With respect to the first two recommendations, several members of the TAG expressed concern with use of the "traditional" CON model as the primary vehicle for oversight of PCI services. The primary concerns expressed can be summarized as follows:

- CON has the potential for denying the ability of programs to develop and operate on grounds other than the ability of the programs to meet quality of care or patient safety standards, which should be the proper focus of regulatory oversight.

- The CON review process is "extensive and expensive." It will inappropriately incorporate consideration of competitiveness and financial issues rather than focusing solely on the quality of care.

- CON is not geared toward fulfilling the primary goal, which is oversight of the quality of PCI services.

- Whether the CON review process and standards can be adapted to fit oversight of PCI appropriately is at issue.

- It is discomforting that existing PCI programs may lose their ability to continue. The only standards applied in oversight should be quality and volume (in the context of quality). CON decisions should not be politically or economically determined.

- The number of programs could be "self-regulating." There needs to be a mechanism for enforcing standards, but capable hospitals should be allowed to develop programs or proceed with programs in place and be continuously monitored. Quality and capability should not be pre-judged through CON. Hospitals are not expected to attempt to provide the service if their likely volume precludes economic viability.

- CON is not necessary to assess need. Primary PCI is the standard of care[3] [4] for patients presenting with an ST-elevated myocardial infarction in progress, but it may not be possible to provide this standard of care in remote areas where a viable level of primary and elective PCI cannot be maintained. These areas will need to be addressed.

The TAG agreed that MHCC is the appropriate agency for PCI oversight, given its current authority to develop standards and policies that address quality of care. However, some members voiced a desire to have an alternative process, different from the current CON process, that would be used in the exercise of that authority.

Some members of the TAG also voiced concerns with a system of oversight that would create the potential for increasing the number of PCI programs and distributing demand for PCI over more sites. These comments can be summarized as follows:

- A desire to achieve larger case numbers for programs will naturally lead to considering limiting the number of programs.

- More centers will have an adverse impact on volume at existing centers, at the facility and practitioner level. Maryland wants to promote the development of a system of care that does not compromise the quality of its PCI services.

- Larger volume numbers are often needed to adequately assess quality of care. It may be less costly over time to use CON to achieve higher average program volume.

- Examples of where CON regulation has subverted the standard of care are lacking.

Consensus Recommendations of the TAG

The following statements express the recommendations of the TAG for which consensus exists, based on the discussion of issues and recommendations at the TAG's meetings.

Recommendations Related to Statutory Changes

1. The Commission's statute should provide explicit and direct authority to the MHCC for oversight of PCI services; this oversight should apply at all health care facilities providing PCI, including those where cardiac surgery is performed on-site.

[3] A commenter on a draft version of this report adds that primary PCI is the standard of care because it reduces acute mortality compared to alternative (thrombolytic/fibrinolytic) therapies.

[4] The 2011 ACCF/AHA/SCAI PCI Guideline (*JACC*, Vol. 58, No. 24, December 6, 2011, page 26) states: "Primary PCI is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center staffed with expert interventional cardiologists and skilled support staff."

2. Maryland law should require that all hospitals that provide PCI services, including those hospitals where cardiac surgery is available on-site, undergo continuing evaluation of performance based on established performance standards, with renewal of authority to provide PCI services based on ongoing compliance with the standards.

3. MHCC should be added to the State agencies listed in legislation regarding the sharing of information for the purpose of investigating quality or utilization of care in regulated facilities.

4. The term "open heart surgery," as used in the CON statute, should be changed to "cardiac surgery."

Recommendations that Can Be Implemented without Statutory Changes

1. Oversight of PCI services should be based on data that are clinically rich, and, wherever possible, MHCC and other oversight agencies should use the American College of Cardiology Foundation's National Cardiovascular Registry (NCDR) Cath PCI Registry and ACTION-GWTG data to evaluate PCI quality performance.

2. To account for patient acuity, risk adjustment should be applied to provider-level outcomes data reported publicly.

3. The standard of care reflected in MHCC rules needs to be kept current, through periodic consideration of changes in nationally-recognized guidelines for PCI.

4. Appropriate use criteria should be used to the extent practical and acceptable to providers and relevant medical professional societies.

Peer Review in the Provision of PCI Services

In the area of ensuring clinical quality and appropriateness through internal and external medical peer review, there appears to be a notable tension between the role that should or could be played by public agencies in actively, systematically, and periodically monitoring and enforcing peer review processes, and the appropriate sphere in which clinical leadership would be relied on to take responsibility for assuring performance and quality. There is a current effort, through the Maryland Hospital Association's Necessary Care Work Group, as well as professional societies, to develop a robust voluntary system of internal and external review. This includes creating partnerships between hospitals to pool and exchange review resources, as well as to identify high-quality firms that undertake clinical review. Moreover, House Bill 286 (Chapter 587 of the 2011 Acts), requiring hospitals to undertake practitioner performance evaluation within credentialing and reappointment processes, as a condition for licensure, may strengthen OHCQ's authority over hospital peer review in the context of PCI.

There was no consensus view expressed by the TAG that the MHCC's statute should mandate specific peer review programs or practices at this time. It was suggested that accreditation, one mechanism for providing external peer review, should remain optional at this time.

Appendices

Appendix A
Summary of the July 26, 2011 TAG Meeting

Appendix B
Summary of the September 13, 2011 TAG Meeting

Appendix C
Summary of the October 11, 2011 TAG Meeting

Appendix D
Summary of the November 8, 2011 TAG Meeting

Additional materials, including presentations to the TAG, are available at the MHCC website, http://mhcc.maryland.gov/pci/index.html.

Appendix A

Summary of the July 26, 2011 TAG Meeting

Maryland Health Care Commission

Summary of the Meeting
of the
Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services

July 26, 2011
4160 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Members Present

Barbara Epke, Sinai Hospital of Baltimore (representative of Maryland Hospital Association [MHA])
Dianne Feeney, Health Services Cost Review Commission
Anne Flood, RN, Union Memorial Hospital (MHA)
Lisa Myers, RN, Maryland Institute for Emergency Medical Services Systems
Joe Moser, MD, Anne Arundel Health System (MHA)
Kerry Prewitt, MD, MidAtlantic Cardiovascular Associates (Society for Cardiovascular Angiography and Interventions [SCAI])
Glenn Robbins, MD, University of Maryland Medical System (MHA)
Kevin Smothers, MD, Carroll Hospital Center (MHA)
Michael Steiner, AIA, Consumer Representative (American Heart Association, Mid-Atlantic Affiliate)
William Vaughan, RN, Office of Health Care Quality, Department of Health and Mental Hygiene
John Wang, MD, Union Memorial Hospital (American College of Cardiology, Maryland Chapter)
Daniel Winn, MD (CareFirst BlueCross BlueShield)

Via Phone:

Blair Eig, MD, Holy Cross Hospital (MHA)
Paul Elder, MD, Chair, Maryland Board of Physicians
Gray Ellrodt, MD, Berkshire MA Medical Center (American Heart Association)

Others Present

Tammy Gregory, American Heart Association - National Center (via phone)
Cheryl Lunnen, MedStar Health
Pat Cameron, MedStar Health
Wayne Powell, SCAI
Beverly Miller, MHA

Maryland Health Care Commission Staff Present

Ben Steffen, Acting Executive Director
Dolores Sands, Chief, Specialized Services Policy and Planning
Theressa Lee, Chief, Hospital Quality Initiatives
Paul Parker, Acting Director, Center for Hospital Services, and Chief, Certificate of Need
Christina Daw, Health Policy Analyst, Specialized Services Policy and Planning

Assistant Attorney General with State Agency (MHCC)
Suellen Wideman, Assistant Attorney General, Office of the Attorney General (via phone)

1. **Call to Order**

Ben Steffen, Chair, opened the meeting at 6:03 p.m. and called on members and staff to introduce themselves.

2. **Review: General Assembly Charge for the Commission (HB 1182)**

Chairman Steffen reviewed House Bill 1182 (Chapter 616, Acts of 2011), the enabling statute for the formation of the Technical Advisory Group on Oversight of PCI Services. He observed that the Legislature has recognized that the proper setting for addressing technical and scientific issues is this advisory type of forum, rather than in the Legislature. HB 1182, which passed in the most recent regular session, consists of only one page and contains two main provisions:

- Hospitals are prohibited from establishing non-primary (elective) percutaneous coronary intervention programs or providing these services unless they already have an open heart surgery program, or are among hospitals that have a waiver to provide PCI without on-site surgical back-up.
- The Maryland Health Care Commission (MHCC) is required to develop and report back recommendations regarding Maryland law covering PCI oversight by the end of this year.

Hence, this group will address the principal question, "Is current law appropriate?," with expertise from the clinical community who will advise MHCC on how to move forward.

Charge, Structure, and Timetable for Technical Advisory Group

The Technical Advisory Group (TAG) responsibilities are to:

- discuss statutory provisions pertaining to PCI oversight;
- identify limitations in State oversight;
- consider recommendations for external peer review of PCI procedures; and
- make recommendations to MHCC for possible legislative changes.

MHCC staff will support the TAG in writing up the report and recommendations, and presenting them to the Commission. The TAG has a relatively short timeframe for doing this work; there will be four meetings in which to accomplish the goals. The 1st meeting will cover MHCC PCI oversight and limitations in current statutory authority. The 2nd meeting will focus on the strengths and weaknesses in the oversight capabilities of other State agencies. The 3rd meeting will be devoted to identifying potential solutions and developing draft recommendations for statutory changes. The 4th meeting is reserved for considering other issues that might have been identified and for finalizing recommendations.

Chairman Steffen noted the importance of thinking broadly and proceeding thoughtfully toward crafting solutions that may be applied to a variety of responsibilities. The group will focus on quality and safety issues that are broader than one sentinel event or incident.

Chairman Steffen provided the following logistics and ground rules:

- The group will follow informal Robert's Rules of Order, where the Chair will recognize members who wish to contribute.
- The primary goal is to reach consensus, though there may be differences of opinions, which may be reflected in the final report to the Commission.
- Communication will be done through email; summaries of the meetings will be made available on the MHCC website.
- The Commission exercises final discretion regarding what will be presented to the Legislature and the Governor.
- MHCC staff is responsible for drafting the report, which will be distributed among the group for comments.

3. Presentation: Overview of Current MHCC Oversight of PCI Services

Dolores Sands, Chief of Specialized Services Policy and Planning in the MHCC Center for Hospital Services, presented slides (distributed by email) and discussed oversight of PCI Services. She began by briefly describing the main oversight responsibilities of other State agencies. The Health Services Cost Review Commission (HSCRC) is responsible for Maryland's unique all-payer hospital rate-setting and has initiated quality-based reimbursement. The Office of Health Care Quality (OHCQ) of the Department of Health and Mental Hygiene (DHMH) licenses facilities; evaluates utilization review, risk management, and credentialing; and, under a new statute, has responsibilities in overseeing hospitals' practitioner performance evaluation process. The Office of the Inspector General ensures protection of private health information that is entrusted to the Department, and is responsible for preventing fraud, waste, and abuse of departmental funds. The Board of Physicians (MBP) licenses practitioners and performs investigations, and takes appropriate disciplinary action when needed. The Maryland Institute for Emergency Medical Services Systems (MIEMSS) is an independent agency, responsible for coordinating emergency medical services throughout the state, and monitoring the recently designated Cardiac Interventional Centers (CICs).

MHCC oversight

In Maryland, a hospital is required by statute to have a Certificate of Need (CON) before providing open heart surgery (cardiac surgery); this specific requirement has been in place since 1988 (House Bill 821). MHCC oversees PCI through its regulation of cardiac surgery because the CON law does not specifically mention PCI. The regulation governing PCI is the State Health Plan (SHP), which allows PCI only in hospitals that have on-site cardiac surgery ("co-location" requirement); the SHP cites the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for PCI in effect at the time. Additionally, the current SHP, adopted as regulation in 2004 and amended in 2009, was based on recommendations by the MHCC Advisory Committee on Outcome Assessment in Cardiovascular Care.

The State Health Plan is required, by law, to address standards of access, cost and quality, including the methodology to project need for services. The current SHP for cardiac services, in effect since 2004, established two types of waivers for hospitals without back-up surgery: one for primary PCI (pPCI) based on available evidence that included research by the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT); and one for non-primary PCI (npPCI) based on a research proposal that developed into the multi-state C-PORT E (elective angioplasty) study. C-PORT E study enrollment ended March 31, 2011; hospitals now

participate in a follow-on registry, and will continue to do so until either they fail to meet the requirements, or the regulatory conditions change. The study results from C-PORT E are expected in 2012; as with the first C-PORT study (a randomized trial conducted from July 1996 to December 1999 to compare pPCI and thrombolytic therapy), the research findings will be used to update the State Health Plan.

In terms of monitoring ongoing performance and compliance with SHP requirements, there are some gaps or limitations. For example, 8 of the cardiac surgery hospitals do not receive the same type of monitoring and enforcement as the 2 most recent facilities to obtain a CON for cardiac surgery. The two more recent cardiac surgery hospitals have conditions attached to their CONs that require continued compliance (e.g., rate-setting, outreach, quality performance). At the same time, there are 13 pPCI waiver hospitals, and 8 of them participate in the npPCI waiver program; these hospitals' PCI programs have close evaluation for ongoing compliance (not required for PCI programs at the cardiac surgery hospitals) based on their waiver status.

As part of the hospital performance evaluation, MHCC requires public reporting of the proportion of patients with an acute myocardial infarction (AMI) whose time from hospital arrival to primary PCI is 90 minutes or less. Also, as of July 1, 2010, as part of public reporting, *all* hospitals (23) must participate in two National Cardiovascular Data Registry (NCDR) hospital-based cardiovascular registries -- ACTION Registry - Get With the Guidelines (GWTG) and CathPCI Registry. (Currently, the MHCC website publishes quality measures [The Joint Commission's Core AMI Measures], such as door-to-balloon times, on all hospitals that reported more than 20 cases during a 12-month period; obtained from external quality-oriented databases, these data are not part of any ongoing compliance review.) MHCC has also convened the Cardiac Data Advisory Committee, stemming from the recommendations of the earlier PCI Data Work Group. The Cardiac Data Advisory Committee will provide recommendations on data collection, risk adjustment, and ways to leverage existing registries for further quality improvement purposes, and will advise on ways to review, interpret and adjudicate data. MHCC is still working to physically obtain the NCDR data and begin its review of the data sets.

MHCC has Medical Review Committee status and, as such, receives reports of certain adverse events occurring in npPCI waiver hospitals from medical review committees established in those facilities. During the last regular session, the General Assembly passed a bill that is intended to facilitate sharing of information across State oversight agencies; nevertheless, this bill does not mention MHCC as one of the agencies to be involved in the referenced disclosure and transfer of information.

One limitation in MHCC's oversight is that it does not have clear authority in law to regulate PCI in a hospital with existing cardiac surgery. If the C-PORT E results demonstrate the safety and efficacy of elective PCI in facilities without co-located cardiac surgery, changes in the regulations would be warranted, further highlighting the difference in oversight across surgical and non-surgical hospitals.

Ms. Sands discussed a slide showing a graphic representation of the pathways in statute and regulation for approval to provide PCI. She noted again that MIEMSS oversees the designation of Cardiac Interventional Centers from among those hospitals that apply. While cardiac surgery programs require a CON, and PCI programs at non-surgical hospitals require a waiver, obtaining CIC designation is voluntary.

4. **Discussion: Limitation in MHCC Oversight through CON and PCI Waivers**

This Technical Advisory Group will advise MHCC on three main questions. The group discussed specific questions concerning current MHCC oversight.

1. ***How can the oversight of PCI services provided at cardiac surgery hospitals be aligned with oversight of PCI services at hospitals without on-site cardiac surgery?***

Question: What is the Commission's current oversight of hospitals without cardiac surgery back-up?
Ms. Sands responded that, for primary PCI, the hospital must complete a renewal application every two years. Hospitals seeking waivers are evaluated on institutional requirements – door-to-balloon time, volume, whether they have appropriate lab and other personnel; physician requirements, such as volume of PCI procedures; and pPCI system requirements, e.g., whether the hospital is doing case review at least every other month, and has multi-area committee (including the Emergency Department, Cardiac Catheterization Laboratory, and Coronary Care Unit) meetings. The requirements are spelled out in COMAR 10.24.17, the State Health Plan for cardiac surgery and PCI services. (COMAR refers to the Code of Maryland Regulations, which is the permanent publication of all regulations adopted by Maryland's administrative agencies.) MHCC may attach conditions to a pPCI waiver if a hospital has not met all of the regulatory requirements. For non-primary PCI programs, the requirements are in COMAR 10.24.05, the regulations governing research waivers for participation in the C-PORT E study and follow-on registry; hospitals must submit quarterly progress reports focusing on C PORT standards – adverse events, deaths, emergency coronary artery bypass graft (CABG) surgery, transfers, changes in the interventional cardiology roster.

Ms. Sands clarified the difference between statute and regulations, and the processes for developing each. The legislature enacts statutes, and administrative agencies develop and adopt regulations that follow the statutes. MHCC authority comes from the Health-General Article within the statutory laws of Maryland, and its regulations have to be within the agency's statutory authority. She noted that this group is discussing changes to the *statute*, not changes to COMAR (regulations / SHP).

Question: Where does MHCC derive authority to regulate PCI?
Ms. Sands and Ms. Wideman clarified: The statute gives MHCC authority to regulate open heart surgery. In considering what it needed to implement the statute, the Commission formed the Advisory Committee on Outcome Assessment in Cardiovascular Care. Based on national ACC/AHA professional guidelines, the committee recommended that regulations include the requirement that PCI be co-located with back-up on-site cardiac surgery.

Question: Is PCI then considered a subset of cardiac surgery?
Ms. Sands and Chairman Steffen responded that PCI is not considered a subset of cardiac surgery. But the professional guidelines call for co-location; linkage between the two arises from these guidelines.

