



MARYLAND HEALTH CARE COMMISSION
4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

DRAFT AMENDMENTS TO

**STATE HEALTH PLAN FOR FACILITIES AND SERVICES:
SPECIALIZED HEALTH CARE SERVICES - CARDIAC SURGERY
AND PERCUTANEOUS CORONARY INTERVENTION SERVICES**

COMAR 10.24.17

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Submit to: Eileen Fleck, Chief
Maryland Health Care Commission
4160 Patterson Ave., Baltimore, MD 21215
Fax: (410)358-1236
Email: Eileen.fleck@maryland.gov*

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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) 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 State Health Plan 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 both primary and elective percutaneous coronary intervention (PCI) services. A Certificate of Conformance is an approval issued by the Commission that allows an acute general hospital to establish primary (emergency) PCI services or elective (non-primary) PCI services and provide those services for a specified period of time. At the end of that period of time, the hospital shall seek renewal of its authorization to provide the specific PCI service or services by applying for 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 seek 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 services 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.¹ In 2012, a team led by Dr. Thomas Aversano, Associate Professor of Medicine, at the 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.² Ten Maryland hospitals participated in one or both of these research studies.

¹ Aversano, T., Aversano, L., Passamani, Knatterud, Terrin, Williams, Forman. “Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery.” *Journal of the American Medical Association*. 287.15 (2002):1943-51.; Jacobs, Normand, Massaro, Cutlip, Carrozza, Marks, Murphy, Romm, Biondolillo, Mauri. “Non-emergency PCI at Hospitals With or Without On-site Cardiac Surgery.” *New England Journal of Medicine*. 368.16 (2013):1498-508;Ting, Raveendran, Lennon, Long, Singh, Wood, Gersh, Rihal, Holmes. “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*. 47.8 (2006):1713-21.

² Aversano, T., Lemmon, C.C., Liu, L. “Outcomes of PCI at Hospitals With or Without On-site Cardiac Surgery.” *New England Journal of Medicine*. 366.19 (2012):1792-802.

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, and elective PCI services; (b) a Certificate of Ongoing Performance review be established as the mechanism for an existing hospital providing certain specified cardiovascular services to seek approvals to continue providing these services; and (c) 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.

.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 emergency PCI services or a hospital with both emergency and elective 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,³ 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

³ Maryland Health Care Commission. "State Health Care Expenditures Report 2011." July 2013.
<http://mhcc.dhmh.maryland.gov/healthinmaryland/Documents/2013_07_Spotlight_SHEA_WEB.pdf>

Medicare, as long as its regulatory system kept the rate of growth in Medicare cost-per-discharge below the national average rate of growth.

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. CMS accepted the application for a new waiver model,⁴ and in January 2014, HSCRC began moving the hospital rate setting system away from a focus on the per case costs of inpatient discharges to a focus on per capita Medicare hospital costs. Ultimately, HSCRC will develop a payment model based on controlling the overall health care expenditures of Marylanders. Under the new payment model, growth in inpatient and outpatient expenditures will be limited by growth in the State's long-term gross state product. All hospitals falling within the scope of HSCRC rate regulation will have a population based budget agreement, a total patient revenue agreement, or a modified charge per episode agreement with HSCRC under the new rate regulation model by the end of FY 2015.

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

⁴ "Final Maryland All-Payer Model Agreement." February 2014.
<http://mhcc.dhmdh.maryland.gov/hospital/Documents/hospital/allpayermodel_agreement.pdf>

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 (STS-ACSD) in 2007 was analyzed.⁵ 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-ACSD 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 others⁶, in addition to the 2011 ACCF/AHA Guideline 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.

⁵Shahian, O'Brien, Normand, Peterson, Edwards. "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*. 139.2 (2010):273-82.

⁶ Miyata, Motomura, Ueda, Matsuda, Takamoto. "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*. 135.6 (2008): 1306-12; Luft, Harold S., John P. Bunker, and Alain C. Enthoven. "Should Operations Be Regionalized? The Empirical Relation Between Surgical Volume and Mortality." *New England Journal of Medicine*. 301.25 (1979):1364-9; Birkmeyer, Siewers, Finlayson, Stukel, Lucas, Batista, Welch, Wennberg. "Hospital Volume and Surgical Mortality in the United States." *New England Journal of Medicine*. 346.15 (2002):1128-37. Hannan, Wu, Ryan, Bennett, Culliford, Gold, Hartman, Isom, Jones, McNeil, Rose, Subramanian. "Do Hospitals and Surgeons with Higher Coronary Artery Bypass Graft Surgery Volumes Still Have Lower Risk-Adjusted Mortality Rates?" *Circulation*. 108.7 (2003):795-801; Clark, Richard E. "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*. 61.1 (1996): 21-6. Rathore, Epstein, Volpp, Krumholz. "Hospital Coronary Artery Bypass Graft Surgery Volume and Patient Mortality, 1998-2000." *Annals of Surgery*. 239.1 (2004):110-7; Welke, Barnett, Sarrazin, Rosenthal. "Limitations of Hospital Volume as a Measure of Quality of Care for Coronary Artery Bypass Graft Surgery." *Annals of Thoracic Surgery*. 80.6 (2005): 2114-9.

