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**MARYLAND HEALTH CARE COMMISSION**

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November 19, 2013

The Honorable Martin O'Malley  
Governor of the State of Maryland  
State House  
100 State Circle  
Annapolis, Maryland 21401

The Honorable Peter A. Hammen  
Chairman  
Health and Government Operations Committee  
The Maryland House of Delegates  
6 Bladen Street, Room 241  
Annapolis, Maryland 21401

The Honorable Thomas M. Middleton  
Chairman  
Senate Finance Committee  
Miller Senate Office Building, 3 East Wing  
11 Bladen Street  
Annapolis, MD 21401

Re: Recommendations on Implementation of Health-General §19-121.1  
(Senate Bill 750/House Bill 1141 – 2012 Session)

Dear Governor O'Malley, Chairman Middleton, and Chairman Hammen:

On behalf of the staff of the Maryland Health Care Commission (MHCC), I am pleased to provide your Committees with recommendations on implementation of the statutory changes established in 2012 addressing regulation of percutaneous coronary intervention (PCI) and cardiac surgery. These changes further align regulation of hospital facilities and services for the treatment of heart disease with the research findings of the last decade. The enclosed draft replacement regulations, COMAR 10.24.17: Cardiac Surgery and Percutaneous Coronary Intervention Services (Chapter), are attached as Exhibit 1. This draft Chapter of the State Health Plan for Facilities and Services implements the statutory changes, and is provided for your review over the next sixty days, consistent with the statute.

**Background**

As you know, Senate Bill 750 / House Bill 1141 (Exhibit 2) specifically authorized regulation of PCI by MHCC as a distinct category of treatment service, rather than a service linked to the provision of open heart surgery. It also established a regulatory process for:

1. Authorizing hospitals to provide primary PCI and elective PCI services at hospitals not providing cardiac surgery; and
2. Monitoring the performance of all hospitals providing these services to assure that they achieve acceptable quality, appropriateness, and safety of patient care, as a requirement for continuing authorization to provide the services.

This law built on the regulatory process that MHCC developed, beginning in 2006, to allow the establishment of primary PCI programs beyond the existing system of cardiac surgery/PCI centers, because research showed that PCI is the state-of-the-art treatment for some heart attacks. Thirteen new sites capable of providing primary, or emergency, PCI to patients experiencing heart attacks and life-threatening coronary artery blockages have been established since 2006. Twenty-three of the forty-six general hospitals now operating in Maryland can provide this service and nearly 90% of the State's population has a hospital program in their home jurisdiction.

The law reaffirmed Certificate of Need (CON) review as the appropriate process for establishing new cardiac surgery programs while establishing an ongoing oversight program for cardiac surgery programs already in existence. Prior to passage of the 2012 law, eight of the ten cardiac programs were not required to meet any performance thresholds including minimum volumes. The ten existing cardiac surgery hospital programs will be subject to ongoing performance reviews, under the same process used in evaluating PCI programs in non-cardiac surgery hospitals.

The 2012 legislation established a process for more direct and on-going regulation of these two services based on measurement of performance, a direction supported by the Commission. In MHCC staff's assessment, this process is the best approach to balancing the need to distribute and financially support primary PCI facility and staff resources to achieve the best care outcomes while not diluting the number of patients among so many sites that quality and economic viability cannot be achieved and maintained. This is also the regulatory plan that allows the State to require a more rigorous and consistent level of effort by physicians and hospitals to assure that treatment choices are based on appropriate criteria and diagnostic information and accurately presented to patients. A foundation for this on-going performance review has been established in the case of PCI services, because of the work done by MHCC since the 1990s, within its existing statutory authority, to support research and reflect new findings in its regulation of PCI. Commission staff has taken a similar approach in establishing the foundation for on-going performance review of cardiac surgery.

### **Implementation of Health-General §19-121.1 to Date - 2012 and 2013**

Following the requirements of the 2012 legislation, MHCC staff convened a Clinical Advisory Group (CAG) as an initial source of advice with respect to the new regulatory approach embodied in the law and how best to evaluate program performance and set expectations for new programs. The CAG met between September 2012 and April 2013 and a final report of its recommendations (Exhibit 3) was issued on June 20, 2013 of this year.

Over the last five months, a draft replacement Chapter (Exhibit 4) was developed by MHCC staff, using the guidance provided by the CAG. This draft Chapter was distributed to hospitals and other interested persons and organizations in September 2013 and was posted on the Commission's website for informal public review and comment. Comments were received by MHCC in the informal review and comment period in October 2013. MHCC staff used these comments (Exhibit 5), to develop a second draft of the SHP chapter (Exhibit 1).

### **Overview of Draft State Health Plan**

#### *Consideration of New Capacity*

The CAG endorsed and MHCC staff is proposing to maintain many of the same standards currently used to guide evaluation of new cardiac surgery and elective PCI programs. We intend to maintain a minimum service threshold in both services of 200 cases per year. Applicants are asked to demonstrate their capability to reach and maintain this minimum service level. The target case load for new primary PCI sites will also be continued, as endorsed by the CAG, at the levels currently established by MHCC, a minimum of either 36 or 49 cases per year.

In 2012, the eighteen hospitals providing elective PCI in Maryland averaged 473 cases per year. All 18 hospitals providing elective PCI met the 200-cases-per-year standard. At the lower end of volume distribution, four, all non-cardiac-surgery programs established between 2006 and 2008, reported total PCI case volume between 200 and 300 cases. The ten cardiac surgery hospitals' average was 627 cases per year.

Five hospital programs currently provide only primary PCI, and it is anticipated that they will likely apply to add elective PCI. The draft plan allows the MHCC to consider new elective PCI sites in the light of the desirability of supporting continued viability of these primary treatment resources in areas distant from the numerous hospital programs operating in our major population centers.

Maryland's cardiac surgery hospitals averaged just under 400 cases in 2012. Significant variation in volume exists among the 10 hospitals, one program, at Prince George's Hospital Center, has averaged fewer than 30 cases per year in the last five years, with only 17 cases

reported in 2012. Three other hospitals had case volumes between 200 and 300 cases in 2012, one of which is the State's newest program, at Suburban Hospital in Bethesda, now in its eighth year of operation.

Each new program, for any service, would be required to demonstrate its program's developmental capabilities and the ability to staff the program to maintain work experience and proficiency for physicians. Minimum PCI caseloads for practitioners of PCI will be lowered from 75 cases per year currently to 50 cases per year to align with the new national guidance in the *American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures*.

MHCC staff is removing the requirement that applications for new cardiac surgery programs be tied to a program failure within a planning region designated for this service, as it is in the current Chapter. An applicant will be able to enter the review process and obtain review of a new surgery program if it has reached agreement with HSCRC under the new payment model currently anticipated to become effective in Maryland in less than 60 days. An applicant will need to demonstrate the capability to grow a program quickly to the 200 annual case level, just as it would under the current plan.

Given the recent declines in total case volume, new programs will undoubtedly involve shifting demand from existing programs. Consideration of impact will be more heavily weighted toward protecting good performing programs in a cardiac surgery CON review. We have proposed that new capacity development should be avoided when existing programs with 200 or more cases and good performance ratings will drop to a sub-200 case level as a result of the expanded capacity. Additionally, we recommend avoidance of new program development if it means sending case volume below 100 cases per year at a hospital with 100-200 cases and good performance ratings.

The draft Chapter does not establish a need projection threshold triggering opportunities for applications. It maintains the current approach of including a regional utilization forecast that an applicant should address and that the Commission can use in analyzing the applicant's need assessment. Primary consideration will rest on the actual service area-level analysis and market share analysis particular to each applicant as the basis for understanding market potential and impact. The regions that serve as a base for the utilization forecast have been revised to reflect the actual patient migration pattern for cardiac surgery, which the current regions do not. On balance, the draft Chapter provides more opportunity and flexibility than the current Chapter for hospitals to present the Commission with proposals for changing the number of cardiac surgery programs in the State.

### *Assuring On-Going High Performance*

The model and mechanisms developed over the last decade for both research and clinical service delivery under MHCC's PCI "waiver" programs will serve as the on-going quality assurance model under these draft regulations. The requirement for periodic formal review of performance is tied to the formal renewal of authorization to continue providing the service. On-going quality assurance is being extended to cardiac surgery programs for the first time. It should be noted that the new capacity policies, described in the preceding section of this letter, are also important secondary mechanisms for quality assurance, intended to create a delivery system for cardiac surgery and PCI that has the best chance for high performance.

Existing data registries developed by physician specialty bodies, the Society for Thoracic Surgeons and the American College of Cardiology Foundation, for cardiac surgery and PCI respectively, will be used by MHCC to measure performance. In addition to requirements for periodic renewal of authority to provide these services, the Plan outlines a process by which "focused reviews" of specific performance issues can take place at any time based on specific triggers. These reviews may lead to findings requiring "plans of correction" which will, in essence, place programs on probationary status, as they seek to resolve problems and raise performance levels. These features of the Chapter are intended to assure that any contraction of services results from performance failures at specific hospitals. The process will be orderly and provide an opportunity for hospitals to improve performance before the Commission requests relinquishment of authority to perform PCI or cardiac surgery.