Question: How are priorities for regulated services determined? For example, intracranial surgery is not on the list of services requiring a CON?
Paul Parker, Chief of Certificate of Need and Hospital Services Policy & Planning, responded that, in addition to certain medical services defined in the statute as requiring a CON, the list of services in this subsection includes neonatal intensive care, organ transplants, and burn units, as well as cardiac surgery. The scope in the CON statute is indeed narrow, with very few medical services explicitly regulated through CON in Maryland

(in comparison to other states), despite Maryland's comprehensive regulatory authority over hospitals and other facilities.

Question: What is the Commission's oversight of PCI at cardiac surgery hospitals?
Ms. Sands replied that the two most recent hospitals to open cardiac surgery programs have conditions on their CONs related to quality performance; other conditions concern rate-setting and outreach. All cardiac surgery hospitals must meet requirements for licensure, accreditation, etc. Despite the requirement that the NCDR data be collected and reported to MHCC, these data cannot be used by MHCC in the same way as with waiver hospitals.

Question: Are all hospitals participating in the NCDR registries?
Ms. Sands said that, before the 2010 mandate, some hospitals participated in CathPCI, others in ACTION, a few in both. (A list of the participating hospitals, as of December 3, 2009, is available on the Commission's website.)

A revised question was posed: *Should MHCC have the authority to oversee PCI uniformly across surgical and non-surgical hospitals?*

Dr. Wang wanted to know what additional data the Commission would get outside of NCDR, now that MHCC is collecting NCDR data.
Ms. Sands reiterated that for pPCI, MHCC evaluates institutional resources (e.g., downtime in cath lab; staffing / equipment in cath labs); physician resources (e.g., credentialing of MDs, minimum volume, participating in call); for npPCI, the Commission reviews physician compliance with C-PORT Device Selection criteria. The Commission also reviews adverse events, including events occurring following transfer-out. The last item would be outside the NCDR (CathPCI) reporting, because CathPCI data collection stops at the Index Hospital – events occurring post-transfer are not captured.

Dr. Wang also asked, regarding the CathPCI data, whether the Commission is looking at raw data or risk-adjusted data.
Ms. Sands said that MHCC expects to have access to record-level data, as well as reports generated from NCDR. (The NCDR risk adjustment model is used to report PCI in-hospital risk-adjusted mortality rates.)

Dr. Elder requested a summary of currently collected data, by category (cardiac surgery facilities without PCI conditions; cardiac surgery facilities with PCI conditions; waiver hospitals). Staff will provide this summary to members.

Ms. Sands reiterated that all hospitals report Core AMI measures for use in Hospital Compare, the hospital performance evaluation program operated through the Centers for Medicare & Medicaid Services (CMS). MHCC publishes the data by hospital on its website. But cardiac surgery hospitals have not reported patient-level data on PCI care directly to the Commission before the recent NCDR mandate.

Question: What happens to the data after it goes to NCDR – does it then go to the Commission?
Ms. Sands said that the Commission is not yet getting the NCDR data, but is in the process of having the data made accessible to MHCC.

Theressa Lee, Chief of Hospital Quality Initiatives in the MHCC Center for Hospital Services, added that the Cardiac Data Advisory Committee is working on the process of identifying key measures from NCDR for public reporting, and is setting up data transfer.

Question: What is the process of adopting regulations?
Ms. Sands explained that, following the drafting, there is a review and public comment process. As part of the drafting process, MHCC may convene an advisory committee to provide recommendations. Following an informal public comment period, the Commission finalizes the proposed regulations, and goes through the COMAR process, which requires an opportunity for public comment. Regulation development is all subsequent to the statutory process. It is not easy to adopt or change regulations; rather, it is a complex process.

Dr. Smothers queried whether this particular advisory process might be part of a response to the sentinel event mentioned earlier. There was a concern about necessary care arising from an event, and the Maryland Hospital Association convened a work group to look at the issue of necessary care. It appears that this effort is part of a response to, "what are responsible people doing to show that there is effective oversight over PCI?" Regarding the charge to this technical advisory group, is it to ensure that there is necessary care in this environment? This particular group is not so concerned about quality of care, but rather asking, is the care necessary? What oversight is there to ensure that on-site cardiac surgery hospitals are providing necessary care, besides an internal audit process?
Chairman Steffen stated that this group's work is not just a response to a single incident. The approach is much broader.

Dr. Wang suggested it would be helpful to have a copy of the CathPCI tool (version 4.3 or above), which is a very extensive and powerful instrument that is taken on every single patient. He referred to an article recently published in the *Journal of the American Medical Association (JAMA, July 6, 2011, Volume 306, Number 1, pages 53-61)*, where CathPCI Registry data were used to estimate the percent of elective stents that are inappropriate, based on appropriate use criteria from CathPCI fields built into the database. Six professional organizations jointly developed the criteria, which were published in January 2009: American College of Cardiology Foundation; Society for Cardiovascular Angiography and Interventions; Society of Thoracic Surgeons; American Association for Thoracic Surgery; American Heart Association; and American Society of Nuclear Cardiology. Since the registries have been mandated beginning in July 2010, the Cath/PCI data could be used to determine appropriate vs. inappropriate use, including in hospitals that currently have on-site cardiac surgery services.

Staff will provide both of the NCDR Registry tools (CathPCI and ACTION - Get With The Guidelines) to members.

Dianne Feeney reported that, in light of contextual events, HSCRC has used the hospital discharge abstract data to examine the stent-to-cath ratios of facilities; ratios above a certain threshold might offer a place to look and note patterns of practice that would warrant further investigation.

Ms. Sands suggested focusing on the charge from the General Assembly, specifically in determining whether administrative agencies have appropriate oversight authority in areas where the statute is not explicit. In the Commission's case, if the randomized controlled trial has relevant results to guide State policy about the

regulation of non-primary PCI, MHCC would go back and look at its SHP policy, and consider potential statutory changes as well. If co-location as the link between cardiac surgery and PCI goes away, what is done through regulation might change. Indeed, there could be a recommendation to alter (or take away) authority for oversight. If C-PORT E results in 2012 suggest a lack of need for co-location, the link between PCI and cardiac surgery may go away, and there might be a need to change the statute to have PCI explicitly covered in the CON section of the law pertaining to MHCC.

Dr. Smothers expressed concern about this gap in oversight faced by MHCC.

Dr. Winn made the following recommendation: Add PCI to the list of services covered under Certificate of Need. **The members reached consensus in support of this recommendation.**

Dr. Robbins agreed that PCI without on-site cardiac surgery may indeed be judged non-inferior per C-PORT E results.

Dr. Moser asked whether the Commission can unlink the on-site cardiac surgery provision from the PCI provision in the regulations as a matter of interpretation, following the C-PORT E study.
Ms. Wideman suggested waiting for the outcome of C-PORT E and seeing whether ACC, AHA, and SCAI change the national guidelines. At such time, the Commission could decide a policy change is needed, and could change their interpretation of what regulation of open heart surgery means.

Dr. Moser observed that the NCDR data mandate gives MHCC an opportunity to review both outcomes and appropriateness selectively, which might require outside medical expertise. Acknowledging that MHCC's Medical Review Committee is triggered when consulted by another Medical Review Committee, he suggested that Medical Review Committee status could be a mechanism to help align oversight across all hospitals. A medical review can provide equal attention regardless of a hospital's entry or "gateway" into PCI. Could Medical Review Committee status be a possible mechanism to bring all facilities to the same level of oversight?

Ms. Wideman noted that Medical Review Committee status gives the Commission authority to see the data coming from another Medical Review Committee. But does MHCC have authority to do anything based on the data received? As to npPCI and pPCI, MHCC exercises regulatory authority at waiver hospitals (based on the SHP co-location policy), but lacks specific statutory authority over PCI at cardiac surgery hospitals. The two most recent CONs approved by the Commission for cardiac surgery and PCI (or angioplasty) programs are subject to conditions that provide for closure of the cardiac surgery programs at those hospitals.

Chairman Steffen recognized Wayne Powell, Senior Director for Advocacy and Guidelines at SCAI, from the audience. Mr. Powell commented that new PCI guidelines are in the process of being rewritten, and are due to be completed by the end of this year. The updated guidelines must undergo review and approval by the American College of Cardiology Foundation Board of Trustees, the American Heart Association Science Advisory and Coordinating Committee, and the Society for Cardiovascular Angiography and Interventions Board of Trustees before publication (estimated to occur by early November 2011).

Question: Do the other State agencies also have uneven authority over PCI?
The respective representatives stated their authority is not uneven across types of hospitals.

Question: What analysis is done now with the data?
Ms. Sands responded that, for npPCI, data are gathered and analyzed through the C-PORT E research project. MHCC receives data and information on volumes, adverse events, and patients lost to follow-up. For example, npPCI waiver hospitals must have 200 total PCI cases per year, beginning in the second year and thereafter. For pPCI, the Commission's ST-segment elevation myocardial infarction (STEMI) registry (which followed the end of the first C-PORT study) provided data such as volumes and door-to-balloon times for use in reviewing waiver applications, and in monitoring and enforcement.

Following further discussion, the group agreed with the recommendation that the oversight of MHCC should be aligned across all hospitals, and reaffirmed that PCI should be in the list of services for which the statute requires a CON.

2. ***How can PCI data-sharing across State agencies be strengthened?***

Ms. Sands reported that MHCC makes available information about the waiver hospitals to its sister State agencies. MIEMSS has a requirement that CICs have a CON or a pPCI waiver in good standing. The agency also requires that CICs participate in a cardiovascular data registry jointly approved by MHCC and MIEMSS. For example, MHCC and MIEMSS have agreed to share NCDR ACTION Registry data across the two agencies. The agencies currently have access to administrative data, which is collected through HSCRC. To reduce the burden on hospitals, MHCC deems providers compliant following their submission of administrative or case-mix data to HSCRC. The recent law on data-sharing does not mention MHCC or MIEMSS, though MHCC and MIEMSS have authority to collect NCDR data. The focus of the recent data-sharing bill was likely on other types of investigative activity than what the group is here discussing.

Chairman Steffen asked State agency representatives to comment on their sharing of data.

Dianne Feeney noted that HSCRC has shared data regarding stent-to-cath ratios with OHCQ to support their auditing activities. This is an example of how HSCRC promotes quality and efficacy through its rate-setting authority.

Lisa Myers noted that MIEMSS is in the process of setting up review of CICs and arranging (cooperatively with MHCC) the data transfer from NCDR. She cannot yet say whether films will be reviewed in auditing the data, but this may occur in the new process. Under the agency's regulations, MIEMSS staff may conduct an on-site review, to include examining the hospital's patient care records related to cardiac intervention, to verify compliance with the agency's regulations. Auditing may include having physicians come from out of state. MIEMSS only looks at primary PCI, though.

Ms. Sands said, regarding primary PCI waiver hospitals, the STEMI Registry used proprietary software and had a database that included a high level of auditing, which will likely not be the case going forward. Because the waiver specified appropriate groups of patients for PCI at hospitals without on-site cardiac surgery, the data included 100% auditing of electrocardiograms (ECGs) -- the senior nurse manager/coordinator for the STEMI Registry reviewed every ECG. If a hospital disagreed, the physician director for the registry could request films and provide adjudication. In addition to the qualifying ECG, scanned documentation included the discharge

summary, cath/PCI report, procedure notes, operative report, etc. Also for hospitals participating in the npPCI program, angiographic films have been sent to the study Principal Investigator (PI) for review and adjudication. Indeed, there was an atypical level of auditing for both npPCI and pPCI waivers.

William Vaughan observed that at OHCQ there is not a significant level of data-sharing. OHCQ investigates hospitals based on complaints; hospitals have deemed status through Joint Commission accreditation, thus effectively closing OHCQ out of systematic review. OHCQ shares complaint-related data freely, but its oversight is done on a case-by-case basis. Films have not been used, but they might validate complaint findings in the future. Due to recent events, auditing may become stronger now.

Chairman Steffen asked for further comment on data-sharing in statutes. Concerning the new law, Ms. Sands noted that MHCC might have data that would be useful for other agencies. In drafting the new law, the legislators may have perceived the original Medical Review Committee law as inadequate to cover/address recent investigative data-sharing among State agencies, and so drafted a statute to make sure it was covered.

Chairman Steffen noted that State agencies also share data through MOUs and Data Use Agreements, which identify the data custodian and those who have access.

Dr. Elder observed that there should be similar requirements and review for evaluation of percutaneous coronary intervention across surgical and non-surgical hospitals. These would span from entry in ER to exit from angioplasty area (pre-, intra-, and post-procedure), and specify what is being done as well as how it is being done.

Dr. Elder asked if MHCC's information is shared with the public.
Ms. Sands reported that STEMI Registry data were posted publicly. The process is now changed with NCDR.

Dr. Robbins recommended that MHCC be added to the State agencies listed in legislation regarding the sharing of information for the purpose of investigating quality or utilization of care in regulated facilities. There was consensus in favor of this recommendation.

3. ***How can hospital quality initiatives be enhanced through the use of existing data that PCI programs systematically collect and report?***

Ms. Sands offered that the NCDR data provide richer clinical data, and as such will further hospital quality initiatives. These data are now being systematically collected and reported.

A concern was raised about not imposing further data-collection burden on hospitals. Ms. Sands responded that the NCDR data collection should not involve extra burden, as the requirement has been in place for a year. The regulatory agencies will have a full year of NCDR data by the fall.

Another observation: While door-to-balloon time is a process measure and doesn't need to be risk-adjusted, outcome measures should be risk-adjusted. Yet another noted that risk-adjustment can be accomplished using the fields that are included at the patient level in NCDR (e.g., demographics, comorbidities). Ms. Sands said that the ACTION Registry does not capture inpatient pPCI cases (that is, patients who are admitted for any

other clinical condition and have pPCI during that admission are not eligible for entry in the registry); while these are excluded from the ACTION Registry, all PCI cases in the waiver hospitals must be reported and have been examined by MHCC in the compliance review.

Ms. Lee reiterated that the Cardiac Data Advisory Committee will make recommendations regarding risk adjustment of NCDR data for reporting purposes.

Anne Flood suggested that hospitals do not engage in enough learning or sharing from organizations that have good results or excellent performance. Ms. Sands noted that the work sessions of the STEMI Registry coordinators included sharing best practices. Currently, MIEMSS has begun hosting meetings of the hospitals that participate in ACTION Registry–GWTG; this has been helpful for the participants.

Chairman Steffen noted that the group had completed the agenda and solicited further comment from the audience.

Cheryl Lunnen of MedStar (in audience) noted that the discussions by the Cardiac Data Advisory Committee suggest there may still be additional costs for processes of collection and auditing related to NCDR. That group still needs to address issues such as, how are data collected? accuracy of data reported? appropriate auditing? Getting data into the system may involve further costs.

5. Adjournment

There were no other matters related to MHCC oversight of PCI services. Chairman Steffen adjourned the meeting at 8:00 p.m. and noted the date of the next meeting, Tuesday, September 13, 2011, 6-8 p.m.

Appendix B

Summary of the September 13, 2011 TAG Meeting

Maryland Health Care Commission

Summary of the Meeting of the
Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services
September 13, 2011

4160 Patterson Avenue, Conference Room 100, Baltimore, Maryland

Members Present

Blair Eig, MD, Holy Cross Hospital (representative of Maryland Hospital Association [MHA])
Paul Elder, MD, Chair, Maryland Board of Physicians
Barbara Epke, Sinai Hospital of Baltimore (MHA)
R.C. Stewart Finney, Jr., MD, St. Joseph Medical Center (representing MedChi)
Anne Flood, RN, Union Memorial Hospital (MHA)
Sonny Klaff, Consumer Representative (American Heart Association, Mid-Atlantic Affiliate)
Lisa Myers, RN, Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Kerry Prewitt, MD, Chesapeake CardioVascular Associates (Society for Cardiovascular Angiography and Interventions [SCAI])
Glenn Robbins, MD, University of Maryland Medical System (MHA)
Kevin Smothers, MD, Carroll Hospital Center (MHA)
John Wang, MD, Union Memorial Hospital (American College of Cardiology, Maryland Chapter)
Daniel Winn, MD (CareFirst BlueCross BlueShield)

Via Phone:

Dianne Feeney, Health Services Cost Review Commission (HSCRC)
Joe Moser, MD, Anne Arundel Health System (MHA)
Charles Silvia, MD, Peninsula Regional Health System (MHA)

Guest Presenters

Renee Webster, Office of Health Care Quality, Department of Health and Mental Hygiene
Yemisi Koya, Maryland Board of Physicians
Irving Pinder, Maryland Board of Physicians

Others Present

Anna Aycock, MIEMSS
Stephen Ports, HSCRC
Wayne Powell, SCAI
Beverly Miller, MHA

Maryland Health Care Commission Staff Present

Ben Steffen, Acting Executive Director
Dolores Sands, Chief, Specialized Services Policy and Planning
Theressa Lee, Chief, Hospital Quality Initiatives
Paul Parker, Acting Director, Center for Hospital Services, and Chief, Certificate of Need
Christina Daw, Health Policy Analyst, Specialized Services Policy and Planning

1. Call to Order

Ben Steffen, Chair, opened the meeting at 6:05 p.m. and called on members and staff to introduce themselves.

2. Approval of Previous Meeting Summary

Chairman Steffen asked if there were questions or comments about the summary of the TAG meeting of July 26, 2011. Hearing none, he asked for approval of the summary. The group approved the summary.

Chairman Steffen reminded the group that currently the TAG is employing the "soft word" consensus. These consensus points may through discussion evolve into recommendations.

Dolores Sands reviewed these points reached through consensus on July 26.

1. The MHCC should have statutory authority to regulate PCI services under Certificate of Need.
2. MHCC's oversight of PCI should be aligned across all hospitals (that is, oversight of hospitals with cardiac surgery on site should be in the same fashion as for non-SOS hospitals).
3. The MHCC should be added to State agencies listed in the new legislation regarding sharing of information for purposes of investigating quality or utilization of care in regulated facilities. (MHCC has Medical Review Committee status, but was not included in the provisions of this bill.)
4. Oversight activities should include the use of data that are more clinically rich than case-mix administrative data, and that are already being systematically collected.