Regarding percutaneous coronary intervention, numerous studies find that a relationship exists between volume and patient outcomes, with lower procedure volume predicting a greater need for CABG and higher in-hospital mortality.⁷ 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.⁸ 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 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

⁷ Hannan, Wu, Walford, King, Holmes, Ambrose, Sharma, Katz, Clark, Jones. "Volume-Outcome Relationships for Percutaneous Coronary Interventions in the Stent Era." *Circulation*. 112.8 (2005): 1171-9; Epstein, Rathore, Volpp, Krumholz. "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*. 43.10 (2004):1755-62; Lin, Heng-Ching, Hsin-Chien Lee, and Chien-Heng Chu. "The Volume-Outcome Relationship of Percutaneous Coronary Intervention: Can Current Procedure Volume Minimums Be Applied to a Developing Country?" *American Heart Journal*. 155.3 (2008): 547-52.

⁸ Harold, Bass, Bashore, Brindis, Brush, Burke, Dehmer, Deychak, Jneid, Jollis, Landzberg, Levine, McClurken, Messenger, Moussa, Muhlestein, Pomerantz, Sanborn, Sivaram, White, Williams, Halperin, Beckman, Bolger, Byrne, Lester, Merli, Muhlestein, Pina, Wang, Weitz. "ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Cardiac Interventional Procedures." *Journal of the American College of Cardiology*. 62.4 (2013): 357-96.

for geographically isolated patients, but also promoting operator proficiency.⁹ However, primary PCI programs that do not clearly fulfill this purpose should be avoided.¹⁰

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).¹¹ Cardiac Interventional Centers are hospitals that have authorization from MHCC to provide primary PCI and are designated by MIEMSS and approved by its EMS Board to receive STEMI patients being transported by ambulance who meet specific criteria determined by the *Maryland Medical Protocols for EMS Providers*.¹²

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.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Maryland Emergency Medical Services Systems. "Statewide STEMI Map MIEMSS 2010"
<http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/Statewide_%20STEMI_%20map_MIEMSS_2010.jpg>

¹² Maryland Emergency Medical Services Systems. "Statewide STEMI Map Narrative."
<http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/Map_narrative_STEMI.pdf>

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, 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.

.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 only be considered in a health planning region if the most recently approved program in the health planning region has been in operation for at least 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. Publication of a review schedule does not indicate that the Commission has determined an additional provider of cardiac services is needed in a region.

(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 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 .04A(2)(c).

B. Closure of Programs.

(1) Cardiac Surgery

(a) Prior to issuance of a 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 rating cycles; 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 fails to comply with the quality or performance standards required for a Certificate of Ongoing Performance; and

(iv) A cardiac surgery program has been given an opportunity to address the 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.

(c) A hospital shall close its cardiac surgery program if the hospital loses its authority to provide PCI services.

(2) Primary and Elective Percutaneous Coronary Intervention

(a) A hospital shall, 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) Has failed to comply with standards for a Certificate of Ongoing Performance or a Certificate of Conformance;

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

(iii) Has 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) A hospital may continue providing PCI services if the hospital has both PCI and cardiac surgery services and voluntarily relinquishes its CON for cardiac surgery, provided that the hospital's PCI services comply with the applicable requirements for a Certificate of Ongoing Performance.

C. Relocation of Programs.

(1) Cardiac Surgery

(a) If a hospital with cardiac surgery seeks to relocate, in addition to meeting all applicable CON standards in section .05 of this chapter, COMAR 10.24.10, and other State Health Plan 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 to establish cardiac surgery services at the other hospital.

(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 or relocate cardiac surgery services shall address and meet the applicable general standards in COMAR 10.24.10.04(A), in addition to the applicable standards in this chapter.

A. Cardiac Surgery Standards.

(1) Minimum Volume Standard

An applicant proposing establishment or relocation of cardiac surgery services 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 .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 Regulation .08 projections are not reasonable as a basis for forecasting case volume.

(2) Impact

(a) A hospital that projects that cardiac surgery volume will shift from one or more existing cardiac surgery hospitals as a result of the relocation or establishment of cardiac surgery services shall quantify the shift in volume and the estimated financial impact on the cardiac surgery program of each such hospital.

(b) 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:

(i) Compromise the financial viability of cardiac surgery services at an affected hospital; or

(ii) Result in an existing cardiac surgery program with an annual volume of 200 or more cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles prior to Commission action on an application dropping below an annual volume of 200 cardiac surgery cases; or

(iii) Result in an existing cardiac surgery program with an annual volume of 100 to 199 cardiac surgery cases and an STS-ACSD composite score for CABG of two stars or higher for two of the three most recent rating cycles 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;

(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 proposing establishment or relocation of cardiac surgery

services 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) An applicant that proposes new construction of one or more operating rooms, cardiac catheterization laboratories, or intensive care units, or any combination thereof, as necessary infrastructure for its proposed new cardiac surgery program shall document why existing resources at the applicant hospital cannot be used to accommodate the proposed cardiac surgery services.