The draft Chapter contains peer review requirements, including external peer review for PCI programs, to address appropriate use. These draft requirements for peer review are consistent with CAG guidance.

### *New Commission Oversight, Guided by Clinical Input*

The draft Chapter, consistent with CAG guidance, recognizes that the Commission should have a sound source for continued expert advice on policy and plan changes that may be needed as the new regulatory approach is implemented. You will note that the standing Oversight Committee, described in the Chapter, will work in conjunction with MHCC's existing Cardiac Data Advisory Committee to assist the MHCC in improving the quality and reliability of data and advising the Commission on use of the data in measuring performance.

The Honorable Martin O'Malley  
The Honorable Thomas M. Middleton  
The Honorable Peter A. Hammen  
Recommendations  
Implementation of Health-General § 19-121.1  
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**Further Implementation of Health-General § 19-121.1 - 2014 to 2019**

Following your Committees' review of this draft State Health Plan chapter, MHCC staff will use the comments and suggestions received to develop a third draft of the replacement Chapter and begin the process of promulgating these regulations. We will also incorporate the new regulatory process outlined in Health-General §19-121.1 into the MHCC's procedural regulations, mandate the sharing of the STS data registry, and continue to work with the ACCF PCI data registries and the Cardiac Data Advisory Committee to assure these registries can meet the Commission's data needs for use in on-going performance reviews.

At the anticipated effective date of the replacement regulations, Commission staff will establish a schedule for Certificate of On-Going Performance Reviews for PCI and cardiac surgery and will be able to accept applications for Certificates of Conformance to establish new PCI programs and Certificate of Need applications to establish new cardiac surgery programs, although it may not be necessary to establish these reviews as scheduled reviews. Commission staff will also convene a standing Oversight Committee for the new regulatory programs.

The Commission and its staff appreciate the additional time you have granted for submission of this report and the draft regulations. We look forward to working with you in the coming months to complete initial implementation of these important regulatory reforms. Please contact me at 410-764-3566 if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Ben Steffen", followed by a long horizontal line.

Ben Steffen  
Executive Director

cc: Josh Sharfstein, M.D., Secretary of Health and Mental Hygiene  
Donna Kinzer, Executive Director, HSCRC

## Exhibit 1



**State Health Plan for Facilities and Services:  
Cardiac Surgery and Percutaneous Coronary Intervention  
Services**

**COMAR 10.24.17**

**DRAFT FOR LEGISLATIVE COMMITTEE REVIEW  
November 19, 2013**



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**.01 Incorporation by Reference.** This chapter of the State Health Plan for Facilities and Services: Cardiac Surgery and Percutaneous Coronary Intervention Services (Chapter) is incorporated by reference in the Code of Maryland Regulations.

**.02 Introduction.**

**A. Purposes of the State Health Plan.**

The Maryland Health Care Commission (Commission) has prepared this chapter of the State Health Plan for Facilities and Services (State Health Plan or SHP) in order to meet current and future health care system needs for all Maryland residents by assuring access, quality, and cost efficiency.

The State Health Plan serves two purposes:

- (1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources; and
- (2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in services for health care facilities are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, methodologies, standards, and criteria that the Commission uses in making decisions on applications for Certificates of Need, Certificates of Conformance, and Certificates of Ongoing Performance.

**B. Legal Authority of the State Health Plan.**

The State Health Plan is adopted under Maryland's health planning law, Maryland Code Annotated, Health-General §§19-114–19-131. This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the SHP as necessary. Health-General §19-118(a)(2) provides that the State Health Plan shall include:

- (1) The methodologies, standards, and criteria for CON review; and
- (2) Priority for conversion of acute capacity to alternative uses where appropriate.

Health-General §19-120.1, which was enacted in 2012, directs the Commission to update the State Health Plan to establish a process and adopt standards for the granting of Certificates of Conformance and Certificates of Ongoing Performance in regulating the supply and distribution of cardiac surgery and percutaneous coronary intervention (PCI) programs. A Certificate of Conformance is an approval issued by the Commission that allows an acute general hospital to establish primary, or emergency, PCI services or elective PCI services and provide those services for a specified period of time. At the end of that period of time, the hospital shall renew its

authorization to provide the specific PCI service or services by obtaining a Certificate of Ongoing Performance. A Certificate of Ongoing Performance is an approval issued by the Commission that renews the authorization of the hospital to continue to provide cardiac surgery services, primary PCI services, or primary and elective PCI services for a specified period of time, based on the hospital's record in providing the services at an acceptable level of performance and quality. Before the end of the specified time period, the hospital shall obtain a renewal of its Certificate of Ongoing Performance for the service.

### **C. Organizational Setting of the Commission.**

The purposes of the Commission, as enumerated at Health-General §19-103(c), include:

- (1) Development of health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission; and
- (2) Promotion of the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system.

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificates of Need, Certificates of Conformance, and Certificates of Ongoing Performance. Health General §19-118(e) provides that the Secretary of Health and Mental Hygiene shall make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. However, Health-General §19-110(a) clarifies that the Secretary does not have power to disapprove or modify any determinations the Commission makes regarding or based upon the State Health Plan. The Commission pursues effective coordination of its health planning functions with the Secretary, with State health-related agencies, and with the Health Services Cost Review Commission in order to assure an integrated, effective health care policy for the State. The Commission also consults the Maryland Insurance Administration as appropriate.

### **D. Plan Content and Applicability.**

Historically, the State Health Plan only allowed hospitals to perform percutaneous coronary intervention, a treatment for obstructed coronary arteries, at hospitals with cardiac surgery on-site, to assure rapid availability of surgical facilities and staff if complications occurred during a PCI procedure. Beginning in 2006, the Commission permitted hospitals that met certain standards to obtain a waiver from the co-location requirement. This approach was adopted because research showed that primary, or emergency, PCI is a lifesaving treatment for patients with acute ST-segment elevation myocardial infarction (STEMI), prompting interest in more widely distributing availability of this service for improved patient access. As cardiologists

gained experience with primary PCI and better techniques evolved, the risks of the procedure declined and results improved. Multiple, well-structured, multi-site clinical trials have validated the safety and efficacy in certain circumstances of performing primary PCI for the treatment of STEMI in hospitals without on-site cardiac surgery.<sup>1</sup> In 2012, a team led by Dr. Thomas Aversano, Associate Professor of Medicine, Johns Hopkins School of Medicine presented new research from a second multi-site clinical trial (C-PORT E), which found that elective (non-primary) PCI could be performed safely and effectively under certain circumstances and conditions at hospitals without on-site cardiac surgery.<sup>2</sup> Ten Maryland hospitals participated in one or more of these research studies.

As a result of these research findings, in 2012, the Maryland legislature enacted a law, codified at Health-General §19-121.1, that directed the Commission to adopt new regulations for the oversight of PCI services at hospitals without on-site cardiac surgery. The law also directed that: (a) the Commission establish a clinical advisory group to advise the Commission on developing standards for cardiac surgery, emergency PCI services (also known as primary PCI), and elective PCI services (also known as non-primary PCI); (b) a Certificate of Ongoing Performance review be established as the mechanism for an existing hospital providing certain specified cardiovascular services to obtain approvals to continue providing these services; and (c) a Certificate of Conformance review be developed as the mechanism for an acute general hospital to establish emergency or elective PCI services.

This chapter of the State Health Plan is applicable to the establishment of a new adult or pediatric cardiac surgery program, the establishment of primary PCI services, the establishment of elective PCI services, the issuance of Certificates of Conformance, the issuance of Certificates of Ongoing Performance, the relocation of a cardiac surgery and PCI program, and the relocation of a PCI program.

#### **E. Effective Date.**

An application or letter of intent submitted after the effective date of these regulations is subject to the provisions of this chapter.

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<sup>1</sup> Aversano, T, Aversano, L, Passamani, E, Knatterud, G., Terrin, M., Williams, D., Forman, S. “Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery.” *New England Journal of Medicine*. 2002 April 17; 287(15):1943-51. Jacobs AK, Normand SLT, Massaro JM, Cutlip DE, Carrozza JP Jr, Marks AD, Murphy N, Romm IK, Biondolillo M, Mauri L; MASS COMM Investigators. “Non-emergency PCI at Hospitals with or without On-site Cardiac Surgery.” *New England Journal of Medicine*. 2013 April 18;368:1498-508; Ting HH, Raveendran G, Lennon RJ, et al. “A Total of 1,007 Percutaneous Coronary Interventions without On-site Cardiac Surgery: Acute and Long-term Outcomes.” *Journal of the American College of Cardiology*. 2006 April 18; 47:1713-21.

<sup>2</sup> Aversano, T., Lemmon, C.C., Liu, L. “Outcomes of PCI at Hospitals with or without On-site Cardiac Surgery.” *New England Journal of Medicine*. 2012 May 10; 366(19):1792-802.