3. Presentations from State Agencies with Current Statutory Oversight of PCI

A discussion of the key limitations in current PCI oversight followed each presentation.

- **Office of Health Care Quality**

Referring to a slide presentation, Renee Webster, RS, Assistant Director of the Office of Health Care Quality (OHCQ), stated that OHCQ is part of the state Department of Health and Mental Hygiene (DHMH) and responsible for regulating all health facilities in the state of Maryland through licensing and certification. The agency uses state and federal regulations, which set forth minimum standards for provision of care, and conducts surveys to determine compliance.

Differences between Licensing and Joint Commission Accreditation: Licensing under the state DHMH is mandatory, while accreditation by the Joint Commission (TJC) is voluntary. Loss of license results in closure of the facility, while a facility can still operate after losing TJC accreditation. All Maryland hospitals (with the exception of one forensic hospital) have Joint Commission accreditation.

In order to obtain reimbursement from Medicare or Medicaid for services, hospitals must also obtain CMS (Centers for Medicare and Medicaid Services) Certification. CMS delegates Medicare certification oversight in Maryland to OHCQ; the CMS regulations used for oversight are the Conditions of Participation (COP). All but three Maryland hospitals have Medicare certification from CMS.

OHCQ regulatory oversight includes: hospital review; follow-up surveys with the Joint Commission; validation surveys if there are serious complaints; authority to review credentialing and utilization review (under section 19-319 of the Health - General Article); complaint investigation; and addressing reports of serious adverse events and all deaths.

Regulatory activity at OHCQ is largely complaint-driven; around 400-500 complaints per year are logged. OHCQ takes complaints from other agencies, individuals, and anonymous sources. All com-plaints are triaged by both CMS and OHCQ. CMS determines whether a matter comes under federal authority or state authority; only 20% of complaints are considered to come under federal authority. In oversight of patient safety, cases of adverse events/deaths will undergo a review of Root Cause Analysis, performed by the hospital; OHCQ does around 300 patient safety reviews per year. Many are related to falls; a few relate to PCI. Accredited hospitals have deemed status in Maryland; however, a hospital loses deemed status if there is one or more federal condition level (COP) deficiency. In this case, the state can issue a directed plan of correction. OHCQ will work with a facility to bring it into compliance. In some cases, OHCQ has levied civil monetary penalties (rare) or taken a license away (extremely rare). Criminal sanctions are possible.

House Bill 600 (Chapter 309 of the 2011 Acts): This 2011 legislation will increase OHCQ's ability to share information and communicate with other agencies in investigative matters. OHCQ has other partners in oversight, getting referrals from HSCRC and MHCC. The Maryland Board of Physicians (MBP) may make referrals back to OHCQ following MBP's determination regarding a practitioner. OHCQ has Medical Review Committee status; the specifics of an investigation can be protected, but after a determination is reached, information would become public. Ms. Webster noted that there are no jurisdictional issues or problems hampering the Office of Health Care Quality (e.g., restrictions on the type of facility that can be reviewed) in its oversight with regard to the provision of cardiac services.

(Note: MHCC has Medical Review Committee status, but is not one of the agencies included in the provisions of HB600 relating to sharing information among State agencies for purposes of investigating health care providers, health care quality, and utilization of health care.)

PCI: OHCQ has no specific regulations related to PCI or cardiac services, nor are there any specific regulations related to any one procedure of any type; rather, the regulations are quite general. However, PCI oversight can be approached in various areas of a hospital: medical staff (credentialing and accountability); surgical services and anesthesiology (appropriate assessments, standard of care for anesthesia met; appropriate maintenance of equipment); physical environment; Quality Assurance and Performance Improvement program – measurement of appropriate indicators; hospital governing body (e.g., Are data being fed to governing body?).

House Bill 286 (Chapter 587 of the 2011 Acts) was passed in the recent session as well. It requires hospitals to have a process to objectively evaluate the performance of each member of the medical staff. The care provided to patients is to be reviewed for quality and appropriateness of care with attention to adverse outcomes. This process must be objective and include a review of randomly selected cases and those with unexpected adverse outcomes. The reviews must be performed by trained staff of the same

specialty with no competing interests. The evaluation must be considered as part of the reappointment / re-credentialing process.

Discussion:

Chairman Steffen asked about the status of the regulations to implement HB286. Ms. Webster responded that OHCQ has drafted regulations, and submitted them to the Department of Health and Mental Hygiene. The draft regulations closely follow the legislative language. The next steps of the process will include a public comment period.

Dr. Eig said that TJC standards for practitioner performance or professional practice evaluation (PPE) have been in place for about three years, and are included in Joint Commission surveys. He noted that the Joint Commission is becoming stricter regarding compliance with PPE and use of ongoing and focused evaluation.

In response to a question about the similarity between HB286 and TJC PPE, Ms. Webster indicated that the draft regulations implementing HB286 are consistent with, and will follow closely, the standards of the Joint Commission. Dr. Smothers pointed out that TJC actively requires that practitioner performance review and evaluation must be ongoing and focused.

Ms. Sands asked about the specific testimony or thinking behind the change to HB286 providing for the review of care by external reviewers at the discretion of the hospital. Ms. Webster replied that she had no direct knowledge of the history, but her sense is that some hospitals have such small clinical staffs, that they have difficulty finding reviewers and so they need external resources for review. About six hospitals about 50 or fewer acute care beds, and a number of hospitals may not have multiple staff of some specialties. Small community hospital staff may have financial relationships which prevent objectivity. Hence, the hospitals will have discretion to have external review for PPE.

Barbara Epke noted that external review can be dissatisfying, and few resources for external review may be available. However, the MHA's Necessary Care Work Group has made suggestions on methods to obtain external review, and obtain high quality external review resources. For example, arrangements between hospitals may be made to have reciprocal external review, particularly when there is distance between the facilities. There are also some firms that do external review, that have good reputations.

Ms. Webster addressed a question about complaints regarding PCI quality: OHCQ does not receive many complaints about quality, but there have been adverse event reports. Since 2004, the Office has received about 10 notifications of adverse events. There are not many complaints in general about specialized services (e.g., cardiac surgery, neurosurgery), and not many adverse events. This low number of complaints may reflect high caliber teamwork developed in the specialty areas.

- **Health Services Cost Review Commission**

Dianne Feeney, Associate Director for Quality Initiatives for the Health Services Cost Review Commission, said that HSCRC has responsibility for rate-setting for the 46 acute care hospitals in Maryland. As shown in the slide presentation, the hospitals are a $13 billion (inpatient and outpatient) industry, with 700,000 discharges per year. HSCRC is an independent commission, with a long history of

setting rates through a waiver from CMS. All payers pay the same rates for the same type of patient, with a slight discount for Medicaid; hospitals receive the same rate for the same type of patient. Subtitle 2 of Title 10 of the Health General Article (§ 19-201 and following sections) is the enabling legislation, while the regulations (which came in 1974) are in Title 10 and Subtitle 37 of the Code of Maryland Regulations (COMAR 10.37). The rate-setting system has been in place for well over 30 years. Rate-setting was intended to: control rapid cost growth; improve access to care; make the health system equitable; provide accountability and transparency; and ensure financial stability and predictability for hospitals and patients.

The rate setting is done through an all-payer system, unlike any other state in the U.S. The system also provides funding for uncompensated care; for example, if an uninsured person needs PCI in the hospital, there are provisions for hospital coverage to provide services (but not for physician bills).

In the HSCRC reimbursement methodology, rates are set prospectively, and a rate is set for each hospital. HSCRC has developed other reimbursement methodologies. There is a charge per case system with an annual update factor. Rates are set for each of 314 APR-DRGS (All Patient Refined - Diagnosis Related Groups, a system of classifying patients) across 4 severity levels. There are some outliers defined for very complex care, but those are the exception. By statute and regulation, the system is meant to promote efficiency and effectiveness. HSCRC has 30 staff members, and a 7 member Commission. The staff is organized in two divisions: Rate-Setting and Methodology.

HSCRC can implement pay-for-performance more broadly because rates apply to all payers and all cases. The incentive structure has several components.

- Reasonableness of Charges (ROC) looks at how efficiently a hospital is performing within a given peer group of facilities; then adjusted for charging capacity. It is intended to allow hospitals to be compared on an equal footing.
- Charge per Case for Inpatient care (CPC) is based on APR-DRGs. This new method calculates average charge per case using Enhanced Ambulatory Patient Groupings (EAPG codes), an ambulatory payment grouper, average charges per visit, then adjusts by hospital case-mix index and patient severity.
- Charge per Visit for Outpatient (CPV) uses CPT codes.
- Admission – Readmission Revenue Bundled Payments (ARR) comprise a component under which payment for a readmission (under 30 days following discharge) is included with the initial stay, in a lump sum payment. Hospitals have agreed to accept this bundled payment based on history, volume (prospectively set as with the main rate-setting system), as of July 1, 2011. If a PCI patient is admitted, discharged, then readmitted, bundled payment would apply.
- Total Patient Revenue (TPR) is a payment structure where a hospital accepts global budget for all care provided. There is a caution: If a hospital is diverting patients to an unregulated setting, but accepting money for care they were historically providing, HSCRC needs to check for unintended consequences.
- Quality-Based Reimbursement (QBR) includes CMS and TJC core process measures for heart attack, pneumonia, surgical care, inpatient satisfaction.
- Maryland Hospital Acquired Conditions (MHAC) initiative examines actual vs. expected rates of conditions present upon admission / discharge. The initiative uses a Present On Admission indicator. If there is a trend of, for example, providing PCI service with more than expected

complications, the hospital can use case-level data to identify problem areas and look at the unit level, particular MD, data for MHAC.

Ms. Feeney then described a PCI-specific analysis requested by the DHMH Secretary and Office of the Inspector General (OIG), which used inpatient and outpatient data on PCI. It was triggered by recent events, and designed to calculate the commensurate cost (to the state) of inappropriate services for PCI at a particular hospital. HSCRC then looked at hospitals across the state. The period of review was July 2007 – June 2010, at the hospital and physician practice level patterns as indicated by the ratio of stents to diagnostic cardiac caths, but excluded cases with certain clinical conditions, transfers from tertiary hospitals, and Emergency Department (ED) cases. Results were risk adjusted for primary diagnosis, age and gender. If a patient had multiple cases of caths, with the same hospital, same operating MD, all but one case were dropped. There was a separate analysis of ED cases. Hospitals with fewer than 50 cases were dropped. The analysis showed that the number of PCI cases dropped dramatically in 2010.

Trends of total PCIs performed – case volumes: FY05 14,079 inpatient (IP); FY06 14,492; FY07 14,217, FY08 12,703; FY09 12,705; FY10 9,947.

This analysis was provided to OHCQ for further review. HSCRC wanted to develop an algorithm to identify potential probability cases, following risk-adjustment. The analysis is not dispositive of the appropriateness of a given PCI procedure. Rather, appropriateness must be determined by independent peer review.

Discussion:

Dr. Elder wanted to know whether the group can have a copy of the study. Ms. Feeney noted that Nancy Grimm, RN, JD, Director of the Office of Health Care Quality, has the study. Ms. Webster noted that OHCQ had received the final report about one month ago, and will handle any investigation as a complaint with further review.

Chairman Steffen asked whether the TAG can get a copy of the methodology and a description of the study design. Ms. Feeney replied that she will check with colleagues and HSCRC's legal counsel to see if she can make it available.

Ms. Epke inquired whether hospitals receive a copy of their own results. Ms. Webster said that OHCQ will be contacting each of the hospitals to discuss what is available to them. Ms. Feeney added that OHCQ will determine if there are problems with the methodology; however, HSCRC came to no specific conclusions, and used the data solely to form more questions.

Dr. Smothers asked for confirmation that the study has not been validated, but yet it will be treated as a "complaint." Ms. Webster reiterated that OHCQ will contact hospitals individually.

Dr. Wang agreed that there was a striking drop-off in cases in 2009; however, it must be noted that literature published throughout this time, since 2005, guided practice, particularly appropriateness criteria. Practice guidelines do not change overnight, but rather over time. The recent *JAMA* article [*Journal of the American Medical Association, July 6, 2011, Volume 306, Number 1, pages 53-61*] shows how appropriate use criteria can change practice over time. Physicians were trying to do the right thing, and

did not have sinister intent. Ms. Feeney stated that HSCRC wants the data to be more useful to the industry and did not want to imply any sinister intent.

Dr. Prewitt observed that the methodology of the HSCRC analysis is complex, and one cannot conclude anything about quality or appropriateness from the data. Ms. Feeney agreed with that assessment, noting that this effort was simply another use of HSCRC data that is not directly linked with payment. It is also an example of working collaboratively with other State entities to identify potential areas for further investigation.

Dr. Smothers pointed out that, to exam a high ratio of stents to caths, one must know more about numerators and denominators to draw any conclusion. The main concern is use of the word "complaint" in reference to the manner in which HSCRC has presented its analysis to OHCQ.

Ms. Webster stated that OHCQ has not made any conclusions at this time from the HSCRC analysis. OHCQ will work with hospitals to find out whether there are issues. While the term "complaint" may arouse concern, she clarified that OHCQ cannot legally investigate a matter unless there has been a complaint; such a referral is the only way that OHCQ can follow up. She reiterated that OHCQ would work directly with facilities on issues raised by such referrals. The agency is not yet at the point of reaching conclusions.

Chairman Steffen noted that at this point, HSCRC data is used as a screening tool to identify potential issues, but not relied upon to render a verdict. At the first meeting, this Technical Advisory Group came to a consensus that administrative data should be supplemented with clinically rich data. Chairman Steffen repeated the request that Ms. Feeney bring back to this group a description of the study design / methodology used in the HSCRC analysis.

In response to a question regarding whether the HSCRC data can be compared to the data in other states, Chairman Steffen noted that Medicare data are commonly used for comparisons across states. Ms. Sands suggested that to examine all patients, one might contact another state agency that has similar case mix data and data elements.

Ms. Webster said that HSCRC used physicians and statisticians in the analysis and prepared many iterations to refine the data before submitting it to OHCQ, so HSCRC did not treat the results lightly.

Sonny Klaff asked about the analytic decision to drop all but one PCI procedure in cases where patients had multiple PCIs. Ms. Feeney volunteered to ask the person in charge of the analysis for the rationale in these exclusions.

- **Maryland Board of Physicians**

Yemisi Koya, MD, JD, Chief of Compliance for the Maryland Board of Physicians, said that the Board is an administrative agency under DHMH. Its broad mission is public protection, yet its actual jurisdiction is limited in scope. The agency has direct oversight over practitioners, and its two main areas of jurisdiction are efficient licensure and effective discipline.

Licensure: The Board ensures that physicians who are licensed have good moral character and have met educational requirements and qualifications. In the license renewal process, the physicians must demonstrate continuing education, to strengthen skills.

Discipline and Investigation: First the Board conducts investigation, then monitoring. The Board makes comprehensive focused investigations. Poor physician conduct may result in loss of license. The Board can refer out issues that are not within its jurisdiction. By statute, the Board has jurisdiction over all licensees; it does not allow a licensee under review to have his or her license lapse, hence the license is still valid for purposes of discipline.

Granted Judicial Powers: First, the Board has the ability to conduct investigations. Also, by statute, the Board may enter the premises where an MD practices; may issue subpoenas for medical and hospital records, and has the power to administer oaths.

The Board has the authority to investigate complaints, which come from patients, family, law enforcement, other State agencies, and the court system. A hospital must provide notice of changes in the privileges of physicians; MBP reviews those changes in privileges, any abridgement of privileges. An investigation may be conducted on other practitioners as needed. The Board's investigations are confidential; the Board is prohibited from releasing details of an investigation. To ensure due process, respondents are provided adequate notice of proceedings.

Purpose: Conduct an objective and comprehensive investigation to determine if allegations have been substantiated. If substantiated, the Board will hear the case. If the Board decides that a charge is warranted, the case goes to the Office of the Attorney General (OAG). The physician has the opportunity to have a confidential settlement. Any prosecution includes a charging document with a notice of due process. Charges are not published on the Board's website. After resolution and a consent order, the decision on the discipline of the physician becomes public. A respondent may decide to settle, or to go to an evidentiary hearing before an Administrative Law Judge (ALJ). Parties are notified of an ALJ decision, and have the opportunity to file exceptions. There is also an expedited track if there is imminent danger. In the case resolution, the Board may monitor the physician's compliance with terms and conditions of the order, e.g., education.

In terms of PCI, a case may go specifically before the Board, where the issue of standard of care (SOC) is addressed. SOC reviews must be done by two objective professionals (peer reviewers), through an independent contract review. There is no longer a mandate to obtain a third review (now discretionary). Should there be consensus that there is a breach of Standard of Care, that will be presented to the Board for action, to determine possible charges.

Probation, with specific terms and conditions, may be ordered.

In response to a questions concerning how the Board arranges external reviews, Dr. Koya said that there is a procurement / contract agreement independent of the Board. Mr. Pinder added that several entities contract with the Board, and the Board always tries to use Maryland physicians. Some are five-year contracts, some with other provisions; there is a recent trend to work with specialty societies for reviews.

With regard to the National Practitioner Data Bank, the Board reports final orders to NPDB, and to other states (Federation of State Medical Boards).

- **Maryland Institute for Emergency Medical Services Systems**

Lisa Myers, Director of Special Programs for MIEMSS, said that the agency designates trauma and specialty referral centers, including stroke and PCI. The focus is on emergency procedures. The purpose of designing the system was to focus coordination of emergency medical services so that EMS providers, as they identify conditions in patients, can take them to the most appropriate treatment. It allows them to bypass one facility in order to go a more appropriate facility for the patient. The focus is on emergency situation; MIEMSS does not address elective PCI.