(b) An applicant shall provide an analysis of how the cost of cardiac surgery services for cardiac surgery patients in its proposed service area and for the health care system will change as a result of the proposed cardiac surgery program, quantifying these changes to the extent possible.

(c) An applicant shall provide an analysis of how the establishment of its proposed cardiac surgery program will alter the effectiveness of cardiac surgery services for cardiac surgery patients in its proposed service area, quantifying the change in effectiveness to the extent possible. The analysis of service effectiveness shall include, but need not be limited to, the quality of care, care outcomes, and access to and availability of cardiac surgery services.

(5) Access

(a) An applicant that seeks to justify establishment of cardiac surgery services, 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 or relocated program can generate at least 200 cardiac surgery cases per year based on projected demand for cardiac surgery by the population in its proposed service area and an analysis of the market share that the applicant expects to capture for each zip code area in the proposed service area. An applicant shall demonstrate the reasonableness of the assumptions relied upon in defining its proposed service area.

(b) An applicant's need analysis for a new or relocated program 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) An applicant's need analysis for a new program shall include current information about the number of patients referred for cardiac surgery following a diagnostic cardiac catheterization at the applicant hospital and address how this information supports the applicant's demonstration that the proposed new program can generate at least 200 cardiac surgery cases per year.

(d) Closure of an existing program, in and of itself, is not sufficient to demonstrate the need to establish a new or replacement program.

(7) Financial Feasibility

A proposed new or relocated cardiac surgery program shall be financially feasible and shall not jeopardize the financial viability of the hospital.

(a) Financial projections filed as part of a Certificate of Need application shall be accompanied by a statement containing each assumption used to develop the projections.

(b) An applicant shall document that:

(i) Its utilization projections for cardiac surgery are consistent with observed historic trends in the use of cardiac surgery by the population in the applicant's proposed service area;

(ii) Its revenue estimates for cardiac surgery are consistent with utilization projections and account for current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, for cardiac surgery, as experienced by similar hospitals;

(iii) Its staffing and overall expense projections for cardiac surgery are based on current expenditure levels and are consistent with utilization projections and with reasonably anticipated future staffing levels as experienced by the applicant hospital, or, if applicable, the recent experience of similar hospitals; and

(iv) Within three years or less of initiating a new or relocated cardiac surgery program, it will generate excess revenues over total expenses for cardiac surgery, if utilization forecasts are achieved for cardiac surgery services.

(8) 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 10.24.10.04A 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, an 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 demonstrate that the proposed program's 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. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

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

(d) The hospital president or Chief Executive Officer, 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 infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency 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 STEMI patients present 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 a hospital 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) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period and an internal review of at least 10 percent of randomly selected PCI cases performed in the applicable time period. These reviews shall:

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

(ii) External reviews shall 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:

(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 GWGTG 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 (elective and emergency) 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 likely projected annual case volume will permit the hospital's overall PCI services to achieve financial viability.

(4) Quality

A hospital shall demonstrate that it provided 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 additional PCI program is needed to provide adequate geographic access for the population in the 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;

(b) A hospital with cardiac surgery services that has a pending application for a Certificate of Need to relocate the hospital and its cardiac surgery and PCI services, prior to the effective date of these regulations;

(c) A hospital in paragraph (b) that has received Certificate of Need approval to relocate the hospital and its cardiac surgery and PCI services if the relocated services have been in operation fewer than 36 months at the relocated hospital; or

(d) A hospital that has cardiac surgery services as of the effective date of these regulations and 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 a scheduled Commission review for consideration of the grant of a Certificate 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 or relocate cardiac surgery services, or a Certificate of Conformance to establish PCI services, a hospital shall 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 subsections .07B(2)(e), .07C(2)(e), and .07D(2)(e).

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

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

(a) Commission staff, or other persons acting on behalf of the Commission, 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.

(b) All evaluations of the quality of patient care will include an auditor with appropriate clinical expertise. 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.

(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:

(i) Receive a detailed list of the deficiencies identified through the focused review;

(ii) Submit a proposed plan of correction to Commission staff within 30 days of receiving notice of the deficiencies identified through the focused review;

(iii) If the initial proposed plan of correction is not acceptable, Commission staff shall provide written notice to the hospital that includes a detailed explanation as to why the initial plan of correction was not approved. Upon request, Commission staff shall meet with hospital representatives to discuss possible changes to the plan of correction. The hospital shall submit a revised proposed plan of correction within 10 business days of receiving written notice from Commission staff that the hospital's initial proposed plan of correction was not approved. The hospital's revised plan of correction shall address the specific deficiencies cited by Commission staff. The timeline in a plan of correction may not exceed eighteen months.

(d) An approved plan of correction shall be timely and successfully completed

before the Commission may grant a Certificate of Ongoing Performance for the hospital's 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.

(e) If the hospital does not submit a plan of correction that addresses deficiencies cited by Commission staff or does not successfully and timely complete an 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.