### **.03 Issues and Policies.**

The broad policy objectives guiding the Commission's regulation of the supply and distribution of cardiac surgery and PCI services in Maryland serve as a foundation for the specific standards of this State Health Plan Chapter and are as follows:

**Policy 1: Cardiac surgery and PCI services will be provided in the most cost-effective manner possible consistent with safely and effectively meeting the health care needs of appropriate patients.**

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

**Policy 3: Community education and outreach will be actively promoted and facilitated by all hospitals providing cardiac surgery and PCI services to reduce the prevalence of preventable cardiovascular disease, and demand for cardiac surgery and PCI services.**

**Policy 4: Cardiac surgery and PCI services will be financially and geographically accessible consistent with efficiently meeting the health care needs of patients.**

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

#### ***Specialized Hospital Services***

Cardiac surgery and PCI services are specialized hospital services. For specialized services, the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base. This pattern promotes both high quality care and an efficient scale of operation. The Chapter outlines standards intended to influence the geographic distribution, capacity, and scope of services for providers of cardiac surgery and PCI services based on considerations of cost-effectiveness, efficiency, access and quality.

This Chapter defines four health planning regions for the purpose of planning and regulating cardiac and PCI services: Eastern; Western; Baltimore Upper Shore; and Metropolitan Washington. The configuration of these regions is based on cardiac surgery utilization patterns. The majority of cardiac surgery patients from each jurisdiction included in a region obtain that surgical service at hospitals located in that region. Although each jurisdiction is only included in one planning region, it does not preclude consideration of the utilization of hospitals in adjoining health planning regions in evaluating the need for cardiac surgery and PCI services.

Eastern Region: Dorchester, Somerset, Wicomico, and Worcester Counties.

Western Region: Allegany, Garrett, and Washington Counties.

Baltimore/Upper Shore: Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties, and Baltimore City.

Metropolitan Washington: Calvert, Charles, Frederick, Montgomery, Prince George's, and St. Mary's Counties, and the District of Columbia.

### *Cost of Care*

With spending on health care continuing to rise nationally and for Maryland residents,<sup>3</sup> there continues to be increased attention to reducing the cost of health care and providing care in a more efficient manner. One model for containing the cost of health care and promoting efficiency that has been used by Maryland since the late 1970's, is having an all-payer system that establishes the rates of payment for inpatient and outpatient hospital care. This system's important all-payer feature was established through the Medicare waiver in §1814(b) of the Social Security Act. Under this waiver, Maryland has been allowed to regulate rates for all payers, including Medicare, as long as its regulatory system kept the rate of growth in Medicare cost-per-discharge below the national average rate of growth. Recently, it has been projected that Maryland could fail to meet the conditions required for maintaining the all-payer system under this waiver test.<sup>4</sup> As a result, the Health Services Cost Review Commission (HSCRC), the Maryland state agency that governs the State's all-payer system has been negotiating with the Centers for Medicare and Medicaid Services on how to reform its all-payer system.<sup>5</sup>

In October 2013, the Maryland Department of Health and Mental Hygiene submitted an application for modernization of Maryland's all-payer model to the Centers for Medicare and Medicaid Services.<sup>6</sup> If CMS accepts the application, HSCRC would move the hospital rate setting system away from a focus on the costs of inpatient discharges to a focus on the overall per capita health care expenditures of Marylanders. Growth in inpatient and outpatient expenditures would be limited by growth in the State's long-term gross state product. Given the uncertainty regarding reform of the all-payer system in Maryland at the time of this writing in the Fall of 2013, it may not be possible for the HSCRC to evaluate the financial viability of additional cardiac surgery services until after HSCRC has reached an agreement on reform of its all-payer model with the Centers for Medicare and Medicaid Services.

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<sup>3</sup> Maryland Health Care Commission. "State Health Care Expenditures Report 2011." July 2013.

<[http://mhcc.dhmdh.maryland.gov/healthinmaryland/Documents/2013\\_07\\_Spotlight\\_SHEA\\_WEB.pdf](http://mhcc.dhmdh.maryland.gov/healthinmaryland/Documents/2013_07_Spotlight_SHEA_WEB.pdf)>

<sup>4</sup> Redmon, P.D. "The Health Services Cost Review Commission FY 2014 Budget: Presentation to the Budget Committees of the Maryland General Assembly"

<<http://www.dbm.maryland.gov/agencies/operbudget/FY2013Testimony/M00R0102.pdf>>

<sup>5</sup>Ibid.

<sup>6</sup> Maryland Department of Health and Mental Hygiene. "Maryland's All-Payer Model Proposal to the Center for Medicare and Medicaid Innovation." September 27, 2013.

<<http://dhmdh.maryland.gov/docs/Maryland%20Model%20Design,%20Waiver%20Application,%20Revised%20September%202013%20with%20cover%20letter.pdf>>

### *Quality of Care*

Numerous research studies show that a strong inverse relationship exists between the volume of cardiac surgery performed and patient mortality and surgical complications. These studies have previously been cited in guidelines of the American College of Cardiology, the American Heart Association, and the American College of Surgeons. The 2011 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guideline for Coronary Artery Bypass Graft surgery (CABG) notes that the apparent strength of the volume–outcome association often diminishes with proper risk adjustment based on clinical (as opposed to administrative) data and that the relationship appears weaker in more contemporary studies. The relationship also appears weaker when hierarchical models are used that properly account for small sample sizes and clustering of observations.

In one study of the impact of CABG volume on patient outcomes, data for a cohort of 144,526 patients from 733 hospitals that participated in the STS Adult Cardiac Surgery Database in 2007 was analyzed.<sup>7</sup> In this analysis, a weak association between volume and unadjusted mortality rate was noted (2.6% unadjusted mortality rate for hospitals performing less than 100 procedures versus 1.7% for hospitals performing more than 450 procedures). The study also noted that the average STS-CABG composite score for the lowest-volume group (less than 100 cases per year) was significantly lower than that of the two highest-volume groups, but volume explained only 1% of variation in the composite score. The Commission’s clinical advisory group (CAG) considered this study as well as others<sup>8</sup>, in addition to the 2011 ACCF/AHA Guide for Coronary Artery Bypass Graft Surgery, in making its recommendation that the Commission’s regulation of cardiac surgery services should place a greater emphasis on quality rather than on volume.

Regarding percutaneous coronary intervention, numerous studies find that a relationship exists between volume and patient outcomes, with lower volume predicting a greater need for CABG

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<sup>7</sup>Shahian DM, O'Brien SM, Normand SL, Peterson ED, Edwards FH. “Association of Hospital Coronary Artery Bypass Volume with Processes of Care, Mortality, Morbidity, and the Society of Thoracic Surgeons Composite Quality Score.” *Journal of Thoracic and Cardiovascular Surgery*. 2010 Feb;139(2):273-82.

<sup>8</sup> Miyata H, Motomura N, Ueda Y, Matsuda H, Takamoto S. “Effect of Procedural Volume on Outcome of Coronary Artery Bypass Graft Surgery in Japan: Implication Toward Public Reporting and Minimal Volume Standards. *Journal of Thoracic Cardiovascular Surgery*. 2008 Jun;135(6):1306-12; Luft HS, Bunker JP, Enthoven AC. “Should Operations Be Regionalized? The Empirical Relation Between Surgical Volume and Mortality.” *New England Journal of Medicine*. 1979 Dec 20;301(25):1364-9; Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I, Welch HG, Wennberg DE. “Hospital Volume and Surgical Mortality in the United States.” *New England Journal of Medicine*. 2002 Apr 11;346(15):1128-37. Hannan EL, Wu C, Ryan TJ, Bennett E, Culliford AT, Gold JP, Hartman A, Isom OW, Jones RH, McNeil B, Rose EA, Subramanian VA. “Do Hospitals and Surgeons with Higher Coronary Artery Bypass Graft Surgery Volumes Still Have Lower Risk-Adjusted Mortality Rates?” *Circulation*. 2003 Aug 19;108(7):795-801; Clark RE. “Outcome as a Function of Annual Coronary Artery Bypass Graft Volume. The Ad Hoc Committee on Cardiac Surgery Credentialing of The Society of Thoracic Surgeons.” *Annals of Thoracic Surgery*. 1996 Jan;61(1):21-6. Rathore SS, Epstein AJ, Volpp KG, Krumholz HM. “Hospital Coronary Artery Bypass Graft Surgery Volume and Patient Mortality, 1998-2000. *Annals of Surgery*. 2004 Jan;239(1):110-7; Welke KF, Barnett MJ, Sarrazin MS, Rosenthal GE. “Limitations of Hospital Volume as a Measure of Quality of Care for Coronary Artery Bypass Graft Surgery.” *Annals of Thoracic Surgery*. 2005 Dec;80(6):2114-9.

and higher in-hospital mortality.<sup>9</sup> One meta-analysis that examined the outcome of PCI in ten reports between 1995 and 2003 concluded that patients treated in high volume hospitals, defined as 600 or more PCI procedures per year, experienced lower in-hospital mortality compared to patients treated in lower volume hospitals, defined as less than 400 PCI procedures per year. As is noted in the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures, a review of the available literature suggests that an institutional volume threshold of less than 200 PCI cases a year appears to be consistently associated with worse outcomes.<sup>10</sup> This finding was considered by the CAG in its recommendations regarding the target volumes that should be achieved for hospitals that provide emergency or emergency and elective PCI services without on-site cardiac surgery.