As indicated in the slide presentation, the independent agency's statutory authority is the Education Article, §§ 13-504 and 13-509. The EMS Board shall develop and adopt an Emergency Medical System plan to ensure effective coordination and evaluation of emergency medical services delivered in Maryland. The Emergency Medical System plan must include criteria for the designation of trauma and specialty referral facilities. These criteria must be promulgated in regulation. The applicable regulations are COMAR 30.08.16 (Designation of Trauma and Specialty Referral Centers – Cardiac Interventional Center Standards). The regulations were promulgated about a year ago, and MIEMSS has proceeded with the designation process. For all designations, MIEMSS uses a regionalized care model, based on the trauma care model, which Maryland has used for a long time and with much success. The Institute of Medicine has recommended this type of regionalized model for other types of centers, e.g., stroke, burn, hand trauma, eye trauma, perinatal care.

The regulations require a hospital seeking designation to have a license through DHMH; the hospital must have a Certificate of Need or waiver from MHCC. MIEMSS worked closely with MHCC to ensure that there are no discrepancies in the regulatory requirements (COMAR 10.24.17, the State Health Plan for Cardiac Surgery and Percutaneous Coronary Intervention Services).

COMAR 30.08.16 requires that designated hospitals submit data to the State using a registry jointly approved by MHCC and MIEMSS – the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR), ACTION Registry – Get With The Guidelines. The focus of this registry is on how the system is performing; the goal is to establish a system of STEMI care in Maryland. MIEMSS and MHCC are currently working with NCDR to obtain this data.

MIEMSS requires hospitals to have a medical review committee which monitors practice patterns and addresses quality improvement. MIEMSS examines the committee's minutes and evaluates quality improvement measures. The purpose is to foster systematic ways of identifying and addressing quality issues. MIEMSS conducts on-site surveys of Cardiac Interventional Centers (CICs), to look at peer review and performance improvement, focusing on process. The MIEMSS survey team interviews hospital team members from the ED, cath lab, ICU. The team does not take Medical Review Committee minutes from the hospital after a site visit, nor does MIEMSS have the hospital submit the documents with its application for designation. The agency does not ask for confidential materials on a regular basis, but rather looks at ongoing performance and compliance with standards, and is constantly looking at data.

If there are quirks in the data, MIEMSS may call the data coordinator to bring up questions about issues with data. The process is ongoing and dynamic.

Ms. Myers noted that MIEMSS is a Medical Review Committee under law, and the agency shares data with MHCC and HSCRC. She does not know why MIEMSS was excluded from specific mention in HB600.

The role of MIEMSS is to look at primary PCI, and the agency does not have access to physician-level data; rather MIEMSS obtains only patient- and hospital-level data.

In response to a question, Ms. Myers stated that MIEMSS does not treat surgical and non-surgical hospitals differently in terms of reviewing data and performance. MIEMSS does not see limitations in its statutory oversight of PCI, because the agency's specific charge, actual **authority**, is to address emergency (not elective) care.

In response to another question, Ms. Myers said that coverage of a large geographic area is a challenge; 23 hospitals are designated in Maryland. The Eastern Shore has limited PCI resources, just Anne Arundel Medical Center and Peninsula Regional Medical Center. Southern Maryland also has limited resources. A great deal of planning is occurring in each EMS region of the state. If a case comes up in a relatively distant place, then there are decisions to be made on whether to take the patient to the closest emergency center, to go to the nearest PCI center, to take a helicopter, etc. MIEMSS also has designated three out-of-state CICs: Washington Hospital Center in Washington, DC; Christiana Hospital in Newark, Delaware; and Bayhealth Medical Center – Kent General Hospital in Dover Delaware. For Western Maryland, the agency may also look at out-of-state centers.

In emergency calls, the 911 dispatcher will dispatch Advanced Cardiac Life Support (ACLS) transport whenever possible. ACLS responders will obtain a 12-lead electrocardiogram (ECG) to determine if the patient is having an ST-elevation myocardial infarction (STEMI); if so, the patient will be transported to a CIC. If the patient is not experiencing a STEMI, then the responders will look at the MIEMSS EMS Provider / Maryland Medical Protocols, or do consultation with a CIC, which then gives guidance to the responders.

Discussion:

To conclude and summarize the discussion of key limitations, Chairman Steffen asked the other State agency representatives if they have observed limitations in their oversight of PCI.

Mr. Pinder responded that the Board's oversight is complaint–driven, so the Board of Physicians does not necessarily get involved at the front end on utilization issues. In the near future, there will be joint promulgation of HB600 regulations. The Board's role depends on the phase of an investigation, but there are not limitations per se.

Ms. Webster replied that OHCQ's limitation is also that their oversight takes place in a complaint-driven process, so the agency is limited from regular, ongoing, and frequent oversight. Such oversight would be difficult with current staffing.

Dr. Eig noted that a significant part of TJC surveys involves regular oversight of the credentialing process.

Dr. Smothers asked whether these credentialing processes are redundant. Ms. Webster pointed out that the Joint Commission is not a government agency. The General Assembly may have had specific reason to bring the practitioner performance evaluation bill forward. Ms Epke said that TJC does not monitor routinely. OHCQ is more reactive but more "hands on" in contrast to TJC.

Dr. Eig noted that MHA's Necessary Care Work Group recognized that multiple agencies have multiple levels of regulation over primary or emergency PCI. The problem is that elective or non-primary PCI does not have near that level of oversight. He stated that this disparity might be the focus of recommendations to come from this body.

Chairman Steffen noted that the group is moving in the direction to get everyone at the same level of oversight, with a suite of organizations working together to identify gaps. He reiterated the group's charge to bring recommendations to the Commission for consideration.

Chairman Steffen offered an opportunity for public comment; no public comment was submitted.

4. Adjournment

With no further business, Chairman Steffen adjourned the meeting at 8:15 p.m., and noted that the next meeting is October 11, **4-6 p.m.**

Appendix C

Summary of the October 11, 2011 TAG Meeting

Maryland Health Care Commission

Summary of the Meeting of the
Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services
October 11, 2011

4160 Patterson Avenue, Conference Room 100, Baltimore, Maryland

Members Present
Blair Eig, MD, Holy Cross Hospital (representative of Maryland Hospital Association [MHA])
Paul Elder, MD, Chair, Maryland Board of Physicians
Barbara Epke, Sinai Hospital of Baltimore (MHA)
Dianne Feeney, Health Services Cost Review Commission (HSCRC)
R.C. Stewart Finney, Jr., MD, St. Joseph Medical Center (representing MedChi)
Anne Flood, RN, Union Memorial Hospital (MHA)
Sonny Klaff, Consumer Representative (American Heart Association, Mid-Atlantic Affiliate)
Joe Moser, MD, Anne Arundel Health System (MHA)
Lisa Myers, RN, Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Kerry Prewitt, MD, Chesapeake CardioVascular Associates (Society for Cardiovascular Angiography and Interventions [SCAI])
Kevin Smothers, MD, Carroll Hospital Center (MHA)
Michael Steiner, AIA, Consumer Representative (American Heart Association, Mid-Atlantic Affiliate)
John Wang, MD, Union Memorial Hospital (American College of Cardiology, Maryland Chapter)
Daniel Winn, MD (CareFirst BlueCross BlueShield)

Via Phone:
Charles Silvia, MD, Peninsula Regional Health System (MHA)
Renee Webster, Office of Health Care Quality, Department of Health and Mental Hygiene

Guests
Beverly Miller, Senior Vice President, Professional Activities, MHA
Gary Walford, MD, Chair, Maryland State Cardiac Data Advisory Committee

Others Present
Pat Cameron, MedStar Health
Amy Dukovcic, Washington Adventist Hospital
Mary Kay Gardenier, Saint Agnes Hospital
Sandra Katanick, Intersocietal Accreditation Commission
Cheryl Lunnen, MedStar Health
Julie Miller, MD
Kelly Miller, MD
Shelly Pieffer, St. Joseph Medical Center
Richard Pomerantz, MD
Wayne Powell, SCAI
Greg Vacek, Franklin Square Hospital Center
Matthew Voss, MD, Saint Agnes Hospital

Maryland Health Care Commission Staff Present
Ben Steffen, Acting Executive Director
Dolores Sands, Chief, Specialized Services Policy and Planning
Theressa Lee, Chief, Hospital Quality Initiatives
Paul Parker, Acting Director, Center for Hospital Services, and Chief, Certificate of Need
Christina Daw, Health Policy Analyst, Specialized Services Policy and Planning

Assistant Attorney General with State Agency (MHCC)
Suellen Wideman, Assistant Attorney General, Office of the Attorney General (via phone)

1. **Call to Order**

Ben Steffen, Chair, opened the meeting at 4:04 p.m. and welcomed members attending in person and via telephone.

2. **Approval of Previous Meeting Summary**

Dr. Elder asked that the summary reflect an observation made at the 9/13 meeting, specifically to confirm that there are no jurisdictional issues or problems hampering the Office of Health Care Quality (e.g., restrictions on the type of facility that can be reviewed) in its oversight with regard to the provision of cardiac services.

3. **Old Business**

Chairman Steffen inquired with Dianne Feeney of HSCRC whether the hospital PCI-to-cath-ratio methodology she mentioned on 9/13 was now available. Ms. Feeney replied that the September 13 TAG Meeting Summary provided the level of detail she had described, and reiterated that an interventional cardiologist had been involved in the analysis. She repeated that the analysis was used as a screening tool and was not dispositive of bad or inappropriate care. Chairman Steffen suggested that HSCRC and MHCC discuss whether more details about the design and analysis of the study could be shared in the future. Ms. Feeney and Ms. Webster reiterated that OHCQ is still reviewing the data submitted by HSCRC, which was handled as a complaint, and that only actual complaint findings (not the nature of each complaint) are made public. Ms. Webster stated that OHCQ staff had begun meeting with the hospitals since the last meeting of the Technical Advisory Group.

Ms. Webster provided an update on the status of the draft regulations to implement Chapter 587, 2011 Laws of Maryland, requiring hospitals and freestanding ambulatory care facilities, as a condition of licensure, to establish a certain practitioner performance evaluation process. She reported that OHCQ had sent the regulations as proposed to MHA for input. Beverly Miller added that MHA had sent the regulations out to its members for comment.

4. **Presentations: The Role of Internal and External Peer Review in Oversight of PCI Services**

A. John Wang, MD, American College of Cardiology, Maryland Chapter, and Kerry Prewitt, MD, Society for Cardiovascular Angiography and Interventions

Drs. Wang and Prewitt provided an overview of ACC, SCAI, and interventional cardiology. They discussed ACC/AHA/SCAI guidelines for PCI, which are classified as Class 1, 2, or 3, based on the strength of research evidence. They also mentioned specific ACCF/SCAI/AATS/AHA/ASNC

Appropriateness Criteria for Coronary Revascularization. The 2009 PCI Appropriateness Criteria covered 180 clinical scenarios, with guidance for assessment of whether an intervention is appropriate, inappropriate, or uncertain. In 2011 SCAI published two sets of quality guidelines.[1] [2]

Many factors go into an interventional cardiologist's decision regarding whether to perform an intervention (PCI), e.g., features of the lesion, number of vessels affected, clinical features of the patient; number of patient medications, patient wishes, operator technical ability, hospital resources available, as well as new research and community standards.

Appropriateness criteria can be applied using data gathered in the National Cardiovascular Data Registry (NCDR) CathPCI Registry. Dr. Prewitt noted that CathPCI is a powerful tool; however, using CathPCI requires accurate and appropriate documentation. Approximately, 5-10% of cases are audited.

Specific Recommendations on PCI oversight and practitioner performance evaluation:

- Continue current oversight
    - Cath PCI Registry; appropriateness (needs audit)
    - ACTION Registry - Get with the Guidelines
    - MIEMSS Cardiac Interventional Center
    - AMI core measures
    - Practitioner Performance Evaluation, e.g. Chapter 587; Joint Commission

- Internal Case Review
    - Multidisciplinary committee
    - Monthly review of randomly selected cases: Approximately 15 cases (10 PCI + 5 diagnostic)/month; each physician should have at least 10 cases/year
    - Cases presented in a blinded fashion that doesn't identify the performing doctor
    - Cases evaluated on: indication, accuracy of interpretation, and appropriateness based on community standards, current guidelines, appropriateness criteria, and applicable data
    - Committee provides written communication to physician of findings that are deemed inappropriate
    - Committee will document and maintain records in program database with reporting to medical staff office as part of performance evaluation

- External Case Review
    - Regular review of randomly selected cases sent for review outside of hospital. Each facility coordinates their own external process.
    - Cases presented in a blinded fashion that doesn't identify the performing doctor
    - Cases evaluated on: indication, accuracy of interpretation, and appropriateness based on community standards, current guidelines, appropriateness criteria, and applicable data
    - External reviewer provides written communication to institution of findings that are deemed inappropriate

[1] Klein LW, Uretsky BJ, Chambers C, Anderson HV, et al. Quality assessment and improvement in interventional cardiology: a position statement of the Society of Cardiovascular Angiography and Interventions, part 1: Standards for quality assessment and improvement in interventional cardiology. *Catheterization and Cardiovascular Interventions* 2011*;* 77:927-935

[2] Klein LW, Ho KK, Singh M, Anderson HV, et al. Quality assessment and improvement in interventional cardiology: a Position Statement of the Society of Cardiovascular Angiography and Interventions, Part II: Public reporting and risk adjustment. *Catheterization and Cardiovascular Interventions* 2011*;* 78:493-502.

    - Institution will document and maintain records in program database with reporting to medical staff office as part of performance evaluation

- Outcomes and Quality Review
    - Multidisciplinary committee (performance improvement meetings can be the same as above)
    - Periodic meetings to review outcomes and quality: each major complication and outcomes from available registries
    - Evaluates results on institution and individual levels
    - Send reports to each individual with institutional and confidential personal results
    - Send report to medical staff office as part of practitioner performance evaluation

- Other recommendations
    - Only use clinical data (such as NCDR) to assess appropriateness
    - Review recently published SCAI cath lab quality guidelines
    - Review Quality Improvement Toolkit (QIT) by SCAI

The presentation included an expression of support for accreditation as well as a statement that it should probably be optional.

Dr. Wang described the internal case review process at Union Memorial Hospital (UMH), which contains the elements outlined above. With regard to the monthly review of cases, he said that it would be difficult to review a higher number within the allotted time of one hour. Appropriate care for diagnostic as well as interventional cases is reviewed. Physicians do not comment on their own cases if reviewed.

External review provides an added layer of reassurance, on top of internal review. UMH submits randomly selected cases for external review; Ms. Flood estimated that less than 10% of cases are sent for review outside of the hospital. The suggestion on external review was left purposefully broad – it ranges from partnering across institutions, or sending for outside review, outside hospital out-of-state. No one type fits all institutions.

Regarding the Outcomes and Quality Review, which at UMH involves a multidisciplinary committee (including internists, cardiac surgeons, and hospitalists in addition to cardiologists), major complication & outcome reports are sent to individual physicians with confidential and personal results, compiled by the Medical Staff Office. ALL major complications identified in the NCDR database are reviewed. It is particularly helpful to have realtime feedback to physicians, and compare outcomes to benchmarks at hospital and NCDR benchmarks (annual comparison to peers' outcomes and national standards).

Question regarding how decisions on appropriateness are made in Union Memorial Hospital committees: Dr. Wang responded that decisions are based on committee consensus; dissents are documented but not tallied in statistics. Dr. Walford suggested that the RAND Delphi method can assist with this process.

Mr. Steiner asked how the review body can keep the operator anonymous during the case review. A physician's not commenting during a review could possibly indicate that the case under review was performed by that physician. Dr. Wang responded that it is possible (and preferable for openness of discussion) for physicians to remain anonymous in the review. It is more difficult (and not currently practical) to de-identify the patient because the cine viewers have the patient's name imbedded;

removing or extracting the name would require additional resources and reduce the quality of the film. Along with the film, the review includes dictated and other reports that are part of the medical record.

Dr. Wang noted that external review could serve as a second check on internal review; he expressed the view that external review cannot be as robust as internal review because of resource issues. In terms of a written report from external reviewer(s), Dr. Prewitt added that the educational advantage to the physicians is not as valuable.

Noting that the process described does not appear to differ greatly from other hospitals, Ms. Epke said that when and how cases are sent out for external review, as well as how an institution works with other hospitals, may differ across hospitals. Dr. Moser stated that, if a hospital observes a trend in inappropriate care on the part of a physician, it should not wait for that physician's scheduled two-year reappointment to take action.

B. Blair Eig, MD, Chair, Maryland Hospital Association's Necessary Care Work Group

Dr. Eig discussed the recommendations of the MHA's Necessary Care Work Group, which was formed in mid-2010 to address, in part, a concern about trust in the ability of entities to oversee care in hospitals.

Specific recommendations on case review:

- Monthly review of a percentage of each PCI practitioner's cases by a medical staff member who is credentialed in PCI, or by a designated multidisciplinary review committee with at least one member who is PCI credentialed.
- Appropriateness Use Criteria from ACCF are the cornerstone of documents in use currently.
- Quarterly review of overall program data, with comparison to national benchmarks, by medical director and/or multidisciplinary committee.
- (At least) annual outside review by independent expert entity of a percentage of each PCI practitioner's cases.
- Post-review for identified problem, pattern: more focused review of practitioner's cases, retroactive or prospective, where a proctor may be appointed.

There are no penalties now for not following the Necessary Care Guidelines. Dr. Eig said that outside review is difficult at many hospitals. Focused review, retrospectively or prospectively, should be done when warranted (such as when an irregular pattern is found). The institution may appoint a proctor; having the individual work with another physician may not necessarily be reportable. The Work Group plans to reconvene to see how hospitals are doing on an ongoing basis. The Work Group also plans to select and begin work on another topic soon.

Dr. Smothers pointed out that the review process should extend to the rest of the organization and be related to peer review in the rest of department, hospital, or system.

With regard to the Appropriateness Use Criteria, Dr. Prewitt noted that the current (2009) criteria are a tool based on 2008 or earlier data. It is important to take into account changes that have occurred since that time and to use best judgment if a case does not fit the criteria.

Dr. Walford noted that public release of audited, clinical data is useful as a tool for quality improvement. Dr. Wang mentioned research that Fred Resnic, MD, has published on the quality of interventional cardiology and unintended consequences of public reporting.

Dr. Moser noted that outside reviews are not 100% of the solution, but internal review has potential for in-bred problem. Some ideas are to review the reviewers, exchange samples across institutions.