(3) Data Collection

Each cardiac surgery program shall participate in uniform data collection and reporting. This requirement is met through participation in STS-ACSD, 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 an STS-ACSD composite score for CABG of two stars or higher. If the composite score for CABG from the STS-ACSD is one star for four consecutive rating cycles, the hospital's cardiac surgery program shall be evaluated for closure based on a review of the hospital's compliance with State regulations and recently completed or active plans of correction. Upon notice from the Executive Director of the Commission, the hospital shall 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 a specific type of cardiac surgery cases, such as CABG 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 hospital's all-cause 30-day risk-adjusted mortality rate for a specific type of cardiac surgery cases.

(c) A hospital with an STS-ACSD composite score for CABG of one star for two consecutive rating cycles will be subject to a focused review.

(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. 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

(a) Commission staff, or other persons acting on behalf of the Commission, 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.

(b) All evaluations of the quality of patient care shall include an auditor with appropriate clinical expertise. 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.

(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:

(i) Receive a detailed list of the deficiencies identified through the focused review;

(ii) Submit a proposed plan of correction to Commission staff within 30 days of receiving notice of the deficiencies identified through the focused review;

(iii) If the initial proposed plan of correction is not acceptable, Commission staff shall provide written notice to the hospital that includes a detailed explanation as to why the initial plan of correction was not approved. Upon request, Commission staff shall meet with hospital representatives to discuss possible changes to the plan of correction. The hospital shall submit a revised proposed plan of correction within 10 business days of receiving written notice from Commission staff that the hospital's initial proposed plan of correction was not approved. The hospital's revised plan of correction shall address the specific deficiencies cited by Commission staff. The timeline in a plan of correction may not exceed eighteen months.

(d) An approved plan of correction shall be timely and successfully completed before the Commission may grant a Certificate of Ongoing Performance for the hospital's elective 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 submit a plan of correction that addresses deficiencies cited by Commission staff or does not successfully and timely complete an approved plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its elective PCI services in a timely manner.

(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) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period.

(d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital;

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period,

or all cases if the interventionalist has performed fewer than 5 cases at the hospital during the relevant period ; or

(iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraph .07C(4)(d)(i).

(e) The external review of PCI cases and the performance review of an interventionalist referenced in Paragraphs .07C(4)(c) and (d) 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.

(5) Patient Outcome Measures

(a) An elective PCI program shall meet all performance standards established in statute or in State regulations.

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

(c) 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. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for elective PCI cases.

(6) Physician Resources

(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24 month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Maryland Health Care Commission on a quarterly basis.

(b) Each physician who performs primary PCI at a hospital without on-site cardiac surgery who does not perform a minimum of 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.

(c) A physician who performs primary PCI at a hospital without on-site cardiac surgery and who does not perform a minimum of 50 PCI procedures annually 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.

(d) The hospital shall notify the Commission in writing of a physician's leave of absence within fourteen days of the initiation of the leave of absence. 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.

(e) 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.

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

(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credit in the area of interventional cardiology during every two years of practice.

(h) 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 subject to a focused review.

(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

(a) Commission staff, or other persons acting on behalf of the Commission, 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.

(b) All evaluations of the quality of patient care will include an auditor with appropriate clinical expertise. 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.

(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:

(i) Receive a detailed list of the deficiencies identified through the focused review;

(ii) Submit a proposed plan of correction to Commission staff within 30 days of receiving notice of the deficiencies identified through the focused review;

(iii) If the initial proposed plan of correction is not acceptable, Commission staff shall provide written notice to the hospital that includes a detailed explanation as to why the initial plan of correction was not approved. Upon request, Commission staff shall meet with hospital representatives to discuss possible changes to the plan of correction. The hospital shall submit a revised proposed plan of correction within 10 business days of receiving

written notice from Commission staff that the hospital's initial proposed plan of correction was not approved. The hospital's revised plan of correction shall address the specific deficiencies cited by Commission staff. The timeline in a plan of correction may not exceed eighteen months.

(d) An approved plan of correction shall be timely and successfully completed before the Commission may grant a Certificate of Ongoing Performance for the hospital's primary 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 submit a plan of correction that addresses deficiencies cited by Commission staff or does not successfully and timely complete an approved plan of correction, the hospital shall, upon notice from the Executive Director of the Commission, voluntarily relinquish its authority and close its emergency and elective PCI services in a timely manner.

(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. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

(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 Chief Executive Officer, 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 evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital;

(ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 5 cases during the relevant period at the hospital; or

(iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).

(d) The performance review of an interventionalist referenced in Paragraph .07D(5)(c) 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.

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

(c) 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. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.

(7) Physician Resources

(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24 month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Maryland Health Care Commission on a quarterly basis.

(b) 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.

(c) 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:

(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.

(d) The hospital shall notify the Commission in writing of a physician's leave of absence within fourteen days of the initiation of the leave of absence. 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.

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

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

(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credit in the area of interventional cardiology during every two years of practice.