### ***Access to Care***

Timely access to care, such as emergency PCI services, has life-saving benefits for appropriate patients, such as those patients with STEMI. For patients located in rural areas, the benefits of having such care available may justify the higher cost of maintaining primary PCI programs with a lower volume of patients. These benefits include not only higher quality care for geographically isolated patients, but also promoting operator proficiency.<sup>11</sup> However, primary PCI programs that do not clearly fulfill this purpose should be avoided.<sup>12</sup>

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) analyzed the drive time to acute care Maryland hospitals and some hospitals outside the State based on 2010 information. The map assembled by MIEMSS shows that the two largest geographic regions beyond a 30-minute drive time to a MIEMSS designated cardiac interventional hospital are: the three southernmost counties of Southern Maryland (Calvert, Charles, and St. Mary's); and the mid-Shore counties of the Eastern Shore (Caroline, Dorchester, Kent, Queen Anne's, and Talbot).<sup>13</sup> Cardiac Interventional Centers are hospitals that have authorization from MHCC to provide primary PCI and are designated by MIEMSS and approved by the EMS Board to receive

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<sup>9</sup> Hannan EL, Wu C, Walford G, King SB 3rd, Holmes DR Jr, Ambrose JA, Sharma S, Katz S, Clark LT, Jones RH. "Volume-Outcome Relationships for Percutaneous Coronary Interventions in the Stent Era." *Circulation*. 2005 Aug 23;112(8):1171-9; Epstein AJ, Rathore SS, Volpp KG, Krumholz HM. "Hospital Percutaneous Coronary Intervention Volume and Patient Mortality, 1998 to 2000: Does the Evidence Support Current Procedure Volume Minimums?" *Journal of the American College of Cardiology*. 2004 May 19;43(10):1755-62; Lin HC, Lee HC, Chu CH. "The Volume-Outcome Relationship of Percutaneous Coronary Intervention: Can Current Procedure Volume Minimums Be Applied to a Developing Country?" *American Heart Journal*. 2008 Mar;155(3):547-52.

<sup>10</sup> Harold, JG, Bass TA, Bashore TM, Brindis RG, Brush Jr. JE, Burke JA, Dehmer GJ, Deychak YA, Jneid H, Jollis JG, Landzberg JS, Levine GN, McClurken JB, Messenger JC, Moussa ID, Muhlestein JB, Pomerantz RM, Sanborn TA, Sivaram CA, White CJ, Williams ES, Halperin JL, Beckman JA, Bolger A, Byrne JG, Lester SJ, Merli GJ, Muhlestein JB, Pina IL, Wang A, Weitz HH. "ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures." *Journal of the American College of Cardiology* (2013).

<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> Maryland Emergency Medical Services Systems. "Statewide STEMI Map MIEMSS 2010" <[http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/Statewide\\_%20STEMI\\_%20map\\_MIEMSS\\_2010.jpg](http://mhcc.dhmdh.maryland.gov/cardiacadvisory/Documents/Statewide_%20STEMI_%20map_MIEMSS_2010.jpg)>



STEMI patients being transported by ambulance who meet specific criteria determined by the *Maryland Medical Protocols for EMS Providers*.<sup>14</sup>

Unlike emergency PCI services, quick access to cardiac surgery and elective PCI services is not essential. One additional cardiac surgery program has been established in Maryland in the past decade and nine additional elective PCI programs have been established, while the volume of both cardiac surgery and PCI have steadily declined, for over ten years, in the case of cardiac surgery, and for seven years in the case of PCI. Geographic access to cardiac surgery services and elective PCI is not a problem in Maryland, with respect to patient travel time or survival.

### ***Policy Guidance***

The Clinical Advisory Group on Cardiac Surgery and PCI Services, which was convened to advise the Commission and to recommend standards to the Commission for inclusion in the updating of the Chapter, recommended that a standing committee be established by the Maryland Health Care Commission that includes representatives of Maryland providers of cardiac surgery, providers of PCI services, and other appropriate organizations. The Commission agrees with this recommendation and will establish a standing committee to provide advice regarding specialized cardiovascular services. This committee, the Cardiac Services Advisory Committee (CSAC) will be comprised of members selected by the Maryland Health Care Commission and will include representatives of providers of cardiac surgery, providers of PCI services, a representative of the Maryland Institute for Emergency Medical Services Systems, and representatives of the Maryland Chapter of the American College of Cardiology and the Maryland Chapter of the Society of Thoracic Surgeons, and others as appropriate. Representatives of providers of cardiac surgery and PCI services will be selected to cover a wide geographic range and multiple health care systems. The Commission shall designate a Chair and Vice-Chair of the Committee and may form subcommittees of the CSAC as needed.

The CAG also recommended that a data advisory committee or subcommittee be convened to provide advice on the performance measures that the Commission will use to evaluate review of requests for Certificates of Ongoing Performance. The Commission agrees and will use its existing Cardiac Data Advisory Committee, which advises the Commission on public reporting on cardiac services, to fulfill this role. The Cardiac Data Advisory Committee includes members with clinical knowledge of cardiac services.

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<sup>14</sup> Maryland Emergency Medical Services Systems. "Statewide STEMI Map Narrative."  
<[http://mhcc.dhmfh.maryland.gov/cardiacadvisory/Documents/Map\\_narrative\\_STEMI.pdf](http://mhcc.dhmfh.maryland.gov/cardiacadvisory/Documents/Map_narrative_STEMI.pdf)>

**.04 Commission Program Policies.**

**A. Consideration of New Programs.**

**(1) Cardiac Surgery**

- (a) A Certificate of Need is required to establish cardiac surgery services.
- (b) A hospital shall have a population-based budget agreement, a total patient revenue agreement, or a modified charge per episode agreement with the Health Services Cost Review Commission before a hospital's CON application to establish a cardiac surgery program will be docketed.
- (c) A hospital shall have provided both primary and elective PCI services for at least three years before filing an application for a CON to establish cardiac surgery services.
- (d) A new cardiac surgery program will not be considered in a health planning region, if the most recently approved program in the health planning region has been in operation less than three years.
- (e) A review schedule for receipt of letters of intent and applications seeking a CON to establish cardiac surgery services will be published in the *Maryland Register* for each health planning region where the condition in .04A(1)(d) is met.

**(2) Elective Percutaneous Intervention**

- (a) A hospital shall obtain a Certificate of Conformance to establish elective PCI services, unless the hospital is exempt from this requirement under Health General §19-120.1(d).
- (b) A hospital shall have been providing primary PCI services for at least two years before seeking a Certificate of Conformance to provide elective PCI services, unless the hospital is located in a part of Maryland that does not have sufficient access to emergency PCI services. In such cases, sufficiency of access will be evaluated by the Commission based on a review of evidence presented by the applicant and collected by Commission staff. An applicant shall show that the population in the primary service area of the proposed program is receiving suboptimal therapy for STEMI. This review shall include an analysis of emergency transport data and patient-level outcome data.
- (c) A review schedule for the establishment of elective PCI programs will be published in the *Maryland Register* at least annually for each health planning region where there is at least one hospital that provides only primary PCI services. An application to establish primary PCI and elective PCI services based on insufficient access pursuant to .04A(2)(b) of this regulation may be filed at any time.

**(3) Primary Percutaneous Coronary Intervention**

(a) A hospital shall obtain a Certificate of Conformance to establish primary PCI services, unless the hospital is exempt from this requirement under Health General §19-120.1(c).

(b) Review schedules for receipt of applications to establish primary PCI programs will be published annually in the *Maryland Register*. All applications will be considered in accordance with the published review schedule, except when an applicant proposes to establish both primary and non-primary PCI services pursuant to .04(2)(c).

**B. Closure of Programs.**

**(1) Cardiac Surgery**

(a) Prior to issuance of Certificate of Ongoing Performance, the closure of a cardiac surgery program that is in existence as of the effective date of this Chapter will be evaluated by the Commission and a determination concerning program closure will be made under the following circumstances:

(i) A cardiac surgery program achieves a one-star composite rating for CABG using the rating scale developed by STS-ACSD for four consecutive six-month reporting periods; or

(ii) A cardiac surgery program records a case volume of less than 100 cardiac surgery cases for two consecutive years; or

(iii) A cardiac surgery program has been given an opportunity to address deficiencies identified by the Commission through an approved plan of correction and has failed to adequately correct the deficiencies.

(b) A new cardiac surgery program that fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation will be evaluated for closure by the Commission.

**(2) Primary and Elective Percutaneous Coronary Intervention**

(a) A hospital must, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority to provide primary or elective PCI and close its program in a timely manner if it:

(i) Failed to comply with standards of ongoing performance;

(ii) Has been given an opportunity to address deficiencies identified by the Commission through an approved plan of correction; and

(iii) Failed to adequately correct the deficiencies.

(b) An elective PCI program is not permitted to continue in the absence of a primary PCI program.

### **C. Relocation of Programs.**

#### **(1) Cardiac Surgery**

(a) If a hospital with cardiac surgery seeks to relocate, in addition to meeting all CON review criteria and applicable standards in COMAR 10.24.10 and other SHP chapters, the hospital shall demonstrate compliance with all standards for a Certificate of Ongoing Performance for both cardiac surgery and PCI services.