Dr. Wang noted that external review can also be done for selected cases (rather than random).

Flexibility and the opportunity for standardization were stressed. Other issues included conducting clinical trials to evaluate technology to address past problems of early adoption of new technologies before they were proven; assuring that recent changes in documentation are incorporated in catheterization reports.

Several public comments concerned data collection and reporting. NCDR documentation requires resources; it is challenging to appropriately enter data. Although it is a rigorous process, dynamic feedback is helpful.

Other public comments focused on the expense associated with accreditation.

5. Brief Presentation and Discussion: Suggestions for Statutory Changes

Ms. Sands presented some points that MHCC staff had drawn from the TAG's previous discussions and suggestions.

- Require Certificate of Need (CON) for PCI services

- Require that all programs meet minimum standards
  Non-SOS hospitals (no cardiac surgery on site) *and* SOS hospitals (surgery on site)

- Add MHCC to list of agencies in data-sharing legislation

Paul Parker spoke briefly regarding the underlying principles of Certificate of Need: to plan to meet current and future health care system needs for all Maryland residents by assuring access, quality, and cost efficiency. The regulations in the State Health Plan are developed based on these principles.

Question: Will PCI programs be limited in number? Chairman Steffen noted that future discussion by a work group will address how access and cost issues affect the process.

Dr. Moser suggested that CON is from a different era, and raised a concern that the process may decrease rather than increase access to care.

Ms. Miller and Dr. Eig noted that MHA wants to be involved in developing regulations on these services.

Chairman Steffen advised that Commission staff will flesh out suggestions for statutory changes, and will share the document with TAG members, as well as with MHA leadership so that MHA can distribute to member hospitals. The staff document will be sent out before the next meeting.

6. Adjournment

There were no other matters related to PCI Oversight. Chairman Steffen adjourned the meeting at 6:25 p.m., and noted the date of the next meeting, Tuesday, November 8, from 6 – 8 p.m.

Appendix D

Summary of the November 8, 2011 TAG Meeting

Maryland Health Care Commission

Summary of the Meeting of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services
November 8, 2011

4160 Patterson Avenue, Conference Room 100, Baltimore, Maryland

Members Present

Paul Elder, MD, Chair, Maryland Board of Physicians
Barbara Epke, Sinai Hospital of Baltimore (MHA)
Dianne Feeney, Health Services Cost Review Commission (HSCRC)
R.C. Stewart Finney, Jr., MD, St. Joseph Medical Center (representing MedChi)
Anne Flood, RN, Union Memorial Hospital (MHA)
Joe Moser, MD, Anne Arundel Health System (MHA)
Lisa Myers, RN, Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Kerry Prewitt, MD, Chesapeake CardioVascular Associates (Society for Cardiovascular Angiography and Interventions [SCAI])
Glenn Robbins, MD, University of Maryland Medical System (MHA)
Kevin Smothers, MD, Carroll Hospital Center (MHA)
Michael Steiner, AIA, Consumer Representative (American Heart Association, Mid-Atlantic Affiliate)
Renee Webster, Office of Health Care Quality (OHCQ), Department of Health and Mental Hygiene

Via Phone:

Blair Eig, MD, Holy Cross Hospital (representative of Maryland Hospital Association [MHA])
Charles Silvia, MD, Peninsula Regional Health System (MHA)
John Wang, MD, Union Memorial Hospital (American College of Cardiology [ACC], Maryland Chapter)

Guests

Gary Walford, MD, Chair, Maryland State Cardiac Data Advisory Committee

Others Present

Nancy Bruce, Frederick Memorial Hospital
Patricia Cameron, MedStar Health
Amy Dukovcic, Washington Adventist Hospital
Dennis Friedman, MD, Shady Grove Adventist Hospital
Cheryl Lunnen, MedStar Health
Beverly Miller, Maryland Hospital Association
Tricia Nay, OHCQ
Benjamin Paul, Adventist HealthCare
Michelle Pieffer, St. Joseph Medical Center
Bridget Plummer, Shady Grove Adventist Hospital
Frank Ryan, ACC
Sharon Sanders, Carroll Hospital Center
Gail Shults, Shady Grove Adventist Hospital

Debra Truxillo, Shady Grove Adventist Hospital
Greg Vacek, Franklin Square Hospital Center

Maryland Health Care Commission Staff Present
Ben Steffen, Acting Executive Director
Dolores Sands, Chief, Specialized Services Policy and Planning
Theressa Lee, Chief, Hospital Quality Initiatives
Paul Parker, Acting Director, Center for Hospital Services, and Chief, Certificate of Need
Christina Daw, Health Policy Analyst, Specialized Services Policy and Planning

Assistant Attorney General with State Agency (MHCC)
Suellen Wideman, Assistant Attorney General, Office of the Attorney General

1. Call to Order

At 6:05 p.m. Chairman Ben Steffen called the meeting to order. Members and staff introduced themselves and members participating by phone were identified.

2. Approval of Draft Summary of Meeting of October 11, 2011

No corrections or additions were suggested by members of the Technical Advisory Group (TAG). The summary of the previous meeting was approved by voice vote.

3. Discussion of Staff Recommendations for Statutory Changes in PCI Oversight

Mr. Steffen reviewed the agenda for the meeting. He noted that a TAG report would be submitted to the Commission and that the Commission would consider finalizing its recommendations to the General Assembly at its December 15, 2011 meeting.

Paul Parker briefly reviewed the staff recommendations sent to the TAG for discussion. He noted that regulating PCI in the Certificate of Need (CON) statute, the first recommendation, reflected an early consensus position of the TAG, as reflected in the group's September 13, 2011 meeting summary. The second recommendation, for CON approval to be conditional on meeting ongoing performance requirements for PCI and cardiac surgery, would build on MHCC recent posture in CON approval of cardiac surgery and the PCI waiver programs. He noted that the third recommendation, regarding MHCC inclusion in statutory language with respect to state agencies sharing information for purposes of investigating quality or utilization of care in regulated facilities, also reflected an early consensus position of the TAG (September 13 meeting summary) and was necessary to implement effective oversight of any kind. The fourth recommendation, replacing the term "open heart surgery" with "cardiac surgery" in the CON statute, was in the nature of a "housekeeping" change, so that the law would reflect contemporary terminology.

Mr. Steffen asked for discussion of the first recommendation.

Dr. Joe Moser stated that, generally speaking, there is no question that PCI needs to be under regulatory oversight; MHCC's experience makes it the logical place to do that. The concept that oversight should be constantly updated is valid; also, oversight should be applied equally across hospital settings (those with and without cardiac surgery). The concern, however, is whether to tie this oversight to traditional CON regulation. Oversight of performance should be the focus of regulation and good performance must be required. There is a concern that using CON would inappropriately rely on consideration of criteria other than performance, yielding the potential for denial of PCI programs for reasons other than the ability of the applicant hospital to meet performance standards.

Dr. Glenn Robbins stated his support for Dr. Moser's comments. The CON application and review process is extensive and expensive. There are issues of competitiveness and financial issues, which are generally considered in CON review, that go well beyond quality of care consideration.

Barbara Epke stated that she was surprised when the discussion moved to CON at the last meeting and felt that quality oversight was the primary concern of the TAG. Oversight is important but she did not see CON regulation as fitting the goal of overseeing quality of care.

Dr. Kerry Prewitt asked if, absent CON regulation of PCI, any hospital could open up a PCI program. Mr. Parker noted that absent a CON statute regulating PCI or a basis for regulating PCI through regulation of cardiac surgery, the "waiver" model that is becoming increasingly inconsistent with contemporary research on the necessity for co-location of these services, the state would not have authority to prohibit provision of this service by hospitals. Regulation of services in this manner has been the province of CON regulation in Maryland. Hospital licensure could potentially be another mechanism for regulating market entry, but has not been historically used in this way. Facilities have been licensed by category but not on the basis of individual services.

Dr. R. C. Stewart Finney, Jr. noted that there is an obvious tension between haves and have-nots. He asked, "If a hospital has the money to start a program, how do you say "no" without CON regulation?"

Mr. Steffen called on Suellen Wideman, the Assistant Attorney General, to comment on CON criteria. Ms. Wideman noted that a key consideration in CON regulation is consistency with the State Health Plan (SHP). If the statute is changed, modification of the SHP will need to take place and an advisory group will be convened to work on the plan. It is likely that a white paper will be developed through this effort, providing guidance on review criteria and standards that should be adopted in the revised SHP. Staff will draft modified standards and obtain information, review and comment prior to developing rules for the Commission to consider.

Dr. Finney noted that a desire to achieve larger case numbers for programs, which is associated with better quality, will naturally lead to considering limiting the number of programs.

Dr. Paul Elder stated that the Board of Physicians did not have a position with respect to CON regulation of PCI *per se*. It supports standards that are clearly stated and applied consistently

and uniformly to all settings for PCI, cardiac surgery hospitals and non-surgical hospitals. All settings should provide uniform reporting of data.

Mr. Steffen asked for discussion of the specific issue of licensure as an alternative to CON regulation. Renee Webster stated that, currently, the Office of Health Care Quality issues a license, in the case of regulated health care facilities, only when CON requirements are met. OHCQ licenses facilities and expect them to follow the licensure standards. Licensure does not typically apply to specific services. Significant statutory changes would be required if Maryland decided to license services without CON.

Mr. Steffen asked for comments from those on the phone. Dr. Blair Eig expressed concern about PCI services being regulated through CON but was in agreement with everything else outlined in the first staff recommendation. Changing CON procedure for regulation of this specific service would be a concern.

Dr. John Wang asked, if C-PORT E results are positive, whether the current C-PORT E research waiver hospitals would automatically meet requirements for CON approval. Mr. Steffen noted that waiver hospitals would need to apply for continuation of the service through a CON review and approval process. Synchronization and alignment of that process with the Commission's objectives and standards for PCI will need to be carefully thought out. The authority of hospitals to perform PCI is linked to duration of the waiver and not beyond. In response, Dr. Wang asked if this essentially meant that there would be no guarantee that a waiver hospital would qualify for a CON. Mr. Steffen indicated that this is correct.

Mr. Parker added that the new state health plan development discussed by Ms. Wideman would take into account the fact that the Commission would be transitioning from a waiver program to a new system. Under the terms of waivers, hospital programs are not guaranteed CONs as replacements of their waivers, but waiver programs that were very successful under the waiver regime would obviously be in a strong position to make the case that they could meet the type of standards that are likely to be established. Conversely, weaker programs that have difficulty complying with the waiver regime would have more difficulty. This will have to play out in state health plan development.

Dr. Wang asked about the procedure used for non-waiver hospitals without elective PCI. Would they need to become "fresh" applicants for a CON?

Mr. Parker answered affirmatively. The process for considering brand-new, non-surgical hospital PCI programs would be addressed in the specific SHP policies and standards developed following statutory changes. He reviewed the six required considerations currently in place for CON application review: (1) Need. If the plan adopted indicates an unmet need for more PCI programs capacity, the typical process would be to create a review cycle based on identified need. New hospitals could respond by filing applications, based on this identified need. These applications would need to address: (2) Is the proposal a cost-effective and reasonable alternative for increasing PCI capacity? (3) The next consideration would be the impact of the proposed program on the system already in place. The criteria for assessing impact would need to be

spelled out in the plan; (4) The next consideration would be consistency with the SHP standards for the technical requirements related to the physical facilities and staffing needed for PCI; (5) Viability would need to be demonstrated; and (6) The applicant's track record in implementing previous CONs would be assessed. Did this hospital implement approved projects on a timely basis and within the approved budget?

Dr. Charles Silvia expressed concern with the notion of facilities being in danger of losing their current programs. He said that he could see new programs being needed in inaccessible regions. The state needs to set a bar on quality and volume but these should be the only standards applied. If these standards are not met, then a program should be re-evaluated. The decisions should not be politically or economically determined.

Dr. Wang noted that, regarding volume of operators, more centers will have an adverse impact on volume at existing centers, at the facility and practitioner level. Maryland needs to be cautious about starting new programs, particularly in view of the annual volume standard expected for physicians. The state does not want to decentralize services to a point where quality is compromised.

Dr. Moser stated that he appreciated that, after decades of using the CON system, his suggestions might "throw a monkey wrench into the usual order." This is not his intent. His concern is that CON regulation can be based on a premise along the lines of the following example. If two hospitals both have CT scanners, twice as many scans will be done. But PCI is a more sophisticated procedure, and PCI standards for appropriateness have become increasingly well-defined. Enforcement of these standards should alleviate concerns with respect to overutilization. Regarding decentralization, the C-PORT E study is primarily focused on safety and is not addressing effectiveness of the procedure. The staff and interventional cardiologists needed for primary PCI cannot be supported unless a program has elective PCI as well. The process can be self-regulating. If primary PCI is the standard of care, then to the extent that elective PCI cannot be provided as well, the state is denying the standard of care in emergencies where door-to-balloon time is critical. Maryland needs to look at a process for enforcing standards that also allows capable hospitals to develop programs and continue to be allowed to offer the service by presenting evidence that they are achieving quality through continuous monitoring of their performance.

Mr. Steffen opined that a more free market process, such as that described, might tend to increase the probability that one or more hospitals would enter the market but fail to maintain standards. This type of closure may create a more chaotic process. Maryland could have a very transitory set of services at hospitals.

Dr. Moser replied that there is recognition that in doing quality and peer review, the outcomes and process used in programs will be more important indicators than volume alone; a hospital that can't maintain volume, referrals or patient satisfaction, will be demonstrating that it is not successful in the market, and will be likely to discontinue the service, as it should. CON does this in a more arbitrary manner. CON makes assumptions in advance about quality and capability. While appreciating Mr. Steffen's concern, if standards are known in advance, he

believes that hospitals on "the borderline" will not attempt to establish a program in the first place.

Dr. Prewitt asked whether there could be a conditional CON for two years for "borderline" hospitals.

Mr. Steffen noted that the Commission has flexibility for experimentation in the CON procedures it adopts. Mr. Parker described the staff recommendation as one that, for both PCI and cardiac surgery, would involve conditional CONs in all cases. CONs would be conditional on the hospital ramping up to meet the standards after it is approved and continuing to meet standards over time to maintain certification. Every CON approval would be conditional.

Dr. Walford noted that larger volumes are often needed to adequately assess outcomes and quality of care at a hospital. It may be less costly to regulate over time with CON than to open up the market to lots of new programs striving to meet standards.

Dr. Moser replied that, if a program declines to truly low volumes, a hospital could not continue to be viable as a PCI provider and the hospital would not want to continue. It would be economically unfeasible to consider doing procedures at very low volumes. Economic feasibility can be self-regulating in this sense, and regulatory oversight would concentrate on quality standards. Such a process, similar to licensure, would be less expensive.

Mr. Steffen moved on to the second staff recommendation. He noted that our standards are evolving and, as new evidence emerges, it will be reflected in regulations. He reminded the group that our focus is on the statute. Regulations are much easier to change than the statute. What constitutes minimum standards can and will change as research and knowledge progress. There is a two-tiered process implicit in the staff recommendations, with changes to statute followed by changes in regulations. Regulation is the appropriate venue for considered the evidence, changing evidence, and the standards suggested by the evidence. Statutes are hard to implement and lawmakers may not bring together the proper scientific expertise to address such detail in law because the legislature has a heavy agenda.

Dr. Elder commented that standards of care need to be kept current. A good system of competence and peer review would serve the state well.

Dr. Wang asked how often a program would be reviewed to maintain its CON and what type of reporting would be required.

Mr. Steffen noted that these are questions that would be best addressed in the regulatory process that would follow statutory changes. Mr. Parker agreed. Currently the Commission uses a two-year period for primary PCI waivers. Regarding data, the Commission and hospitals have a shared vision that the process is data-driven and that the needed data will be continuously provided by hospitals to registries and that this information will be available to MHCC. The process will continue to be data-driven, through ongoing review of data. The Commission and hospitals will be able to see when problems develop at programs over time.

Mr. Steffen noted that it would not be likely that any review period shorter than two years would be established.

Dr. Eig asked whether there were other examples of conditional CONs, with ongoing performance conditions and regular review cycles.

Mr. Parker replied that the two most recently established cardiac surgery programs were approved conditionally and that organ transplant programs are only able to obtain conditional CONs under the current SHP.

Dr. Eig noted that hospitals and agencies may be moving from a volume standard to more comprehensive data review. If there is to be significant enough change to CON from the waiver process, all need to take pause. Maryland certainly needs common reporting and quality requirements across programs, but the challenge of adjusting the CON process as well gives him concern.

Dr. Elder stated that the data should capture information on other incidental medical procedures that may take place during the course of PCI; these incidental procedures need to be identified and their outcomes monitored. There is a concern about self-referral with these procedures. He asked whether a hospital that proves capable of meeting the minimum cardiac surgery requirements would get a CON.

Mr. Parker replied that the Commission would look at the evidence of an applicant to meet the minimum volume requirement and would have to be satisfied that the hospital had this potential. Commission staff doesn't currently think there is a place in Maryland where development of an eleventh cardiac surgery program meeting the standard would be likely. But if the opportunity arose, a hospital would need to demonstrate capacity and resources to achieve an appropriate volume.

Dolores Sands outlined the extensive process of consultation with experts used to amend the State Health Plan Chapter (COMAR 10.24.17) in 2004 and noted that a similar process would be employed in this case. She also noted that recent information indicates that PCI volumes and cardiac surgery volumes are declining. Volume standards would be reviewed when convening a group to update the SHP. The current Table A-1 came from such a process.

Mr. Steffen asked for discussion of the data-sharing recommendation.

Dr. Moser stated there is an easy answer, i.e., no comment.

No further comments were voiced on this recommendation.

Dr. Robbins noted that, currently, there are areas in Maryland that do not have access to primary PCI: the current standard of care. Ms. Sands noted that there was a primary PCI program at a hospital without cardiac surgery on the Eastern Shore but its volumes had only been in the single digits for at least four years; the hospital closed the program before the Commission began the current process of issuing primary PCI waivers.