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

(i) A physician who completed an interventional cardiology fellowship less than three years ago shall have performed primary PCI on a minimum of 50 patients with acute myocardial infarctions during fellowship training or ten proctored cases before being permitted to perform primary PCI alone.

(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 is 11 or more primary PCI cases annually.

(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 or 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) believes 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.

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(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) believes that transfer to a tertiary institution may be harmful for the patient.

.08 External Peer Review.

A. Scope.

These regulations govern the external peer review process for primary and elective PCI procedures performed in Maryland hospitals.

B. Number of Cases and Case Selection.

(1) Number of Cases to be Reviewed

(a) A hospital shall review on a semi-annual basis at least five percent of randomly selected PCI cases based on the total number (excluding STEMI cases) of attempted PCI procedures, within a preceding six-month review period, as determined by the Commission; or

(b) A hospital shall review on a quarterly basis at least five percent of randomly selected PCI cases based on the total number (excluding STEMI cases) of attempted PCI procedures, within a preceding three month period.

(2) Method for Selecting Cases to be Reviewed

(a) Cases to be reviewed under this regulation shall be randomly selected in the following manner:

(i) A hospital shall create a list of the medical record numbers for all PCI cases (excluding STEMI cases) for the applicable review period and then the external review organization shall generate a random number to assign to each case through the use of software that randomly generates numbers within a specified range greater than or equal to the number of PCI cases for the applicable review period for the hospital.

(ii) After all PCI cases on the list have been assigned a random number, the external review organization or a Commission-approved agent acting on behalf of the

external review organization shall order the cases on the list according to the assigned random numbers, from lowest to highest.

(iii) The external review organization shall then select the required number of cases beginning with the lowest random number assigned to a case and choosing consecutive cases on the list until the required number of cases has been reached.

(c) For a patient who has not yet been discharged from the hospital for any reason, a hospital may delay review of the patient's case until the next review cycle, if the decision is documented and retained as part of the documentation of the random selection of cases.

(d) A hospital that chooses to combine the required external review of a hospital's selected PCI cases with the required review of the PCI cases of individual interventionalists in .07C(4)(d) or .07D(5)(c).07 shall create a list of PCI cases for each individual physician from the cardiac catheterization laboratory records and require that the external review organization randomly select cases from those lists, consistent with the random sampling of cases described in this subsection.

(3) Documentation. A hospital shall retain documentation of the random selection of cases, and exclusion of STEMI cases, until a Certificate of Ongoing Performance that covers each applicable review period has been granted by the Commission.

C. Requirements for External Peer Review.

(1) Required questions. At a minimum, the following questions must be answered or issues addressed, as appropriate, for each PCI case reviewed:

(a) For PCI cases in which the patient received emergency PCI due to acute coronary syndrome, did the operator appropriately diagnose the patient as suffering from acute coronary syndrome?

(b) What is the estimated numerical percentage of stenosis, based on visual assessment of the patient's angiogram?

(c) Was treatment of the lesion appropriate based on current ACCF/AHA Guidelines or ACCF/AHA/SCAI Guidelines?

(d) Is the patient's clinical situation one that is not addressed by the current ACCF/AHA Guidelines or ACCF/AHA/SCAI Guidelines?

(e) Was it appropriate to treat the lesion, in the reviewer's judgment and understanding of good clinical care?

(f) Was PCI successful, partially successful, or unsuccessful?

(i) A partially successful PCI procedure is defined as achievement of twenty percent to less than or equal to fifty percent residual stenosis and TIMI 3 flow.

(ii) An unsuccessful PCI procedure is defined as greater than twenty percent residual stenosis with a stent, or greater than fifty percent residual stenosis with plain balloon angioplasty or less than TIMI 2 flow.

(g) Was there any complication during the procedure or resulting from the procedure, based on the reviewer's evaluation of the angiogram, cardiac catheterization laboratory report, and the patient discharge summary?

(h) Is there documentation in the patient record that treatment other than PCI, such as cardiac surgery, was considered in cases where it would have been appropriate to consider alternative treatment, based on current ACCF/AHA Guidelines?

(i) Are there additional comments regarding the patient's procedure, appropriateness of treatment, or other issues, that the reviewer wants to provide based on the review of the angiogram, cardiac catheterization laboratory report, the patient discharge summary, or other information provided?

(2) Additional review. In addition to answering the required questions, an external review organization shall have a second reviewer evaluate all cases where a procedure was determined by the first reviewer to be rarely appropriate or inappropriate, based on the ACCF/AHA Guidelines or ACCF/AHA/SCAI Guidelines. If the judgment of the two reviewers conflicts, a third external reviewer shall also review the case.

D. Requirements for External Peer Review Organizations.

(1) Commission approval.

(a) To be approved by the Commission to conduct external peer reviews, an external peer review organization shall file an application in a form and manner specified by the Commission and shall demonstrate that the organization is appropriate for conducting external peer reviews, and has:

(i) A plan that describes an appropriate blinding process that the organization will use to assure that an external reviewer does not know the identity of any physician or the hospital that is undergoing the external review;

(ii) Appropriate and qualified external reviewers;

(iii) A detailed description of an appropriate process that will be used to distribute cases to reviewers; and

(iv) A description of an appropriate process for assuring consistency and quality among its reviewers.