(b) A merged hospital system may not relocate its existing cardiac surgery capacity and emergency and elective PCI services to another hospital within its system without obtaining a Certificate of Need.

#### **(2) Elective and Primary PCI Services**

If a hospital with primary PCI services or both primary and elective PCI services, and without cardiac surgery, seeks to relocate, the hospital shall obtain a new Certificate of Conformance for each PCI service in conjunction with its Certificate of Need for relocation.

### **.05 Certificate of Need Review Standards for Cardiac Surgery Programs.**

An applicant for a Certificate of Need to establish cardiac surgery services shall address and meet the general standards in COMAR 10.24.10(A), in addition to the standards in this Chapter.

#### **A. Cardiac Surgery Standards.**

##### **(1) Minimum Volume Standard**

An applicant shall document that the proposed cardiac surgery program will meet the following standards:

(a) For an adult cardiac surgery program, demonstrate the ability to meet a projected volume of 200 cardiac surgery cases in the second full year of operation; the program shall attain a minimum annual volume of 200 cardiac surgery cases by the end of the second year of operation.

(b) For a pediatric cardiac surgery program, demonstrate the ability to meet a projected minimum case volume of 130 cardiac surgery cases per year; the program shall attain a minimum annual volume of 130 cases by the end of the second year of operation.

(c) For a program performing both adult and pediatric cardiac surgery, demonstrate the ability to meet a projected minimum of 50 pediatric cardiac surgery cases per year, and 200 adult cardiac surgery cases per year; the program shall attain a minimum annual volume of each type of cardiac surgery cases by the end of the second year of operation.

(d) The applicant's demonstration of compliance with the Minimum Volume and Impact standards of this Chapter shall address the most recent published utilization projection of cardiac surgery cases in Regulation Part .08 for the health planning region in which the applicant hospital is located and any other health planning regions from which it projects drawing 20 percent or more of its patients. The applicant shall demonstrate that its volume projections and impact analysis are consistent with the projection in Regulation .08 or, alternatively, demonstrate why the methods and assumptions employed in the Part .08 projections are not reasonable as a basis for forecasting case volume.

## **(2) Impact**

An applicant shall demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:

- (a) Compromise the financial viability of cardiac surgery services at an affected hospital; or
- (b) Result in an existing cardiac surgery program with an annual volume of 200 or more cardiac surgery cases and an STS composite score of two stars or higher for two of the three most recent reporting periods prior to Commission action on an application dropping below an annual volume of 200 cardiac surgery cases; or
- (c) Result in an existing cardiac surgery program with an annual volume of 100 to 199 cardiac surgery cases and an STS composite score of two stars or higher for two of the three most recent reporting periods prior to Commission action on an application dropping below an annual volume of 100 cardiac surgery cases.

## **(3) Quality**

(a) An applicant shall demonstrate its commitment to provide high quality health care. An applicant seeking to establish cardiac surgery services shall have utilization or peer review and control programs with regularly scheduled conferences to:

(i) Establish protocols that govern the referral, admission, and discharge of cardiac surgery patients;

(ii) Establish and review a list of indications and contraindications to govern selection of patients for cardiac surgery;

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- (iii) Establish a program to educate patients about treatment options;
  - (iv) Establish mechanisms for monitoring long-term outcomes of discharged patients.
  - (v) Review morbidity and mortality rates and other indicators of patient outcomes, and compliance with established processes of care as compared with regional or national averages;
- (b) Prior to first use approval, an applicant shall provide documentation of (i)-(iv).

### **(4) Cost Effectiveness**

An applicant shall demonstrate that the benefits of its proposed cardiac surgery program to the health care system as a whole exceed the cost to the health care system.

- (a) A hospital that projects that cardiac surgery volume will shift from one or more existing cardiac surgery hospitals as a result of establishment of its proposed new program shall quantify the shift in volume and the estimated financial impact on the cardiac surgery program of each such hospital.
- (b) An applicant that proposes new construction of one or more operating rooms, cardiac catheterization laboratories, or intensive care units, or any combination thereof, shall document why existing resources at the applicant hospital cannot be used to accommodate the proposed new cardiac surgery program.

### **(5) Access**

- (a) An applicant that seeks to justify a new program, in whole or in part, based on inadequate access to cardiac surgery services in a health planning region shall:
  - (i) Demonstrate that access barriers exist; and
  - (ii) Present a detailed plan for addressing such barriers.
- (b) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement cardiac surgery program.

### **(6) Need**

- (a) An applicant shall demonstrate that a new program can generate at least 200 cardiac surgery cases based on projected demand for cardiac surgery by the population in its service area.
- (b) The applicant's need analysis shall account for the utilization trends in the most recent published utilization projections of cardiac surgery cases in Regulation .08 for:

- (i) The health planning region in which the applicant hospital is located; and
- (ii) Any other health planning regions from which it projects drawing, or from which available evidence indicates that it will draw, 20 percent or more of its patients.
- (c) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement program.

**(7) Preference in Comparative Reviews**

In the case of a comparative review of applications in which all policies and standards have been met by all applicants, the Commission will give preference based on the following criteria.

- (a) The applicant whose proposal is the most cost effective for the health care system.
- (b) An applicant with an established record of cardiovascular disease prevention and early diagnosis programming that includes provisions for educating patients about treatment options.
- (c) An applicant with an established record of cardiovascular disease prevention and early diagnosis programming, with particular outreach to minority and indigent patients in the hospital's regional service area.
- (d) An applicant whose cardiac surgery program includes a research, training, and education component that is designed to meet a local or national need and for which the applicant's circumstances offer special advantages.

**.06 Certificate of Conformance Criteria.**

**A. Primary PCI Services.**

A hospital issued a Certificate of Conformance to establish a primary PCI service shall agree to voluntarily relinquish its authority to provide primary PCI services if it fails to maintain compliance with the applicable standards for a Certificate of Conformance.

**(1) General Standards**

An applicant seeking a Certificate of Conformance to establish primary PCI services shall address and meet the general standards in COMAR 10.24.10(A) in its application.

**(2) Need**

(a) A hospital shall demonstrate that the proposed program is needed for its service area population through an analysis of current utilization patterns of the population for primary PCI services.

(b) At a minimum, the applicant shall demonstrate that its proposed program will achieve, by the end of the second year of operation, an annual case volume of at least 36 cases if the hospital is located in a rural area or an annual volume of at least 49 cases if the hospital is located in a non-rural area.

**(3) Access**

(a) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrates that the proposed program's primary service area population:

(i) Has insufficient access to emergency PCI services; and

(ii) Is receiving suboptimal therapy for STEMI.

**(4) Institutional Resources**

(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction, 24 hours per day, seven days per week.

(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients.

(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

(d) The hospital president or CEO, as applicable, shall provide a written commitment stating the hospital administration will support the program.

(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

(f) A hospital shall complete a PCI development plan that includes appropriate training for the emergency room, catheterization laboratory, coronary care unit and, if applicable, post-procedure unit. The plan shall include protocols for both routine and usual emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency coronary artery bypass graft (CABG) surgery, and primary angioplasty system failure. In addition, there shall be an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more



than one hospital on a given shift, as well as when two simultaneous STEMIs occur at the hospital.

(g) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

(h) The hospital shall design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

(i) The hospital shall have a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

(j) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

## **(5) Quality**

(a) A hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

(b) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(c) A hospital shall conduct an annual external review of at least five percent of randomly selected PCI cases and internal review of at least 10 percent of randomly selected PCI cases performed within the past 12 months. These reviews shall:

(i) Include a review of angiographic images, medical test results, and patients' medical records; and

(ii) Be conducted by an external reviewer who shall meet all standards established by the Commission to ensure consistent rigor among external reviewers.

(d) A hospital shall evaluate the performance of each interventionalist through an annual review of:

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(i) At least 10 cases or 10 percent of the interventionalist's cases, whichever is greater;  
or

(ii) If fewer than 10 cases have been performed by the interventionalist, then all cases shall be reviewed.

(e) The hospital shall participate in the American College of Cardiology's National Cardiovascular Data Registries (ACC-NCDR) known as ACTION GWTG and CathPCI.

### **(6) Physician Resources**

Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery shall:

(a) Meet the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures; and

(b) Achieve an average annual case volume of 50 or more PCI cases over a two-year period.

### **(7) Patient Selection**

The hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI for Percutaneous Coronary Intervention.)

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

(c) Patients for whom primary PCI services were not initially available and who received thrombolytic therapy that subsequently failed. Such cases should constitute no more than 10 percent of cases.

(d) Patients who experiences a return of spontaneous circulation following cardiac arrest and presents at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believe that transfer to a tertiary institution may be harmful for the patient.

**B. Elective PCI Services.**

A hospital issued a Certificate of Conformance to establish an elective PCI service shall agree to voluntarily relinquish its authority to provide elective PCI services if it fails to meet the applicable standards for a Certificate of Conformance. An applicant seeking to establish elective PCI services shall meet all applicable criteria for a Certificate of Conformance for a primary PCI program, and shall meet the following additional requirements:

**(1) Need**

The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.