Dr. Walford said that considerations such as transport to a high-volume program would be part of a CON process.

Dr. Moser expressed the view that, while the CON process in Maryland would be used to identify places with need, this is not necessary. The state can identify need without a CON process. Remote areas with need should be addressed.

Ms. Sands replied that the MHCC process has been driven by guidelines. The Commission has regulated on the basis that there is a need to get patients to the best programs, and this may require reliance on patient transport. Maryland needs to look at delivery of PCI as a system. She also noted that the C-PORT E study includes an economic analysis, which is being performed by the Duke Economics and Quality of Life Coordinating Center at the Duke Clinical Research Institute.

4. <u>Discussion of Draft Report Outline</u>

Mr. Parker noted that this document was created to stimulate discussion and the group had already begun discussing the key report component, the oversight options. He noted that licensure, HSCRC regulation of hospital revenue, and practitioner performance review were identified in this report as alternative oversight approaches but, realistically, they are more logically viewed as adjuncts to CON, rather than clear and comprehensive alternatives. He envisioned a planning process in which the best distribution, from the standpoint of travel time access, of economically viable PCI programs would be identified. Filling the access gaps would rely on the emergency medical transport system or, conceivably, subsidization of non-viable PCI programs in order to achieve access goals, if HSCRC was authorized to make such subsidization work. Mr. Steffen noted that the last two bullets in this part of the outline could co-exist with current oversight.

Dr. Moser stated his total agreement with Commission goals and with MHCC as the appropriate agency to carry out oversight of PCI. In the end, the question is that of the proper mechanism, CON or some other process? The state needs to address concerns about potential denial of access to care based on factors other than quality performance, which is the concern with the CON model.

Ms. Sands asked the group to help her to conceptualize and construct the alternative regulatory framework (i.e., an alternative to CON regulation).

Dr. Elder restated that requirements need to be consistent across all hospitals. Ms. Sands noted that data reporting requirements are now consistent across all hospitals. Effective July 1, 2010, the Commission requires all Maryland acute general hospitals with a waiver from the Commission to provide primary PCI services or with a CON issued by the Commission for a cardiac surgery and PCI program to enroll in the NCDR ACTION Registry-GWTG and the NCDR CathPCI Registry.

Dr. Moser stated that an alternative would probably look like CON but without certain considerations, such as impact on another hospital, and it could be called a licensure or certification process. It could be similar to an accreditation process, and could lend itself to different types of accreditation.

Dr. Prewitt asked if this model could be extended to cardiac surgery. Dr. Moser replied that some states do that successfully but he believes cardiac surgery is different from PCI and a more conventional CON process is probably more appropriate in overseeing this service. The ACC has done a remarkable job developing clear standards for PCI and these are probably responsible, to some extent, in bringing PCI numbers down recently. He conceded that his position is not noncontroversial.

Ms. Sands suggested that Dr. Moser's alternative would be an SHP that would limit oversight of PCI to a template of standards similar to that outlined in Table A-1 of COMAR 10.24.17. He replied that, if the performance standards are well understood upfront, permission could be granted to hospitals that show they are ready to perform within the standards; so he would agree that something like Table A-1 is a useful analogy.

Ms. Webster offered her view that, whether CON or some other approach is used for oversight, there needs to be a regulatory framework of some type in place and perhaps the timeliness of review is what is up for debate. CON regulation would be recreated in some form. Dr. Moser reiterated his chief concern that economic or political considerations should not drive the oversight process. This should be limited to patient care standards.

Dr. Prewitt expressed the view that this sounded like *de facto* accreditation; if a hospital meets certain criteria, then it gets a license or certification.

Dr. Walford asked if there are examples of services in which CON regulation has subverted the standard of care. Dr. Moser responded that he did not have an example but reiterated his view that the number of programs would be regulated through rational self-interest of the hospitals, that would not be "innately self-destructive" in trying to initiate or maintain non-complying programs.

Ms. Sands asked Dr. Moser, when the term "licensure" is used, does this imply a change of oversight to another agency? Dr. Moser replied that he did not mean to imply this. The oversight should stay with MHCC.

Chairman Steffen offered an opportunity for the public to comment before closing the meeting.

Michelle Pieffer, of St. Joseph Medical Center, addressed the TAG regarding the data reporting requirements. She noted that hospitals in Maryland are required to report to the ACTION-GWTG registry, but the requirements are not uniform. Some hospitals participate in the Limited version; some participate in the Premier version. She said that Maryland may need to look at pushing hospitals to use the Premier version.

Ms. Sands responded that MHCC did allow hospitals to choose between the Limited and Premier versions of the ACTION Registry. (The Premier includes 280 fields, and the Limited includes 140 fields.) She added that some hospitals have told the Commission that requiring the use of two NCDR registries is burdensome. The Cardiac Data Advisory Committee may consider whether this requirement should be made uniform.

Mr. Steffen thanked the TAG members for their work over the four TAG meetings. He noted the aggressive time frame confronting staff to get the report turned around for consideration by the Commission in December. He also thanked staff for their participation.

5. Adjournment

Mr. Steffen adjourned the meeting at 8:10 p.m.

Appendix C:

Comments Received on the Report of the Technical Advisory Group on Oversight of PCI Services

Anne Arundel Medical Center

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December 13, 2011

Ben Steffen, Acting Executive Director
Christina Daw
Health Policy Analyst, Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Informal Written Comments on the Summary Report of Technical Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention Services

Acting Director Steffen and Commission Staff:

Anne Arundel Medical Center ("AAMC") submits these Informal Written Comments on the Summary Report of the Technical Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention (PCI) Services. AAMC currently offers both primary and non-primary PCI services to its community under waivers granted by the MHCC from the requirement in the current State Health Plan that PCI services can only be offered in hospitals with on-site open heart surgery capability. We understand that the MHCC must respond to the General Assembly in accordance with § 2–1246 of the State Government Article as required by Chapter 616, Laws of 2011, which Act requires that the MHCC develop recommendations for statutory changes needed to provide appropriate oversight of PCI services in Maryland and deliver a report and recommendations to the Governor by December 31, 2011. The TAG was created to assist in meeting the requirements of Ch. 616, and met four times and submitted a Summary Report released on December 8, 2011 on which comments were solicited. Informal comments must be submitted by 4 pm on December 13 to be considered at the MHCC meeting to be held on December 15, 2011. Due to the time constraints, AAMC reserves its right to submit additional comments at a later time.

AAMC must congratulate the members of the TAG and the MHCC Staff for their efforts in preparing the TAG report on such an important subject in a constrained time frame. AAMC in general supports the TAG Recommendations, and endorses the four "Recommendations Related to Statutory Changes" in the Report, summarized below, with one important exception:

1. MHCC statute should provide authority for oversight of PCI services which should apply at all hospitals providing PCI, with and without on-site cardiac surgery;

2. All programs providing PCI services should be required by law to undergo continuing evaluation of performance based on established and uniform standards, with renewal of authority to provide PCI Services being based on compliance with such standards;
3. MHCC should be added to the list of State agencies that can share information with respect to investigating quality or utilization review
4. The term "open heart surgery" in the statute should be changed to "cardiac surgery".

AAMC recognizes that the MHCC has experience in reviewing PCI under the waivers that have been granted, and there is considerable benefit in continuing to use that experience. The concept that PCI services should be reviewed wherever they are provided also makes sense, in light of the recent negative publicity that has surrounded PCI activities at two hospitals in the State, both of which have on-site open heart surgery programs. Uniformly applied, clinically based standards designed to enhance quality are always highly desirable, and are heartily endorsed.

However, the consensus recommendations indicate that TAG does not feel that the certificate of need (CON) process is appropriate or useful for a review of the ability of any hospital to continue to offer PCI Services. AAMC wholeheartedly agrees.

The pPCI and npPCI programs, were approved through a waiver process and have been operating successfully without ever having undergone full CON review. The waiver, and the expedited process that was finally adopted for the waiver process, allow us to provide these valuable services to our community. Some version of the waiver program, focused on quality and periodic review, is the only practical alternative to keep these valuable and indeed life saving services available to communities such as ours. While in the past we have espoused the benefits of licensure, we think the process to be followed is more important than which agency is responsible for its administration, and support consolidating the review and oversight before the MHCC.

However, if a CON process for PCI services is to be adopted; the existing providers should be grandfathered. We will, of course, welcome any clinically approved quality indicators, including those that are related to volumes, but firmly believe that programs such as ours, which have been in existence for years, should not be subjected to CON review. We strongly support the views of those TAG members who expressed the view that "the only standards applied in oversight should be quality and volume (in the context of quality)".

We also support the four recommendations of the TAG that are identified as "Can be implemented without statutory changes." With respect to the issue of peer review, however, AAMC firmly believes that the MHCC should not mandate any specific peer review practices, most especially a mandated external peer review process. Hospitals are required to conduct peer

review and quality review processes for all services provided at the hospital, and hospitals should be free to craft a peer review for PCI services that is appropriate for the hospital.

The benefits of the waivered PCI services at AAMC are many. The CON process cannot be permitted to destroy that benefit.

Respectfully submitted,

Victoria W. Bayless
President and Chief Executive Officer

cc: Delores Sands
Paul Parker
Joseph D. Moser, M.D.
Vanessa Aburn

Adventist HealthCare
1801 Research Boulevard, Rockville, MD 20850

Mr. Ben Steffen
Acting Executive Director
Mr. Paul Parker
Acting Director, Center for Hospital Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Comments on the report of the
Technical Advisory Group on Oversight of
Percutaneous Coronary Intervention Services

Dear Mr. Steffen and Mr. Parker:

Thank you for the opportunity to comment on the report and recommendations of the Technical Advisory Group (TAG) on oversight of Percutaneous Coronary Intervention (PCI) services (the TAG Report). Adventist HealthCare (AHC) has been deeply committed to providing quality cardiac services for many years, predating 1962, when Washington Adventist Hospital became the first community hospital in Maryland to perform open heart surgery. This commitment has continued to the present at Washington Adventist as well as Shady Grove Adventist Hospital, which has been an early and continuing participant in the waiver and subsequent PCI programs providing substantial data and demonstrating compliance with performance criteria pertaining to primary and nonprimary PCI services.

We wish to express our appreciation for the Commission's efforts to establish and maintain a framework for PCI services, enabling these services to be made available at qualified hospitals meeting established performance criteria. We appreciate the timely and detailed report that has been prepared for the General Assembly in response to the mandate in Chapter 616, Laws of Maryland, 2011. We wish to convey our thanks to the Commission staff, as well as to the volunteer members of the TAG for their work.

Reviewing the TAG Report's Consensus Recommendations, we offer the following comments:

1. The Commission should continue to be authorized to regulate the establishment of primary and/or nonprimary PCI programs by hospitals without cardiac surgery programs. If legislative clarification of this authority is needed, this should be enacted.

Mr. Ben Steffen
Mr. Paul Parker

Re: Comments on the report of the
Technical Advisory Group on Oversight of
Percutaneous Coronary Intervention Services

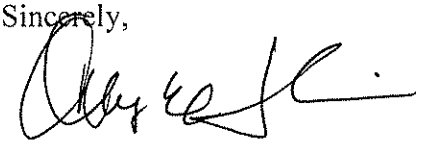
2. An application approval process managed by the Maryland Health Care Commission is important to prevent over-proliferation of programs while at the same time allowing for necessary access to health care services. Currently, there are effective, separate processes by which hospitals are able to apply for authorization to establish a primary or nonprimary PCI program. This formal, two-part approval process should be maintained. In this way, the Commission may consider a proposal to provide primary PCI in a facility without onsite cardiac surgery services. Following a period of time in which a facility provides primary PCI, and based on a demonstrated record of compliance with established standards of quality, the Commission may consider a proposal from such facility to provide nonprimary PCI.

3. Hospitals that have already demonstrated compliance with the Commission's existing standards and who have established primary and/or nonprimary PCI programs in facilities with or without cardiac surgery programs should be "grandfathered" into any new approval process, rather than undergo an additional lengthy and expensive regulatory process. These programs have already demonstrated effective, quality services and compliance with applicable standards, often not only through an initial approval but also through a successful renewal of the Commission's approval.

4. The Commission can and does have an effective oversight role. We support the Commission's continued collection of relevant data from all providers of PCI services to evaluate adherence to standards associated with quality care and patient safety. This should serve as the basis for ongoing monitoring of the services. Where there is noncompliance, the Commission should have the ability to act proactively, while also adhering to a process that should be established for noncompliance that is subject to notice and an opportunity to cure deficiencies not requiring more immediate intervention. The Commission's data should be shared with the Office of Health Care Quality as the existing oversight agency for all hospital services.

Thank you for the opportunity to comment on these important matters.

Sincerely,



Amy F. Carrier
Associate Vice President, Clinical Service Lines
Adventist HealthCare

CARROLL HOSPITAL CENTER

John M. Sernulka
President and CEO

December 13, 2011

Christina Daw
Health Policy Analyst, Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215

sent by fax: 12-13-11 3:00 pm to 410-358-1311

Re: Summary Report of Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services

Dear Ms. Daw:

Thank you for the opportunity to provide comments on the Summary Report of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services ("TAG Report").

Carroll Hospital Center ("CHC") is the only acute care hospital in Carroll County. We have provided primary percutaneous coronary intervention ("PCI") services since October 2008 pursuant to a waiver granted by the Commission. Having PCI services available within Carroll County is of vital importance to Carroll County residents. Accordingly, in moving to any new regulatory scheme, the Commission should ensure that there will be no disruption of existing PCI programs. The people of this community depend on this important service being continuously available within the County.

CHC supports the consensus recommendations of the TAG, supports quality-based, continuing regulatory protection of existing and new PCI programs in all settings in which those services are provided. However, for the reasons expressed in the TAG Report, we agree that this oversight should not take the form of a CON requirement. The focus should be to ensure that PCI programs meet evidence-based quality of care and patient safety standards. The CON process is ill-suited to serve that purpose. It is particularly inappropriate to require a CON for primary PCI, which has become widely accepted as the standard of care for treating acute ST segment elevation myocardial infarctions without cardiac surgery backup. Nor is a CON process appropriate for establishing a new non-primary program which should also be reviewed based on quality of care standards, not need and the other CON review criteria that are unrelated to quality of care.

If, notwithstanding the objections to a CON requirement expressed in the TAG Report, the Commission was to recommend a CON process or any other process in which PCI programs are judged on criteria other than evidence-based quality of care and patient safety standards alone, existing programs should be grandfathered from being required to obtain a CON. CHC has

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consistently met the MHCC's quality-based criteria for primary PCI programs and over 270 patients have received this cardiac muscle sustaining intervention within the timeframes required for best outcomes. We would willingly continue participation in a non-con oversight system to ensure that those exceptional qualities of care standards are maintained.

However, subjecting CHC's existing primary PCI program (which is deemed to be part of the Baltimore Metropolitan planning region in the State Health Plan) to a competitive, need-based review process is unfair and threatens the continuation of a high quality, life-saving emergency service that Carroll County residents have a right to expect to continue to be available in their community.

CHC also supports the other consensus recommendations of the TAG, including adding MHCC to the agencies eligible for information sharing related to quality or utilization of care in regulated facilities and changing the term "open heart surgery" to "cardiac surgery."

Thank you for your consideration of these comments.

Very truly yours,

John M. Sernulka
President and CEO

FREDERICK MEMORIAL HEALTHCARE SYSTEM

400 West Seventh Street Frederick, Maryland 21701-4593 240-566-3300

December 13, 2011

Sent by email to cdaw@mhcc.state.md.us

Ben Steffen, Acting Executive Director
Christina Daw
Health Policy Analyst, Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Informal Written Comments on the Summary Report of Technical Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention Services

Director Steffen and Commission Staff:

Frederick Memorial Hospital (the "FMH") submits its informal written comments on the Summary Report of the Technical Advisory Group (TAG) on oversight of Percutaneous Coronary Intervention (PCI) Services. We understand that the MHCC must respond to the General Assembly as required by Chapter 616, Laws of 2011, which requires that the MHCC develop recommendations for statutory changes needed to provide appropriate oversight of PCI services in Maryland and deliver a report and recommendations to the Governor by December 31, 2011. The Summary Report was released on December 8, 2011, and informal comments must be submitted by 4 pm on December 13 to be considered at the MHCC meeting to be held on December 15, 2011. FMH reserves its right to submit additional comments at a later time.

FMH would like the Commission to understand our position on the importance of continuing to provide interventional cardiology services (both emergency and elective procedures) to our growing community. As the sole healthcare system within Frederick County our primary PCI (pPCI) program has been providing emergency angioplasty since March 2008. Our pPCI patient volumes have averaged between 110 and 125 patients annually. In July 2009, FMH started participation and patient enrollment in the C Port E Research Study providing non-primary PCI (npPCI) and FMH has performed over 200 total PCI procedures each year since it added npPCI services. The PCI program allows us to provide many benefits to our community in the battle against the number 1 cause of mortality in the county, the state and the nation. FMH applauds the TAG recommendation that the MHCC should monitor and apply quality based standards that permit effective community based angioplasty programs to continue.

FMH congratulates the members of the TAG and the MHCC Staff for their efforts in preparing the TAG report on such an important subject in a constrained time frame.

FMH supports the TAG Recommendations, and with one important caveat endorses the four "Recommendations Related to Statutory Changes" in the Report, summarized below:

1. MHCC statute should provide authority for oversight of PCI services which should apply at all hospitals providing PCI, with and without on-site cardiac surgery;
2. All programs providing PCI services should be required by law to undergo continuing evaluation of performance based on established and uniform standards, with renewal of authority to provide PCI Services being based on compliance with such standards;
3. MHCC should be added to the list of State agencies that can share information with respect to investigating quality or utilization review;
4. The term "open heart surgery" in the statute should be changed to "cardiac surgery".

FMH recognizes that the MHCC's experience in reviewing PCI under the waivers makes it the logical choice to oversee PCI services going forward. FMH supports the concept that PCI services should be reviewed wherever they are provided. Uniformly applied, clinically based standards designed to enhance quality are highly desirable, and are endorsed by FMH.