(v) If the organization's external peer reviewers include at least one physician who is licensed to practice in Maryland or has privileges at a hospital that is part of a system with hospitals that provide PCI services in Maryland:

(i) Evidence that four or more hospitals from at least two health care systems are likely to participate,; and

ii) The organization will use a Commission-approved blinded process.

(2) The Commission may rescind its approval of an external peer review organization, if the Commission finds that the external peer review organization:

(a) Has not provided the level of quality review that the Commission views as necessary to ensure appropriate oversight of PCI services at Maryland hospitals; or

(b) Failed to comply with:

(i) Each standard for conducting external reviews of PCI cases for Maryland hospitals; or

(ii) Any condition placed on the Commission's approval of an external peer review organization.

(3) A hospital may use an external review organization that has not been approved by the Commission, provided that the hospital certify and, if requested by Commission staff, demonstrate as part of its application for a Certificate of Ongoing Performance that the external review organization conducted its review consistent with Commission standards for external reviews.

E. Qualifications of External Reviewer. In order to conduct an external review of an attempted or completed PCI under these regulations, a reviewer must have the minimum following qualifications:

(1) Be board certified in interventional cardiology, except for an interventional cardiologist who performed interventional procedures before 1998 or completed training before 1998 and did not seek board certification before 2003;

(2) Shall have practiced interventional cardiology, as evidenced by maintenance of hospital privileges and the provision of PCI services to patients, within the five-year period immediately prior to conducting the external peer review under this regulation; and

(3) Shall have a lifetime PCI case volume over 750 cases.

F. Review Schedule for External Review. A hospital shall maintain a consistent case review schedule.

(1) Quarterly review. The case review periods for quarterly reviews are January 1 to March 31; April 1 to June 30; July 1 to September 30; and October 1 to December 31.

(2) Semi-annual review. The case review periods for semi-annual reviews are either January 1 to June 30 and July 1 to December 31; or April 1 to September 30 and October 1 to March 31.

(3) A hospital shall timely submit its cases for external review and shall obtain a report on the results of the external review within three months of the closing date of the case review period for quarterly external reviews, and within four months of the closing date of the case review period for semi-annual external reviews.

(4) The dates for inclusion in the quarterly and semi-annual review schedules may be altered by the MHCC through publication of a dated posting on the Commission's website and

in the *Maryland Register*, and direct notification to the director of the cardiac catheterization laboratory or another appropriate contact designated by each hospital.

G. Data Sources Used for External Review. For each PCI case submitted for external review, a hospital shall provide the external review organization or its agent that will conduct blinding for the external peer review organization with the following patient information:

- (1) Medical history;
- (2) Physical exam;
- (3) Laboratory studies;
- (4) Angiogram;
- (5) Cardiac catheterization laboratory report;
- (6) Cardiac catheterization laboratory log sheet; and
- (7) Discharge summary.

H. Blinding of Cases for External Review. All PCI cases submitted for external review under these regulations shall be appropriately blinded in such a way that each medical record does not disclose, the following, by timing of submission, blinded information size, location, or otherwise:

- (1) The identity of the hospital where the PCI procedure under review was performed; and
- (2) The identity of the physician who performed the PCI.

.09 Internal Review of Interventionalists.

For a hospital that evaluates the performance of interventionalists annually or semi-annually through an internal review, cases shall be randomly selected by a person who is independent from interventional cardiologists with privileges at the hospital and from the hospital's cardiac catheterization laboratory.

(1) The procedure for case selection is the following:

(a) A hospital shall create a list of the medical record numbers for all PCI cases (excluding STEMI cases) for the applicable review period and then the selected independent person shall generate a random number to assign to each case through the use of software that randomly generates numbers within a specified range greater than or equal to the number of PCI cases for the applicable review period for the hospital.

(b) After each PCI case on the list has been assigned a random number, the selected independent person shall order the cases on the list according to the assigned random numbers, from lowest to highest.

(c) The selected independent person shall then select the required number of cases beginning with the lowest random number assigned to a case and choosing consecutive cases on the list until the required number of cases has been reached.

(d) The list of selected cases shall be provided to the cardiac catheterization laboratory director or other individual responsible for the internal review of interventionalists.

(2) Documentation. A hospital shall retain documentation of the random selection of cases until a Certificate of Ongoing Performance that covers each applicable review period has been granted by the Commission.

.10 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 the population of a health planning region is estimated by calculating the cardiac surgery use rates by each age group in the 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 by summing the five annual percentage changes in use rates calculated for the six-year time period and dividing that sum by five.

(4) The estimated use rate of the resident population in each 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 patients residing outside of a health planning region, including 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 the health planning region. 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 patients residing outside a health planning region is the same as the proportion of these patients who underwent cardiac surgery in the health planning region in the base year.

E. Data Sources.

(1) Cardiac Discharges.

(a) The source of cardiac discharge data for hospitals in the District of Columbia is the discharge abstract for these hospitals.