**(2) Volume**

The hospital shall demonstrate its proposed elective PCI program will achieve a volume of 200 or more total PCI cases by the end of the second year of providing elective PCI services.

**(3) Financial Viability**

The Commission may waive the volume requirement in subsection (2) if the applicant demonstrates that adding an elective PCI program to its existing primary PCI program at its projected annual case volume will permit the hospital's overall PCI services to achieve financial viability.

**(4) Quality**

A hospital shall demonstrate its ability to provide high quality emergency PCI services over a period of two years or longer, unless the hospital is not required to obtain a Certificate of Conformance to establish emergency PCI services before establishing elective PCI services.

**(5) Preference**

A hospital that was providing primary PCI services on January 1, 2012 will be given preference over another hospital that was not providing primary PCI services on January 1, 2012, when the two hospitals have service areas that overlap and only one PCI program is needed to provide adequate geographic access for the population in the primary service areas of both hospitals.

**(6) Patient Selection**

The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate for elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of

Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI for Percutaneous Coronary Intervention.

(b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

**.07 Certificate of Ongoing Performance.**

**A. General.**

(1) A hospital may not provide cardiac surgery services without a Certificate of Ongoing Performance, except for:

(a) A hospital that receives Certificate of Need approval to establish cardiac surgery services after the effective date of these regulations and that has been in operation fewer than 36 months; or

(b) A hospital that has cardiac surgery services as of the effective date of these regulations and that has not yet completed a scheduled Commission review for consideration of the grant of a Certificate of Ongoing Performance.

(2) A hospital with primary and elective PCI services may not provide PCI services without Certificates of Ongoing Performance, except for a hospital that as of the effective date of these regulations:

(a) Has received an exception from the requirement to obtain a Certificate of Conformance to continue to provide non-primary PCI services;

(b) Has a waiver from Certificate of Need review to provide primary PCI services; and

(c) Has not yet completed scheduled Commission reviews for consideration of the grant of Certificates of Ongoing Performance.

(3) A hospital may not provide primary PCI services without a Certificate of Ongoing Performance, except for a hospital that as of the effective date of these regulations:

(a) Has a waiver from Certificate of Need review to provide primary PCI services; and

(b) Has not yet completed a scheduled Commission review for consideration of the grant of a Certificate of Ongoing Performance for primary PCI.

(4) A hospital granted a Certificate of Conformance to establish PCI services after the effective date of these regulations shall apply for a Certificate of Ongoing Performance before the end of the second year of operation or by the date specified in its Certificate of Conformance.

(5) As a condition of a Certificate of Ongoing Performance for cardiac surgery or PCI services, a Certificate of Need to establish cardiac surgery services, or a Certificate of Conformance to establish PCI services, a hospital must agree that it will voluntarily relinquish its authority to provide the cardiac surgery or PCI services if it:

(a) Fails to complete an approved plan of correction in a satisfactory and timely manner, as provided in Regulation .07D(5) or .07E(5); and

(b) Receives notice from the Executive Director of the Commission that the hospital must voluntarily relinquish its authority to provide cardiac surgery or PCI services and close its program in a timely manner.

(6) A hospital that holds a Certificate of Conformance to establish PCI services shall apply for a Certificate of Ongoing Performance before the end of the second year of operation or by the date specified in the Certificate of Conformance issued.

## **B. Cardiac Surgery.**

### **(1) Schedule of Reviews**

A review schedule for Certificates of Ongoing Performance will be published in the *Maryland Register*. A Certificate of Ongoing Performance will be granted for a maximum of five years. The Commission at its discretion may choose to grant a Certificate of Ongoing Performance for a shorter period of time.

### **(2) Focused Reviews**

Commission staff may review a program's clinical records at any time for the purpose of auditing data. In addition, reported patient safety concerns, aberrations in data identified by Commission staff, failure of an established program to meet a volume threshold of 100 cardiac surgery cases annually, or failure to meet quality standards established in State and federal regulations may lead to a focused review that investigates the quality of patient care or the accuracy of a hospital's data. A hospital shall cooperate with Commission staff, and other persons acting on behalf of the Commission, and shall timely provide all information and data requested.

### **(3) Data Collection**

Each cardiac surgery program shall participate in uniform data collection and reporting. This requirement is met through participation in the STS-ACSD registry, with submission of duplicate information to the Maryland Health Care Commission. Each cardiac surgery program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care

Commission to assure a complete, accurate, and fair evaluation of Maryland's cardiac surgery programs.

**(4) Quality**

(a) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

(ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

**(5) Performance Standards**

(a) A cardiac surgery program shall meet all performance standards established in statute or in State regulations. Applicable performance measures include:

(i) The hospital shall maintain a composite score of two stars or higher. If the composite score from the STS-ACSD registry is one star for four consecutive six-month reporting periods, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its cardiac surgery services in a timely manner.

(ii) The hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(b) A hospital with an all-cause 30-day risk-adjusted mortality rate for cardiac surgery cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for the statewide all-cause 30-day risk-adjusted mortality rate for cardiac surgery cases.

(c) A hospital with a composite score of one star for two consecutive six-month reporting periods will be subject to a focused review.

(d) A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance following a focused review shall:

(i) Submit a proposed plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff;

(ii) A hospital shall submit a new proposed plan of correction within 10 business days of receiving notice that its initial proposed plan of correction was not approved by Commission staff.

(e) An approved plan of correction shall be timely and successfully completed before the Commission may grant a Certificate of Ongoing Performance for its cardiac surgery program. The Executive Director may extend the end date of a Certificate of Ongoing Performance for a reasonable period of time, as determined by the Executive Director, in order to determine if the hospital has successfully completed an approved plan of correction.

(f) If the hospital does not successfully and timely complete the plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its cardiac surgery services in a timely manner.

#### **(6) Volume Requirements**

(a) A cardiac surgery program shall maintain an annual volume of 200 or more cases

(b) A cardiac surgery program that fails to reach an annual volume of 100 cardiac surgery cases will be subject to a focused review.

(c) If the focused review indicates that the hospital's cardiac surgery services do not meet quality standards and the Commission requires completion of a plan of correction, the hospital will not be granted a renewal of a Certificate of Ongoing Performance for its cardiac surgery services. The Executive Director may extend the end date of a Certificate of Ongoing Performance for a reasonable period of time, as determined by the Executive Director, in order to determine if the hospital has successfully completed an approved plan of correction.

(d) If the hospital does not successfully and timely complete the approved plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its cardiac surgery services in a timely manner

#### **C. Elective PCI Program.**

##### **(1) Schedule of Reviews**

A review schedule for Certificates of Ongoing Performance will be published in the *Maryland Register*. A Certificate of Ongoing Performance will be granted for a maximum of five years. The Commission at its discretion may choose to grant a Certificate of Ongoing Performance for a shorter period of time.

## **(2) Focused Reviews**

Commission staff may review a program's clinical records at any time for the purpose of auditing data. In addition, reported patient safety concerns, aberrations in data identified by Commission staff, failure to meet minimum volume standards, or failure to meet quality standards established in State and federal regulations may lead to a focused review that investigates the quality of patient care or the accuracy of the data. A hospital shall cooperate with Commission staff, and other persons acting on behalf of the Commission, and shall timely provide all information and data requested.

## **(3) Data Collection**

Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

## **(4) Quality**

(a) The hospital shall develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for PCI patients.

(b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(c) The hospital shall conduct an annual external review of at least five percent of randomly selected PCI cases

(d) The hospital shall evaluate the performance of each interventionalist through an annual review of:

(i) At least 10 cases or 10 percent of randomly selected PCI cases performed by the interventionalist, whichever is greater; or

(ii) If fewer than 10 cases have been performed, then all cases shall be reviewed.

(e) The performance review shall:

(i) Include a review of angiographic images, medical test results, and patients' medical records; and



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(ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

(ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

### **(5) Patient Outcome Measures**

(a) An elective PCI program shall meet all performance standards established in statute or in State regulations. Applicable performance measures include that a hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(b) A hospital with a risk-adjusted mortality rate for elective PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review.

(c) A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance following a focused review shall submit a proposed plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff. A hospital shall submit a new proposed plan of correction within 10 working days of receiving notice that the initial proposed plan of correction was not approved.

(d) An approved plan of correction shall be timely and successfully completed before the Commission may grant a Certificate of Ongoing Performance for its PCI program. The Executive Director may extend the end date of a Certificate of Ongoing Performance for a reasonable period of time, as determined by the Executive Director, in order to determine if the hospital has successfully completed an approved plan of correction.

(e) If the hospital does not successfully and timely complete the plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its Certificate of Ongoing Performance and close its PCI services in a timely manner.

**(6) Physician Resources**

(a) Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

(b) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform an annual minimum of 50 PCI procedures averaged over a 24-month period, and who took a leave of absence of less than one year during the 24-month period measured, may resume the provision of primary PCI provided that:

(i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;

(ii) The physician continues to satisfy the hospital's credentialing requirements; and

(iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

(c) The hospital shall notify the Commission in writing of a physician's leave of absence within fourteen days thereafter. This notification shall provide documentation of:

(i) The number of PCI cases that the physician performed in the 12-month period preceding the leave of absence;

(ii) An estimated time frame for the leave of absence;

(iii) An estimate of the impact of the leave of absence on the physician's PCI case volume; and

(iv) An estimate of the impact of the leave of absence on the hospital's PCI case volume.