However, FMH does not agree that the certificate of need (CON) process as it currently exists is either appropriate or useful for a review of the ongoing ability of any hospital to offer PCI Services. The TAG Report indicates that many members of the TAG expressed concern with the use of traditional CON as the vehicle for oversight of PCI services, and we agree with those reservations.

The CON process is elaborate, cumbersome, expensive, litigious and slow. In Western Maryland it tends to permit only one hospital in a large area to provide open heart services. It contains many provisions that are only appropriate in the consideration of major construction projects but are irrelevant in the consideration of the continuation of an existing program. This is particularly the case when considering continuing the pPCI and npPCI programs at FMH, which were approved through a waiver process and have been operating successfully without ever having undergone full CON review. Indeed, the programs could never have been approved under a full CON review, since FMH would have been precluded from even filing a CON application for open heart surgery in Western Maryland due to a lack of "need" under that process. The waiver, and the process that was finally adopted for the waiver process, allows FMH to provide these valuable services to its community. Applying the CON process would require revising the State Health Plan for cardiac surgery programs, which has proven throughout the history of the MHCC and its predecessors to be a slow and contentious proceeding. The simple truth is that there is no time to rewrite the SHP and the CON process before the current waiver extensions expire. Some version of the waiver program, focused on quality, is the only practical alternative.

If a CON process for PCI services is to be adopted, the existing providers should be grandfathered. FMH welcomes any clinically approved quality indicators, including those that are related to volumes, but firmly believe that programs which have been in existence for years should not be subjected to CON review. We strongly support the views of those TAG members who expressed the view that "the only standards applied in oversight should be quality and volume (in the context of quality)".

FMH supports the four recommendations of the TAG that are identified as "Can be implemented without statutory changes". With respect to the issue of peer review, however, FMH does not believe that the MHCC should mandate any specific peer review practices. Hospitals are required to conduct peer review and quality review processes for all services provided at the hospital, and hospitals should be free to craft a peer review for PCI services that is appropriate under the circumstances of the program.

Yours truly,

Thomas A Kleinhanzl
President and CEO
Frederick Memorial Hospital

cc: Delores Sands
Paul Parker

HOLY CROSS HOSPITAL

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Via E-Mail and U.S. Mail

December 13, 2011

Mr. Ben Steffen
Acting Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Steffen:

Holy Cross Hospital supports the Summary Report of the Technical Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention (PCI) Services. We appreciate the opportunity to provide comment on it to the Maryland Health Care Commission (MHCC).

We believe MHCC oversight of PCI services is appropriate to ensure programs are well developed and that quality measures are met. However, we understand that MHCC staff is recommending that the CON program be the vehicle for regulatory oversight. We do not believe the CON program, in its current form, would be an effective vehicle for oversight, since it is fundamentally focused on resource allocation and does not have effective mechanisms for ongoing quality and performance monitoring. The CON program would have to be significantly restructured to meet the TAG's oversight recommendations.

Thank you again for the opportunity to comment on this important initiative.

Sincerely,

Kevin J. Sexton
President & CEO

Anne Langley
Director
Health Policy Planning

Health Care Transformation
and Strategic Planning
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JOHNS HOPKINS
MEDICINE

December 13, 2011

Ben Steffen
Acting Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

RE: Comments on the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services Summary Report

Dear Mr. Steffen:

On behalf of the Johns Hopkins Health System ("JHHS") and its four Maryland member hospitals, I offer the following comments regarding the Summary Report and Recommendations of the Technical Advisory Group ("TAG") on Oversight of Percutaneous Coronary Intervention ("PCI") Services.

We support the consensus recommendations of the TAG. These recommendations, four that will require statutory changes to implement and four that will not, represent in our view a path to thoughtful resolution of some of the inconsistencies and unclear aspects of the existing patchwork of regulations governing PCI in Maryland. While these recommendations are not perfect, they are a positive next step in the evolution of PCI regulation in Maryland, and we hope the legislature and the Maryland Health Care Commission ("MHCC") will move forward with implementation.

We are strongly opposed to a certificate of need ("CON") requirement for the establishment or continuation of PCI services. A "need" requirement is problematic in the context of a health care service that is life-saving when it is immediately available, and for which well-established quality and appropriateness measures exist. The question is not whether a need exists for a program at a given hospital; it is simply whether or not the hospital is able to offer the service through a program that meets all established quality and safety standards. Rigorous oversight of the quality of PCI services can and should be achieved—in fact, has been achieved to date—without the imposition of a CON structure.

Finally, we urge the MHCC and the legislature to incorporate timely updates to the standards of care and clinical competency guidelines that are incorporated into the state's PCI regulatory structure, and to strive to integrate criteria such as clinical

outcomes, appropriateness, board certification, peer review, and lifetime experience in lieu of single, discrete, arbitrary criteria. A volume requirement, for instance, can be a valid surrogate for some degree of quality, but it is weak and there is very little data to support a specific number for operator or institutional volume. Truly high quality care can best be achieved through a more complex, nuanced set of criteria.

Thank you for the opportunity to offer these comments. We would like to express our enthusiastic interest in participating in the process of updating the Cardiac Surgery and PCI Services Chapter of the State Health Plan, COMAR 10.24.17, when that opportunity arises in the coming year. Please feel free to contact me if you have any questions or need additional information, by email at alangle2@jhmi.edu or at 443-997-0727.

Sincerely,

Anne Langley

cc: Patricia M.C. Brown, Esq.

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Warren A. Green
President and
Chief Executive Officer

December 13, 2011

SENT BY EMAIL TO cdaw@mhcc.state.md.us

Christina Daw
Health Policy Analyst, Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Ms. Daw:

I am writing on behalf of LifeBridge Health, Inc., the parent of, among other entities, Sinai Hospital of Baltimore and Northwest Hospital. These comments are being submitted during the informal public comment period in response to the Summary Report and Recommendations of the Technical Advisory Group on Oversight of PCI Services ("Report"). I am commenting specifically on the first and second recommendations described on page 5 of the Report.

We recognize that the Commission desires to ensure that Marylanders have access to the safest, most effective, highest quality specialized health care services, and we commend Commission staff for seeking creative solutions for continued oversight of percutaneous coronary intervention (PCI) services.

We agree that, given the Commission's long history of overseeing PCI and open heart services, the MHCC should be the agency responsible for ongoing oversight of PCI programs. We also agree that the standards for a hospital's eligibility to operate a PCI program, and the process for assessing whether a hospital meets those standards, should be clearly set forth in regulations or other official guidance developed and promulgated in accordance with the Commission's statutory authority. We agree as well that hospitals which operate non-primary PCI programs should be required to demonstrate compliance with the specified standards in order to remain eligible to operate such a program.

We understand that there is some disagreement about the appropriate vehicle for the Commission to exercise this authority. We concur with the Staff that the means through which the Commission has historically exercised its regulatory authority – the certificate of need (CON) – is appropriate for this purpose. The CON process is well understood by hospitals across the State and can readily be adapted for this new function. While a waiver program may be an appropriate alternative for a examining a new means of providing a certain service (as was the case with PCI), it is not an adequate or appropriate method of ensuring quality, access, and

efficiency on a permanent basis. We see no need to develop an entirely new regulatory apparatus for PCI services, and agree that the Commission should ask the legislature to provide it with the authority to adapt the CON process as appropriate for the Commission's oversight of these services.

The Report was not clear about which hospitals would be required to seek Commission approval for continued operation of a PCI program. While this may have been implicit in the Staff's recommendations, it should be clear that, whatever regulatory vehicle is chosen for determining initial eligibility to operate a PCI program, hospitals which operate a PCI program in conjunction with an approved cardiac surgery program should not be required to re-apply for the right to perform PCI. It would plainly be irrational for a hospital to be authorized to perform open heart surgery but denied the right to perform PCI. While we have no objection to requiring all hospitals with PCI programs – including those with open heart surgery programs – to meet universally appropriate quality measures, it would be a waste of resources to require such hospitals to go through a new initial approval process.

Thank you for the opportunity to comment, and please contact me at 410-601-5134 if you have any questions.

Sincerely,

Warren A. Green

Warren A. Green

Maryland
CHAPTER

SCAI

December 13, 2011

Ben Steffen
Acting Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Director Steffen:

On behalf of the Maryland Chapter of the American College of Cardiology (MD-ACC) and the Society for Cardiovascular Angiography and Interventions (SCAI), we respectfully submit our comments in response to the MHCC's report of the Technical Advisory Group's (TAG) recommendations on Percutaneous Coronary Interventions. We appreciate the opportunity to contribute our clinical and professional expertise as Maryland works to become a national model for patient safety and quality cardiovascular care.

We gladly participated in the process to address critical issues that need resolution now, not at an undetermined time. Further, we participated with the expectation that patients would receive statutory and regulatory protections to ensure their safety by addressing the actions and protocols of hospitals, cardiologists and cardiac care personnel so that stent overuse could never happen again.

We believe the recommendations on peer review fail to provide statutory and regulatory protections as mandated by the Maryland General Assembly. Upon reviewing HB 1182 referenced as the basis of the Commission's authority to proceed, we note that the Commission did not reference the joint letter from the Chairman of the Senate Finance Committee, Senator Mac Middleton and Health Subcommittee Chair, Senator Rob Garagiola as part of the record in its review. We believe that document should be included as part of the legislative intent of HB 1182 and in the documentary record here.

The joint letter specifically asked the Commission to "develop recommendations for statutory changes needed to provide appropriate oversight of PCI services" and submit them to the General Assembly. The recommendations should address "the form and scope of peer review that should be required for PCI services, including whether innovative options for independent, external peer review of PCI services might provide for higher quality, more cost effective services." (Emphasis added).

Additionally, the draft recommendation to expand MHCC "oversight" to CABG facilities is excessively vague. It is unclear what authority this would give the MHCC. For example, would MHCC have de facto "certificate of need" authority? Would MHCC have the ability to revoke PCI hospital certification? Would MHCC extend its current mandate for minimum PCI volumes to all physicians and hospitals? Recommend sanctions against cardiovascular providers? Furthermore, the report is silent on granting the General Assembly specific statutory direction on how MHCC will exercise its authority to request external peer review --- whether by an independent

body, or a consortium of facilities to ultimately provide the minimal standards for patient safety and confidence in the most cost-effective means.

The first recommendation is vague as to whether the General Assembly would delegate its authority of "oversight of PCI service." We are unsure whether oversight includes the ability to levy fines, determine the safety of equipment or the ability of an interventionalist to perform a PCI procedure. For example, does oversight of "PCI services" include the procedure itself or does it include administrative components that lead up to the procedure? Is peer review a "service" as contemplated?

MD-ACC and SCAI strongly support legislation to establish a Task Force that will complete a comprehensive assessment of peer review for PCI procedures. The TAG did not resolve any "tension" in the issue. HB 1182 has not provided the solution and HB 286 does not go far enough. We believe this report should include this statutory recommendation. (Emphasis added)

We are concerned with the second recommendation. It states: "Maryland law should require that all hospitals that provide PCI services, including those hospitals where cardiac surgery is available on-site, undergo continuing evaluation of performance based on established performance standards." While the professions has guidelines, appropriate use criteria, clinical competency statements and other related documents and resources to guide our members, the draft does not specify what will be used as criteria.

The third recommendation states, "MHCC should be added to the State agencies listed in legislation regarding the sharing of information for the purpose of investigating quality or utilization of care in regulated facilities." While we certainly want an efficient flow of valid information among the various state agencies, there needs to be clarification as to what types of information will be used.

A fourth recommendation states, the term "open heart surgery," as used in the CON statute, should be changed to "cardiac surgery." The state has extended its authority over surgical procedures to review percutaneous coronary revascularizations (PCIs); however, PCI is not surgery. Additionally, there are numerous other surgical and percutaneous procedures being performed on the heart, and the agency has not expanded oversight to those procedures.

We are also surprised by the "Recommendations that Can Be Implemented Without Statutory Changes". There is an existing panel, the Cardiac Data Advisory Group, that is charged with reviewing these issues. (see: http://mhcc.maryland.gov/cardiac_advisory/index.html)

These draft regulatory recommendations also state that "To account for patient acuity, risk adjustment should be applied to provider-level outcomes data reported publicly." This matter is under the jurisdiction of the Cardiac Data Advisory Committee and is not consistent with any discussions of this panel. All discussions were about the release of facility based data – not individual and much more than mere risk adjustment should be done before releasing physician based performance data. As the presentations to the panel elaborated upon, the data presented to the public must clearly indicate whether results show a statistically significant difference and negative outcomes need to be adjudicated to ensure that the outcome was related to provider performance.

While we appreciate the draft recommendations to the profession's appropriate use criteria and look forward to working with policymakers to incorporate the AUC to the benefit of patients, we urge caution since MHCC plans to use the AUC are unclear. Many patients do not fit neatly into the various categories that are outlined in the AUC. Just because a patient doesn't meet the AUC definition for necessity, it is not sufficient to consider PCI on that patient as unnecessary. All such situations require an individual review of the patient involved.

Recommendations for Transparent Peer Review and the Use of Data Registries

1. The root cause for the failure of PCI services at two Maryland hospitals was inadequate, voluntary, internal review and a culture of acquiescence to medical hierarchy with conflict avoidance. In essence, the failure of MHCC TAG to recommend a degree of standardize oversight ignores the root cause of St Joe's failure. MHCC's position is that clinical leadership at each hospital can assure compliance with quality and safety standards. The failure at St Joe's was that of clinical leadership and a culture of conflict avoidance and deference to the medical hierarchy.

2. We acknowledge that hospital peer review activity has been significantly strengthened since these events became publically reported through sharing of best practices by MHA's Necessary Care Work Group and the leadership of cardiologists at each institution.

3. We applaud the collaboration for voluntary external peer review by the University of Maryland and Johns Hopkins Hospital. This model has the potential to serve many hospitals in Maryland. But in reality, external PR is optional and there is no guarantee to prevent internal PR from sliding back to another St Joe's.

4. MHCC has demonstrated national leadership in the mandatory use of ACCF-NCDR Registry for Cath/PCI and Action/GWTG and hospitals have the same NCDR data. Hospitals will use this to drive internal review of aggregate performance, enhance accuracy of data entry, and develop action steps for performance improvement. Most of this is achieved through selected case review.

5. Mere reporting of NCDR data is meaningless without critical analysis of the data that leads to performance improvement.

6. The foundation for strengthened internal and external peer review is a robust system of oversight and accountability. To distinguish from formal peer review, we would organize this administratively under a "Cath Lab PI Committee". Minutes should be kept and practitioner names de-identified. A quarterly report of quality and safety would be made to share with senior leadership – and such a report could be sent to MHCC for oversight. Since all of this work is a natural part of internal review, there is no additional burden for the hospital to send such a quarterly report to MHCC. Here's where MHCC adds value if it adopts the above suggestion. They see "outlier" data on the NCDR report for hospital A. They inquire, "What assessment have you made of this data and what action steps were taken?" All of this would appear in the minutes of the Cath Lab PI Committee. Both hospital A and MHCC will find out in future reports if the action steps produce NCDR improvement. If the PI committee is sloppy or barely existent, then MHCC would have the authority to visit and require compliance.

7. Voluntary oversight will be highly effective for those institutions with a true commitment to quality healthcare.

8. Voluntary oversight provides no guarantee that all citizens in Maryland are afforded equal, high quality healthcare as evidenced in comment #1 above. Over time, the risk is that the foundation of peer review weakens. Good hospitals have nothing to hide or fear (bad ones do) and we fail to see added cost in the scenario above. "Marginal" providers will get feedback and have the opportunity to improve. Additionally, it would appear that budgetary decisions are being made that may outweigh patient safety. We are acutely aware of budgetary restraints. However, it also appears that MHCC is trying to avoid increasing cost because they do not have staff to dedicate to a new section of PCI Oversight. We request transparency in the "tension" between money and budgetary decisions and quality and patient safety.

9. With NCDR data, the MHCC can identify outlier performance. The collaborative approach for MHCC, hospitals, and physicians is for MHCC to initially inquire into, not investigate, areas of concern. Reports from cath lab performance improvement committees, appropriately de-identified as to patient and practitioner, will indicate that the hospital identifies and implements action steps for improvement.

10. MHCC can identify hospitals having sub-optimal performance with inadequate internal peer review. MHCC oversight will help these hospitals improve.

11. We agree that external accreditation of cath labs should not be mandatory.

12. We advocate for external peer review. There are many options including #3 above. We believe that restoring public confidence in PCI services is significantly strengthened by unbiased, independent external review and we stand by our request for legislation that will establish a balanced Task Force on the Peer Review issue.

In the best interest of our patients, we conclude that the failure of the TAG to fulfill its mandate to the General Assembly to provide specific statutory recommendations on peer review and to address the specific requests of the joint letter from the Senate Finance Committee as to external peer review is an inadvertent result of the unbalanced membership of the TAG committee with only two seats provided to the physician groups involved. The reality is that the hospital representation is significantly greater than that of the Cardiologists recommending external peer review. The General Assembly should be fully aware why the MHCC would find in regards to external peer review "a notable tension between the role that should or could be played by public agencies actively, systematically, and periodically monitoring and enforcing peer review processes, and the appropriate sphere in which clinical leadership would be relied on to take responsibility for assuring performance and quality."

We again note the failure to include a reference to patient safety and confidence. That omission will result in a potential patients' indecision or even aversion to seek professional cardiac advice and to heed the advice given. It will ultimately serve to increase health care costs as patients avoid necessary care that can alleviate their symptoms and improve their quality of life.

Sincerely,

Samuel D. Goldberg, MD, FACC
President

Christopher J. White, M.D., FSCAI
President

Maryland
CHAPTER

SCAI

December 19, 2011

Mr. Ben Steffen
Acting Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Director Steffen:

On behalf of the Maryland Chapter of the American College of Cardiology (MDACC) and the Society for Cardiovascular Angiography and Interventions (SCAI), we incorporate our comments made in our timely filed December 13, 2011 letter, and submit this clarifying and supplementary addendum to our concerns expressed at the December 15, 2011 Board meeting.