(b) The source of cardiac discharge data for hospitals in Maryland is the discharge abstract for Maryland hospitals.

(2) Population.

(a) Base year population data, by area of residence and age, is obtained from the following sources.

(i) Maryland population is obtained from the most recent Maryland Department of Planning projections; and

(ii) District of Columbia population is obtained from the most recent projections prepared by a local government agency charged with preparing the projections, or from the U.S. Census Bureau.

(b) Projections of future target year population, by area of residence and age, are obtained from the following sources:

(i) Maryland population is obtained from the most recent Maryland Department of Planning projections; and

(ii) District of Columbia population is obtained from the most recent projections prepared by a local government agency charged with preparing the projections, or from the U.S. Census Bureau. If official population projections are not available through a local government agency or the U.S. Census Bureau or have not been updated for over three years, a commercial vendor will be used.

(3) Patient Residence. The Commission may use either the county variable or the zip code area variable as the location of residence for discharges from Maryland and District of Columbia hospitals, provided that the variable chosen is relied upon for all discharges unless Commission staff determines that use of the variable would perpetuate a known reporting error.

F. 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.

G. Projection of Cardiac Surgery Utilization by the Adult Population.

(1) Use Rate Calculations

(a) Calculate the rate of cardiac surgery for the residents of each health planning region, for each of the six most recent years of available data for each adult age group, by dividing the total number of cardiac surgery cases performed at hospitals with a cardiac surgery program for each adult age group, in each health planning region, by the corresponding population for each health planning region.

(b) Calculate the average annual percentage change in cardiac surgery use rates for each adult age group, in each health planning region, by summing the five percentage changes in use rates calculated for the six-year time period and dividing this sum by five.

(c) Calculate the target year use rate of cardiac surgery cases for each adult age group, in each health planning region, by multiplying one plus the average annual percentage change in the cardiac surgery use rate for each age group, raised to the sixth power, by the corresponding use rate in the base year.

(2) Projection of Total Utilization

Calculate the projected utilization of cardiac surgery in the target year for the residents of each health planning region, for 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 and health planning region.

(3) Adjustments to Projections Due to Migration Patterns

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

(b) Calculate the proportion of patients in each adult age group and each health planning region who underwent cardiac surgery in the health planning region where they reside by dividing the number of cardiac surgery discharges for patients who had surgery in the health planning region where they reside, by adult age group and health planning region, by the total number of cardiac surgery discharges for residents of the corresponding health planning region and adult age group.

(c) Calculate the proportion of patients in each adult age group and each health planning region who underwent cardiac surgery in a health planning region other than where they reside by dividing the number of cardiac surgery discharges for patients who had surgery outside the health planning region where they reside, by adult age group and health planning region, by the total number of cases for residents of the corresponding health planning region and age group.

(d) For the target year, allocate cardiac discharges for residents of the health planning regions to each health planning region according to the migration patterns calculated in (b) and (c).

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

Allocate to each health planning region the proportion of adult patients from outside the health planning regions, including residents of foreign countries and patients of unknown origin, and including those from an unknown county or city in Maryland, who underwent cardiac surgery in each health planning region in the base year.

H. Projection of Cardiac Surgery Utilization by the Pediatric Population.

(1) Use Rate Calculations

(a) Calculate the rate of cardiac surgery for residents of each health planning region 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 cardiac surgery cases performed on residents of each health planning region at a hospital with a cardiac surgery program, by the corresponding 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, raised to the sixth power, by the corresponding use rate in the base year.

(2) Projection of Total Utilization

Calculate the projected utilization of cardiac surgery in the target year for 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.

(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 base year proportion of pediatric patients in each health planning region who underwent cardiac surgery in the health planning region where they reside by dividing the number of pediatric patients who had cardiac surgery in the health planning region where they reside by the corresponding total number of pediatric patients who are residents of the health planning region, for each health planning region.

(c) Calculate the base year proportion of pediatric patients in each health planning region who underwent cardiac surgery in a health planning region other than where they

reside by dividing the number of pediatric patients who had cardiac surgery outside the health planning region where they reside by the corresponding total number of pediatric patients who are residents of the health planning region, for each health planning region.

(d) For the target year, allocate cardiac discharges for residents of the health planning regions to each health planning region according to the migration patterns calculated in (b) and (c).

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

Allocate to each health planning region with pediatric cardiac surgery services the actual number of pediatric patients from outside the planning regions, 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 with pediatric cardiac surgery services in the base year.

I. Mathematical Formulas.

(1) The utilization projection methodology described in sections G and H of this regulation are shown in this section in mathematical form.