(d) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or who completed training before 1998 and did not seek board certification before 2003.

(e) Each physician shall obtain board certification within three years of completion of a fellowship in interventional cardiology

(f) An interventionalist shall complete a minimum of 24 hours of continuing medical education credit in the area of interventional cardiology during every two years of practice.

(g) Each physician who performs primary PCI shall agree to participate in an on-call schedule.

**(7) Volume Requirements**

- (a) The target volume for existing programs with both primary and non-primary PCI services is 200 cases annually
- (b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subjected to a focused review.
- (c) An approved plan of correction shall be timely and successfully completed before the Commission may grant a Certificate of Ongoing Performance for a PCI program. The Executive Director may extend the end date of a Certificate of Ongoing Performance for a reasonable period of time, as determined by the Executive Director, in order to determine if the hospital has successfully completed an approved plan of correction.
- (d) If the hospital does not successfully and timely complete the plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its cardiac surgery services in a timely manner.

**(8) Patient Selection**

The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

- (a) Patients described as appropriate for elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention).
- (b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

**D. Primary PCI Program.**

**(1) Schedule of Reviews**

A review schedule for Certificates of Ongoing Performance will be published in the *Maryland Register*. A Certificate of Ongoing Performance will be granted for a maximum of five years. The Commission at its discretion may choose to grant a Certificate of Ongoing Performance for a shorter period of time.

## **(2) Focused Reviews**

Commission staff may review a program's clinical records at any time for the purpose of auditing data. In addition, reported patient safety concerns, aberrations in data identified by Commission staff, failure to meet minimum volume standards, or failure to meet quality standards established in State and federal regulations may lead to a focused review that investigates the quality of patient care or the accuracy of the data. A hospital shall cooperate with Commission staff, and other persons acting on behalf of the Commission, and shall timely provide all information and data requested.

## **(3) Data Collection**

Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

## **(4) Institutional Resources**

(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction, 24 hours per day, seven days per week.

(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for 75 percent of appropriate patients.

(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

(d) The hospital president or CEO, as appropriate, shall provide a written commitment stating the hospital administration will support the program.

(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the cardiac catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

(g) The hospital shall have a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

(h) The hospital shall have a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

(i) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

**(5) Quality**

(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

(b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(c) The hospital shall conduct an annual external review of at least five percent of randomly selected PCI cases.

(d) The hospital shall evaluate the performance of each interventionalist through an annual review of:

(i) At least 10 cases or 10 percent of randomly selected PCI cases performed by the interventionalist, whichever is greater; or

(ii) If fewer than 10 cases have been performed, then all cases shall be reviewed.

(e) The performance review shall:

(i) Include a review of angiographic images, medical test results, and patients' medical records; and

(ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

(ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

#### **(6) Patient Outcome Measures**

(a) A primary PCI program shall meet all performance standards established in statute or in State regulations. Applicable performance measures include that a hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(b) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review.

(c) A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance following a focused review shall submit a proposed plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff. A hospital shall submit a new proposed plan of correction within 10 working days of receiving notice that the initial proposed plan of correction is not approved.

(d) The Commission requires the successful and timely completion of an approved plan of correction before a hospital is granted a renewal of a Certificate of Ongoing Performance for its PCI program for 60 days or more beyond the end date of the plan of correction.

(e) If the hospital does not successfully and timely complete the accepted plan of correction, the hospital agrees to voluntarily relinquish its authority to provide PCI services and to proceed to close its program in an approved orderly process, upon receipt of notice from the Commission.

#### **(7) Physician Resources**

(a) Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

(b) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

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(i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;

(ii) The physician continues to satisfy the hospital's credentialing requirements; and

(iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

(c) The hospital shall notify the Commission in writing of a physician's leave of absence within fourteen days thereafter. This notification shall provide documentation of the number of PCI cases that the physician performed in the 12-month period preceding the leave of absence, an estimated time frame for the leave of absence, an estimate of the impact of the leave of absence on the physician's PCI case volume, and an estimate of the impact of the leave of absence on the hospital's PCI case volume.

(d) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 and/or completed their training before 1998 and did not seek board certification before 2003.

(e) Each physician shall obtain board certification within three years of completion of a fellowship in interventional cardiology.

(f) An interventionalist shall complete a minimum of 24 hours of continuing medical education credit in the area of interventional cardiology during every two years of practice.

(g) Each physician who performs primary PCI agrees to participate in an on-call schedule.

### **(8) Volume**

(a) For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

(b) The target volume for primary PCI operators should be at least 11 primary PCI cases annually.

(c) If the focused review indicates that the hospital's PCI services do not meet quality standards, the Commission will require the submission and successful and timely completion of an approved plan of correction before a hospital is granted renewal of a Certificate of Ongoing Performance for its PCI services for 60 days or more beyond the end date of the plan of correction.

(d) If the hospital does not successfully and timely complete the accepted plan of correction, the hospital agrees to voluntarily relinquish its authority to provide PCI services and to proceed to close its program in an approved orderly process, upon receipt of notice from the Commission.

**(9) Patient Selection**

A hospital shall commit to only providing primary PCI services for suitable patients. Suitable patients are:

(a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction and Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI for Percutaneous Coronary Intervention.)

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

(c) Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

(d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believe that transfer to a tertiary institution may be harmful for the patient.

**.08 Utilization Projection Methodology for Cardiac Surgery.**

**A. Period of Time Covered.**

(1) The base year for utilization projections is the most recent calendar year for which data is available from both the Commission's uniform hospital discharge abstract data set and the District of Columbia discharge abstract data set.

(2) The target year for which utilization projections are calculated is six years after the base year.

**B. Age Groups and Services.**

(1) Adult cardiac surgery cases are projected for three age groups; persons aged 15 to 44 years, 45 to 64 years, and 65 years and over.

(2) The utilization of adult cardiac surgery services is expressed in terms of the projected annual number of cardiac surgery cases.

(3) Pediatric cardiac surgery cases are projected for persons aged 0 to 14 years.

(4) The utilization of pediatric cardiac surgery services is expressed in terms of the projected number of cardiac surgery cases.



**C. Patient Migration.**

The following assumptions are used for the allocation of projected adult cardiac surgery cases to health planning regions:

- (1) The migration pattern of patients to health planning regions observed in the base year is assumed to remain the same in the target year; and
- (2) In accounting for new programs in the utilization projections, no adjustment in patient migration patterns will be made until at least one year after the program has come into operation.

**D. Assumptions.**

- (1) The pediatric cardiac surgery use rate will remain constant from the base year to the target year.
- (2) Projected adult cardiac surgery utilization for Maryland residents is estimated by calculating the cardiac surgery use rates by each age group in each health planning region, for each of the most recent six years of reported data.
- (3) The average annual percentage change in cardiac surgery use rates in each health planning region for each age group is calculated for the six-year period by graphing a line that best fits the trend over six years and calculating the slope of the line.
- (4) The estimated use rate of Maryland residents by health planning region is calculated from discharge data for Maryland and District of Columbia hospitals.
- (5) The target year cardiac surgery use rate for each health planning region is calculated from the use rate in the base year for residents in each age group for each health planning region and the corresponding average annual percentage change in cardiac surgery use rates by age group and health planning region for the six-year period.
- (6) The projected utilization by out-of-state adult patients, including residents of the District of Columbia, and patients of foreign or unknown origin, is assumed to be equal to the proportion of discharges for patients who underwent cardiac surgery in the base year, for each of the health planning regions. Discharges identified as Maryland residents, from an unknown jurisdiction, will be counted as patients of unknown origin in calculations of projected utilization.
- (7) Projected utilization by out-of-state pediatric patients in the Baltimore/Upper Shore and Metropolitan Washington Regions is the same as the actual volume of these patients who underwent cardiac surgery in each health planning region in the base year.

**E. Publication and Re-computation of Utilization Projections.**

- (1) Utilization projections calculated using the methodology in this Chapter are to be used by the Commission in evaluating Certificate of Need applications to establish cardiac surgery services.
- (2) Updated utilization projections are published as notices in the *Maryland Register* prior to use in Certificate of Need decisions.
- (3) The most recently published utilization projections supersede any previously published projections.
- (4) Published utilization projections remain in effect until the Commission publishes updated projections.

**F. Projection of Cardiac Surgery Utilization by the Adult Population.**

**(1) Use Rate Calculations**

- (a) Calculate the rate of cardiac surgery for Maryland residents for each of the six most recent years of available data for each adult age group, in each health planning region by dividing the total number of surgery cases performed for each adult age group, in each health planning region, by the corresponding Maryland population for each health planning region.
- (b) Calculate the rate of cardiac surgery for District of Columbia residents for each of the six most recent years of available data for each adult age group, by dividing the total number of surgery cases performed for each adult age group, in each health planning region, by the corresponding District of Columbia population.
- (c) Calculate the average annual percentage change in cardiac surgery use rates in each adult age group by drawing a line that best fits the use rates calculated for the six year time period and calculating the slope of the line.
- (d) Calculate the target year number of cardiac surgery cases for each adult age group, in each health planning region, by multiplying the average annual percentage change in the cardiac surgery use rate for each group by the use rate in the previous year, beginning with the use rate in the base year.