We appreciate the MHCC's recognition that peer review deserves further attention and discussion. But without a specific statutory recommendation on peer review, this merely becomes acquiescence to support the status quo of voluntary review. It is not the way Maryland should respond to the patients who need assurance that the best practices are being followed in determining when to perform a stent procedure.

It has been over two years since the issues surrounding Drs. Midei and McClain have become public knowledge. Our professional societies' recommendations have been on the table for quite some time and were further defined in detail during the TAG meetings. How long do Maryland's patients afflicted with coronary artery disease need to wait to be assured that their best interests are being given proper oversight?

PCI procedures are performed to salvage jeopardized heart muscle in the throes of heart attack or unstable angina or to relieve symptoms effecting quality of life. If Inspectors General and State Auditors – who are external review officers of the State – can review how a school purchases pencils or how the Department of General Services purchases toilet paper to make sure the procurement officer doesn't have a conflict with the firms providing the goods, why can't the State authorize a process that is applied to ensure that patient safety and quality of care are just as valuable?

The professional societies have clearly and unequivocally recommended that peer review incorporating specific elements be required by appropriate regulation or legislation. To accept a voluntary program that might be followed by some facilities and less so by others is abrogation of our responsibilities as professionals and, in our opinion, MHCC's as the state agency responsible for oversight of these procedures.

We ask who is being protected? The doctors? The hospitals? Certainly, not the patients who need the most assurance. Physicians, especially those who care about quality care, should welcome this, and not just on a "trust me, we can do this voluntarily" basis. What precipitated the stent dilemma in Maryland was precisely a voluntary, internal review process.

In defense of the patients, we must insist that to lob back over the net to the Legislature that "tension" exists between "public agencies" to monitor and enforce the peer review process versus "clinical leadership" is to lose the point. If the "tension" cannot be resolved here, the proper response should be to "develop recommendations for statutory changes" that will resolve this peer review "tension," not recite the problem. To do any less is to assure that we will be back here in 5 or 10 years wondering why we didn't solve the problem.

It is for this reason and others, we must absolutely insist, that the MHCC fulfill its duty and the spirit of the enabling legislation and request that legislation be introduced that will establish a Task Force, balanced by membership to authorize the establishment of agreed upon elements of peer review for stent procedures.

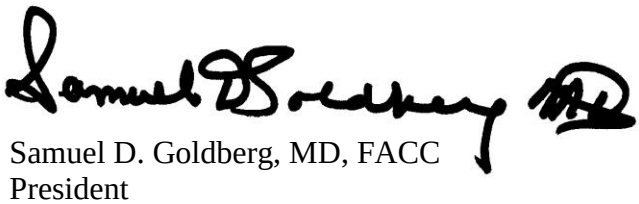
Respectfully, if this specific recommendation is not made by MHCC in its wisdom to the Legislature, we must request that it be included in a separate section indicating it is a "Minority Report" on behalf of the Maryland Chapter of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions.

Since the Midei issue occurred in large part due to an inadequate internal peer review process at the hospital level, all Maryland hospitals should be required to report in writing that they are doing the required internal case review and document their individual plan for accomplishing required external review. This should be in the form of a document submitted periodically to the MHCC. The appropriate percentage of cases reviewed externally and the timing of the reports should be determined by the Task Force or appropriate patient care committee allowing minor variations from hospital to hospital. If a significant variation or issue arises in the future, MHCC can then ascertain whether the hospital was carrying out its respective peer review process. With the ongoing review of data received from the NCDR Registries and the proper functioning of the Data Advisory Committee, this should close the loop of providing quality and safety for Maryland patients.

The Maryland Hospital Association's Necessary Care Committee has the same recommendations however, compliance is voluntary and does not have force of law requiring each facility to carry this out. We feel this is essential and will assure that Maryland patients are receiving safe and quality care across the State.

We look forward to participating in the development of a paradigm here in Maryland that can be a national model for patient safety and quality cardiovascular care.

Sincerely,



Samuel D. Goldberg, MD, FACC
President
Maryland Chapter, American College of Cardiology

Christopher J. White, MD, FSCAI
President
Society for Cardiovascular Angiography and Interventions

MedStar Health

December 13, 2011

Ben Steffen
Acting, Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: Summary Report of Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services

Dear Mr. Steffen:

On behalf of MedStar Health, this letter is written to provide our comments on the Summary Report of Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services. Due to the very short time period to provide comment, please consider these comments preliminary in nature.

The Maryland Health Care Commission is to be commended for the time and attention devoted to how to ensure appropriate oversight and quality of care for the delivery of non-primary PCI in hospitals without on-site cardiac surgery capability. The Commission's evidence-based approach has consistently been based on solid data and clinical guidelines and research.

We strongly support the continued focus on quality of care oversight for PCI services, including ongoing monitoring and evaluation. However, at this juncture it is unclear what regulatory oversight mechanism is actually being recommended. The Technical Advisory Committee consensus recommendation contained in the report states *"The Commission's statute should provide explicit and direct authority to the MHCC for oversight of PCI services"*. The presentation document provided at the MHA Legislative Council meeting last Friday states the consensus position as: *"PCI should be added to the section of the MHCC's statute that identifies the establishment of an open heart surgery service as requiring a CON"*. And, during the presentation and discussion at the MHA Council on Legislative and Regulatory Affairs MHCC staff indicated that *while they were recommending subjecting non-primary PCI to the CON rules, the rules would be different from the Commission's traditional CON requirements.*

There are no details provided in the report describing this new type of CON approach or the criteria or standards that would be utilized under the approach. Key questions include: Would "need" have to be demonstrated before a new entrant is allowed to offer the service? What quality standards would be required? Would programs that fail to meet quality standards lose

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their CON? Would programs currently providing non-primary PCI services under the research waiver be required to apply for a CON? Would health care facilities with a CON to provide cardiac surgery have to obtain a CON to provide non-primary PCI services?

We believe it is critical to have further clarification and detail regarding the regulatory mechanism being proposed in order to develop an informed position on this issue. This will also be particularly important as this issue moves into the legislative arena in the 2012 session.

Thank you for the opportunity to comment. If you need additional information or would like to further discus, please do not hesitate to contact me.

Sincerely,

Pegeen A. Townsend

Pegeen A. Townsend
Vice President
Government Affairs

December 13, 2011

Meritus Health

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Christina Daw
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
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RE: Summary Report and Recommendations of the Technical Advisory Group (TAG) on Oversight of PCI Services

Dear Ms. Daw:

I am writing to provide comment on the above referenced report. I was pleased with the recommendations of the TAG and wish to comment on the issue of Certificate of Need (CON) for future programs. CON is not the appropriate oversight structure for the future. In this era of increased focus on outcomes and accountability, oversight should focus on accountability for clinical outcomes and volume standards.

If the Commission chooses to recommend some form of certificate of need, the existing waiver programs, who otherwise demonstrates quality outcomes and proficiency, should be "grandfathered" in as part of the transition.

As we prepare for the impact of health reform, using the traditional CON model as the vehicle for oversight may have unintended consequences.

Programs may develop on a basis other than the ability to achieve quality and patient safety. The CON regulation process is extensive and expensive. It is a program more about the political influence of competitors than quality or safety. CON does not focus on quality nor does it focus on outcomes. We need to take advantage of the data systems being developed in the hospital and develop new models of clinical oversight.

The non-primary PCI hospital should be permitted to convert to ongoing authority to operate, provided they have met the quality and patient safety standards. These institutions have invested millions of dollars in equipment and skilled teams to bring this service to their communities. Collectively these programs have advanced cardiac services and have proven the ability to safely take care of this patient population. The standard for continuing this service should be quality, proficiency and safety. To risk denying access to these needed services by forcing them through an expensive CON review will only add cost to the delivery system.

I encourage the commission and staff to grandfather the existing non-primary PCI programs.

Thank you for opportunity to comment.

Sincerely,
Joseph P. Ross
President/CEO

Maryland
Hospital Association

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December 13, 2011

Ben Steffen
Acting Executive Director
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Dear Mr. Steffen:

On behalf of the 66 member organizations of the Maryland Hospital Association (MHA), this letter is our preliminary response to the request for comments on the Summary Report of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention (PCI) Services. We consider these comments preliminary because we received the report late last Thursday, December 8, and the deadline for comments is today at 4:00 p.m. Therefore, a more thorough response is not yet possible.

MHA commends the Maryland Health Care Commission for the time and attention devoted to this issue and, in particular, for the presentation of the report you and Paul Parker provided to MHA's Council on Legislative and Regulatory Policy at its December 9 meeting. As you heard at that meeting, there are several areas of consensus on how to move forward with oversight of PCI services, but there also are concerns.

We agree that there should be state oversight of PCI services, and that the Commission is the appropriate state agency to perform that oversight. We also support a process of ongoing monitoring and evaluation of PCI services by the Commission across all hospitals, using established standards, and adding the Commission to the list of state agencies allowed to share data.

Our primary concern is with the staff recommendation--not clearly stated in the report, but documented in the November Technical Advisory Group minutes and verbally stated at our December 9 Council meeting--to require Certificate of Need (CON) for the establishment of PCI services. The existing CON process is not appropriate. An alternative mechanism could and should be established within the Commission (similar to certification or a state regulatory designation), with specific criteria adopted in advance. Approval of PCI services would be granted based on an organization's ability to meet those standards, as well as its continued adherence to those standards over the life of the program.

The focus of PCI oversight should be on quality. Under a CON process, services could be denied for political, economic or competitive reasons, none of which serve the best interests of patients in the community. These views were clearly expressed by several members of the

- more -

Technical Advisory Group during its November meeting, and are more accurately reflected in the minutes of that meeting than in the Summary Report. The report also leaves unanswered important questions about the impact of a CON requirement on existing programs, and the potential gap in services that could result after moving from the current process to a costly, time consuming CON process.

Nothing prevents the Commission from adopting new mechanisms or regulatory models that may be required as the state moves forward with health care reform. While staff points out that the development of an alternative mechanism to CON may require statutory change that could be challenging to enact, PCI oversight should be based on developing the most appropriate and effective tool to ensure the best outcomes for patients.

We appreciate the opportunity to have participated in the Technical Advisory Group, and we welcome the opportunity to collaborate with the Commission to identify a more appropriate regulatory mechanism for PCI oversight.

Sincerely,

Denise Matricciani
Vice President, Government Relations

Beverly Miller
Senior Vice President, Quality Advocacy

UNIVERSITY of MARYLAND MEDICAL SYSTEM

December 13, 2011

Ms. Christina Daw
Health Policy Analyst, Specialized Services
Maryland Health Care Commission
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Reference: Comments regarding Summary Report of Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services.

Dear Ms. Daw:

The University of Maryland Medical System (UMMS) appreciates the opportunity to provide comments regarding the Summary Report of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services. UMMS represents the collective views of our regional health system comprised of our academic medical center and community hospitals located across the State. Our hospitals include the University of Maryland Medical Center, University Specialty Hospital, Kernan Hospital, Maryland General Hospital, Baltimore Washington Medical Center, Shore Health System (Memorial Hospital At Easton & Dorchester General Hospital), Upper Chesapeake Health System (Harford Memorial & Upper Chesapeake Medical Center), Chester River Hospital Center, and Civista Medical Center.

We would like to make the following comments for your consideration related to the Summary Report:

1. Certificate of Need Requirement For Percutaneous Coronary Intervention ("PCI") Services.

We believe that the situation presents the MHCC with an opportunity to develop a process for review and approval of new entrants in the market desiring to deliver PCI services as well as the monitoring of existing providers' compliance in meeting required performance standards based on quality and clinical outcomes, without requiring the issuance of a Certificate of Need. We believe the MHCC should develop a process for hospitals to secure a waiver, or exemption, from CON that is less consuming of time and resources to prepare, review and approve, while remaining committed to assuring the residents of this State that PCI care is provided in a safe, accessible, and cost effective manner. Our suggestions for this process are described below.

Regarding current hospital PCI programs, there are currently thirteen Primary PCI ("pPCI") or, "emergency PCI" waiver hospitals, of which eight participate in the Non-Primary ("npPCI") or "elective" PCI waiver program. These hospitals are currently providing a clinical service that is now deemed a standard of care for patients presenting with a progressing ST-elevated myocardial infarction. These thirteen hospitals with current pPCI programs are evaluated for ongoing compliance with mandatory performance requirements based on the waiver program. If each of these hospitals is meeting the volume and quality standards currently in place, these existing providers should not have to go through a new Certificate of Need process to be able to continue clinical operations of an existing PCI service. They should be grandfathered into any changes to the regulatory approval process, while

continuing to be monitored and reviewed every two-three years for compliance of current or future volume and quality metrics. Also, there should be a process in place to allow those five hospitals currently performing pPCI but not npPCI, to be able to expand their services to npPCI without going through a Certificate of Need process, if they are able to demonstrate minimum standard volumes to expand into npPCI. A waiver or exemption process should be developed for these five hospitals. Being able to provide npPCI services assists in making pPCI programs operate more effectively and efficiently. Therefore we believe it would be unnecessary and inefficient for the MHCC to require current waiver hospitals to apply for continuation of their PCI service through a CON application and approval process.

For hospitals wishing to develop new PCI programs, we believe that MHCC should develop an alternative approval process similar to a waiver program or formal request for exemption from CON. We recommend that this be a two-phased program whereby hospitals seeking establishment of a new service would first apply and be approved to provide "emergent" pPCI based on demonstrating need, volume potential, and their ability to support necessary and appropriate physician resources as "phase one." New pPCI providers would then be required to establish volumes and demonstrate compliance with quality metrics for a 2-3 year period before being able to request approval to perform npPCI procedures as "phase two".

Overall, we believe this approach would allow for a more controlled entry of new PCI programs while not penalizing those hospitals that have already invested resources and participated in the C-PORT studies and waiver programs.

2. Standard Evaluation For All PCI Programs.

We agree with the recommended policy that all PCI programs, including those with on-site cardiac surgery services, would undergo continuing evaluation based on a standard set of performance / quality metrics. We believe that Maryland law should require that all hospitals that provide PCI services, including those hospitals where cardiac surgery is available on-site, undergo continuing evaluation of performance based on established performance standards, with renewal of authority to provide PCI services based on ongoing compliance with such standards.

Again, we appreciate the opportunity to comment on the Summary Report of the Technical Advisory Group on Oversight of Percutaneous Coronary Intervention Services.

Sincerely,

Jeffrey L. Johnson

Jeffrey L. Johnson, FACHE
Vice President Corporate Planning

CC: Alison Brown, UMMS
Glenn Robbins, M.D., Chief Medical Officer, UMMS
Kathy McCollum, Baltimore Washington Medical Center
Dean Kaster, Upper Chesapeake Health System
LuAnn Brady, UMMC
Dana Farrakhan, UMMC
Donna Jacobs, Esq., UMMS

Appendix D:

Maryland Hospitals Providing Cardiac Surgery and/or PCI

Maryland Acute Care Hospitals and participation in cardiac surgery/percutaneous coronary intervention programs.

Region	Jurisdiction	Hospital	OHS	CIC	pPCI waiver	npPCI waiver	Cath lab w/o OHS, no waiver
Western Maryland	Allegany County	Western Maryland Regional Med. Ctr.	X	X			
	Frederick County	Frederick Memorial Hospital		X	X	X	
	Garrett County	Garrett County Memorial Hospital					
	Washington County	Meritus Medical Center			X	X	
Montgomery County	Montgomery County	Holy Cross Hospital of Silver Spring		X	X		
		Montgomery General Hospital					X
		Shady Grove Adventist Hospital		X	X	X	
		Suburban Hospital	X	X			
		Washington Adventist Hospital	X	X			
Southern Maryland	Calvert County	Calvert Memorial Hospital					X
	Charles County	Civista Medical Center					X
	Prince Geo. County	Doctors Community Hospital					X
		Fort Washington Medical Center					
		Laurel Regional Hospital					X
		Prince George's Hospital Center	X	X			
		Southern Maryland Hospital Center		X	X	X	
	St. Mary's County	St. Mary's Hospital					
Central Maryland	Anne Arundel County	Anne Arundel Medical Center		X	X	X	
		Baltimore Washington Medical Center		X	X	X	
	Baltimore City	Bon Secours Hospital					X
		Good Samaritan Hospital of MD					X
		Harbor Hospital					X
		James Lawrence Kernan Hospital					
		Johns Hopkins Bayview Medical Ctr.		X	X	X	
		Johns Hopkins Hospital	X	X			
		Maryland General Hospital					X
		Mercy Medical Center					X
		Sinai Hospital of Baltimore	X	X			
		Saint Agnes Hospital		X	X	X	
		Union Memorial Hospital	X	X			
		University of MD Medical Center	X	X			
	Baltimore County	Franklin Square Hospital Center		X	X		
		Greater Baltimore Medical Center					X
		Northwest Hospital Center					X
		St. Joseph Medical Center	X	X			
	Carroll County	Carroll Hospital Center		X	X		
	Harford County	Harford Memorial Hospital					
		Upper Chesapeake Medical Center		X	X		
	Howard County	Howard County General Hospital		X	X		
Eastern Shore	Cecil County	Union Hospital of Cecil County					
	Dorchester County	Dorchester General Hospital					X
	Kent County	Chester River Hospital Center					X
	Somerset County	Edward W. McCready Memorial Hos.					
	Talbot County	Memorial Hospital at Easton					X
	Wicomico County	Peninsula Regional Medical Center	X	X			
	Worcester County	Atlantic General Hospital					

OHS is open heart surgery; CIC is cardiac interventional center; pPCI is primary PCI; npPCI is non-primary PCI.

Notes: Northwest Hospital Center participated in the Atlantic C-PORT Primary Angioplasty Trial. Memorial Hospital at Easton, Doctors Community Hospital, and Mercy Medical Center participated in the Atlantic C-PORT Primary Angioplasty Registry.

Source: Maryland Health Care Commission (http://mhcc.maryland.gov/); Maryland Institute for Emergency Medical Services Systems (http://miemss.umaryland.edu/home/); Maryland Health Services Cost Review Commission (http://www.hscrc.state.md.us/).