**(2) Projection of Total Utilization**

- (a) Calculate the projected utilization of cardiac surgery in the target year for Maryland residents in each adult age group for each health planning region by multiplying the projected target year cardiac surgery use rate by the corresponding projected target year population for each adult age group and health planning region.

(b) Calculate the projected utilization of cardiac surgery in the target year for District of Columbia residents in each adult age group by multiplying the projected target year cardiac surgery use rate by the corresponding projected target year population for each adult age group.

**(3) Adjustments to Projections Due to Migration Patterns**

(a) For Maryland residents, calculate the base year number of cardiac surgery cases for each adult age group and health planning region from the hospital discharge abstracts for the District of Columbia and Maryland hospitals.

(b) For Maryland residents, calculate the proportion of patients in each adult age group and each health planning region who underwent cardiac surgery in each health planning region by dividing for each adult age group the number of patients who had cardiac surgery in each health planning region by the corresponding total number of cardiac surgery patients for each adult age group and health planning region who are residents of the health planning region.

**(4) Allocation of Additional Utilization by Out-of-State Patients**

Allocate to each health planning region the proportion of adult patients from other states, foreign countries, or of unknown residence, including those from an unknown county or city in Maryland, who underwent cardiac surgery in each health planning region in the base year, except for residents of the District of Columbia, use the projected number of discharges rather than the base year.

**G. Projection of Cardiac Surgery Utilization by the Pediatric Population.**

**(1) Use Rate Calculations**

(a) Calculate the rate of cardiac surgery for Maryland residents for each of the six most recent years of available data for persons age 0 to 14 years (the pediatric age group), in each health planning region by dividing the total number of surgery cases performed in each health planning region, by the corresponding Maryland population for each health planning region.

(b) Calculate the average annual percentage change in open heart surgery use rates for the pediatric age group by summing the five percentage changes in use rates calculated for the six year time period and dividing by five.

(c) Calculate the target year number of cardiac surgery cases for the pediatric age group, in each health planning region, by multiplying the average annual percentage change in the cardiac surgery use rate by the use rate in the previous year, beginning with the use rate in the base year.

**(2) Projection of Total Utilization**

(a) Calculate the projected utilization of cardiac surgery in the target year for Maryland residents in the pediatric age group for each health planning region by multiplying the projected target

year cardiac surgery use rate by the corresponding projected target year population for the health planning region.

(b) The projected utilization of cardiac surgery for residents of the District of Columbia is the same number of cases observed in the base year.

### **(3) Adjustments to Projections Due to Migration Patterns**

(a) Calculate the base year number of cardiac surgery cases for the pediatric age group in each health planning region from the hospital discharge abstracts for the District of Columbia and Maryland hospitals.

(b) Calculate the proportion of pediatric patients in each health planning region who underwent cardiac surgery in each health planning region by dividing the number of pediatric patients who had cardiac surgery in each health planning region by the corresponding total number of pediatric patients who are residents of the health planning region.

### **(4) Allocation of Additional Utilization by Out-of-State Patients**

Allocate to each health planning region the actual number of pediatric patients from other states, foreign countries, or of unknown residence, including those from an unknown county or city in Maryland, who underwent cardiac surgery in each health planning region in the base year.

## **.09 Definitions.**

*Approved Plan of Correction.* A plan submitted by a hospital to Commission staff that details how deficiencies in compliance with the standards and policies in this Chapter will be addressed and a timeline for the hospital's proposed actions that has been approved by Commission staff and agreed upon by the hospital.

*Cardiac Catheterization* means an invasive diagnostic procedure whereby a catheter is inserted into a blood vessel in the patient's arm or leg, and guided into various chambers of the heart, permitting the securing of blood samples, determination of intracardiac pressure, and detection of cardiac anomalies, identified by the following International Classification of Diseases (9<sup>th</sup> Revision) procedure codes: 37.21-37.29 or the corresponding International Classification of Diseases (10<sup>th</sup> Revision) procedure codes. The list of procedure codes will be updated as necessary through notification in the *Maryland Register* and on the Maryland Health Care Commission web site.

*Cardiac Surgery* means surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery, identified by the following International Classification of Disease (9<sup>th</sup> Revision) procedure codes: 35.00-35.06; 35.08,35.09, 35.10-35.14; 35.20-35.28; 35.31-35.35; 35.39-35.42; 35.50-35.54;35.60-35.63; 35.70-35.73; 35.81-35.84; 35.91-35.95; 35.97-35.99,36.03,36.10-36.17;36.19,36.30, 36.31, 36.91,36.99, 37.10,37.11, 37.31- 37.33; 37.37, and 37.40 , or the corresponding International Classification of Diseases (10<sup>th</sup> Revision) procedure

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codes. The list of procedure codes will be updated as necessary through notification in the *Maryland Register* and on the Maryland Health Care Commission web site.

*Coronary Artery Bypass Graft Surgery (CABG)* means an open heart surgery procedure in which a piece of saphenous vein from the leg, or the internal mammary artery from the chest, is used to bypass the blocked section of one or more coronary arteries and restore blood supply to the heart, identified by the following International Classification of Diseases (9<sup>th</sup> Revision) procedure codes: 36.10-36.19 or the corresponding International Classification of Diseases (10<sup>th</sup> Revision) procedure codes. The list of procedure codes will be updated as necessary through notification in the *Maryland Register* and on the Maryland Health Care Commission web site.

*Elective PCI* (also known as “non-primary PCI”) includes PCI provided to a patient who is not suffering from an acute coronary syndrome, but whose condition is appropriately treated with PCI based on regulations established by the Commission.

*Emergency PCI* (also known as “primary PCI”) includes PCI capable of relieving coronary vessel narrowing associated with STEMI or, as defined by the Commission in Regulations, STEMI equivalent.

*Focused Review* means an investigation of limited scope that is undertaken directly by Commission staff and or other persons, such as auditors with clinical expertise, to determine whether a cardiac surgery or PCI program is complying with the standards included in these regulations as well as with the expectation that a hospital shall provide high quality patient care and accurately report data collected for evaluating the quality of care provided.

*Jurisdiction* means a Maryland county, Baltimore City, or the District of Columbia.

*Leave of absence* means a period during which a physician is excused from his or her normal work schedule and that is expected to potentially compromise a physician’s ability to meet the applicable case volume standards.

*Minority* means a person who has one or more of the following ethnic heritages: American Indian or Alaskan Native, Asian and Pacific Islander, Black, or Hispanic. The term minority also refers to persons who are not native English speakers and who may require a translator to interact with health care providers.

*Percutaneous Coronary Intervention (PCI)* means a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing; includes rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, and other catheter devices for treatment of coronary atherosclerosis; and is identified by the following International Classification of Diseases (9<sup>th</sup> Revision) procedure codes: 36.01; 36.02; 36.05-36.07 or the corresponding International Classification of Diseases (10<sup>th</sup> Revision) procedure codes.

*Primary PCI operator* means a physician who performs primary PCI services.

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*Rural area* means a jurisdiction where at least two-thirds of the census tracts are classified as rural by the federal Office of Rural Health Policy (ORHP).

*Service Area* means the zip code areas from which the greatest number of patient reside, which when ordered from largest to smallest, compromise the top 85 percent of patients who received diagnostic cardiac catheterization that resulted in a referral for cardiac surgery, for a proposed cardiac surgery program. For an existing cardiac surgery program, service area means the zip code areas from which the greatest number of patient reside, which when ordered from largest to smallest, compromise the top 85 percent of patients who received cardiac surgery.

*Suboptimal Therapy for STEMI* means therapy other than primary PCI because STEMI is not available rather than because the patient's condition requires other medical treatment instead.

## Exhibits 2-5 Are Available Through the Following Links:

Link to Exhibit 2 (HB1141/SB752)(2012 Session):

<http://mgaleg.maryland.gov/2012rs/bills/hb/hb1141t.pdf>

Link to Exhibit 3 (Report of Clinical Advisory Group, June 20, 2013):

[http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/cardiac\\_advisory/Cardiac%20Advisory%20Group%20Report.pdf](http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/cardiac_advisory/Cardiac%20Advisory%20Group%20Report.pdf)

Link to Exhibit 4 (First Draft of Chapter Released for Informal Public Comment):

[http://mhcc.dhmh.maryland.gov/shp/Documents/statehealthplan/comar102417/10\\_24\\_17\\_FOR\\_INFORMAL\\_COMMENT\\_POSTED\\_093013.pdf](http://mhcc.dhmh.maryland.gov/shp/Documents/statehealthplan/comar102417/10_24_17_FOR_INFORMAL_COMMENT_POSTED_093013.pdf)

Link to Exhibit 5 (Informal Public Comments received on First Draft Chapter):

[http://mhcc.dhmh.maryland.gov/shp/Pages/Comar102417\\_Comments.aspx](http://mhcc.dhmh.maryland.gov/shp/Pages/Comar102417_Comments.aspx)