(2) Terms used in sections F and G of this regulation are defined in alphabetical order as follows:

<u>Term</u>	<u>Definition</u>
f	Future year (values 1, 2, 3, 4, 5, 6; 1 is first future year)
h	Historic year (values 1, 2, 3, 4, 5, 6; 1 is most recent year)
i	Health planning region where patient resides (Eastern, Western, Baltimore Upper Shore, and Washington Metropolitan)
j	Age groups (0-14 (pediatric); 15-44, 45-64, 65 and older)
k	Location of care (Eastern, Western, Baltimore/Upper Shore, and Washington Metropolitan)
$ACHG_{ihj}$	Annual historic change in rate of cardiac surgery by health planning region where patients reside and age group.
$AVGCHG_{ihj}$	Average annual historic change in rate of cardiac surgery by health planning region where patients reside.
$BCASES_{ij}$	Base year number of cardiac surgery cases by age group and health planning region where patients reside.
$BCASES_{ijk}$	Base year number of cardiac surgery cases by age group, health planning region where patients reside, and location of care.
$BDIS_{jk}$	Number of discharges in the base year by location of care and age group for residents of the health planning regions.

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DIS _{ihj}	Cardiac surgery discharges originating in the health planning region, historic year, and age group.
DIS_OTH _{jk}	Number of discharges by location of care and age group for patients from outside the health planning regions (foreign, unknown origin, unknown jurisdiction in Maryland).
HPR_T _{jk}	Target year number of cases by age group and location of care after adjustments for the migration pattern in the base year for discharges of residents of the health planning regions and the proportion of discharges from outside the health planning regions.
LPCT _{ijk}	Proportion of patients who underwent cardiac surgery in the health planning region where they reside, by age group.
OTHPCT _{jk}	For the base year, the proportion of discharges, by age group and location of care, who reside outside the health planning regions, including foreign countries, and discharges of unknown origin, including an unknown county or city in Maryland.
OUTPCT _{ijk}	Proportion of patients who underwent cardiac surgery in a health planning region other than where they reside, by age group.
POP _{ihj}	Population by health planning region, historic year, and age group.
RATE _{ihj}	Historic rate of cardiac surgery by health planning region and year and age group
TCASES _{ij}	Target year number of cardiac surgery cases by age group and health planning region where patients reside.
TDIS _{jk}	Target year number of discharges by location of care and age group accounting for in-migration and out-migration by residents of the health planning regions.

TPOP_{ij} Target year population by age group and health planning region where patients reside.

TRATE_{ij} Target year use rate of cardiac surgery cases by age group and health planning region where patients reside.

Formulas

(1) Use Rate Calculations

RATE_{ihj} (DIS_{ihj})/(POP_{ihj})

CHG_{ih} (RATE_{ihj} - RATE_{i(h+1)j})/(RATE_{ihj}), where h=1 to 5;

AVGCHG_{ihj} [$\sum_{ihj} (ACHG_{ihj})$]/5, where h=1 to 5;

TRATE_{ij} (1+AVGCHG_{ihj})⁶*(RATE_{ihj})

(2) Projection of Total Utilization

TCASES_{ij} TRATE_{ij}*TPOP_{ij}

(3) Adjustments to Projections Due to Migration Patterns

LPCT_{ijk} (BCASES_{ijk})/(BCASES_{ik}), where i=k;

OUTPCT_{ijk} (BCASES_{ijk})/(BCASES_{ik}), where i≠k;

TDIS_{jk} [$\sum_{ijk} \text{OUTPCT}_{ijk} * \text{TCASES}_{ij}$]+(LPCT_{ijk}*TCASES_{ij})

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

OTHPCT_{jk} (DIS_OTH_{jk})/(BDIS_{jk})

HPR_T_{jk} (TDIS_{jk})*(1+OTHPCT_{jk})

.11 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) *Acute coronary syndrome* means a group of conditions resulting from reduced blood flow to the heart that requires immediate medical intervention such as cardiac surgery or PCI.

(2) *ACCF/AHA Guidelines* means the adopted Guidelines of the American College of Cardiology Foundation/American Heart Association for Management of Patients with Acute Myocardial Infarction that are referenced by a dated posting on the MHCC website and published in the *Maryland Register*.

(3) *ACCF/AHA/SCAI Guidelines* means the adopted Guidelines of the American College of Cardiology Foundation/American Heart Association/ Society for Cardiovascular Angiography and Interventions that are referenced by a dated posting on the MHCC website and published in the *Maryland Register*.

(4) *Approved plan of correction* means a plan submitted by a hospital to Commission staff that details how the hospital will address deficiencies in its compliance with the standards and policies in this chapter, including a timeline for the hospital's proposed actions that has been approved by Commission staff.

(5) *Board-certified* means that the physician is certified by a public or private board, including a multidisciplinary board, and that the certifying board is one of the following: a member of American Board of Medical Specialties; an American Osteopathic Association certifying board; the Royal College of Physicians and Surgeons of Canada; or the College of Family Physicians of Canada.

(6) *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 (9th Revision) procedure codes: 37-.21-37.29 or the corresponding International Classification of Diseases (10th 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.

(7) *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 (9th Revision) procedure codes: 35.00-35.09; 35.10-35.51; 35.53-35.95; 35.97-35.99; 36.03; 36.10-36.19; 36.31; 36.91-36.99; 37.10-37.11; 37.32- 37.33; and 37.37; or the corresponding International Classification of Diseases (10th 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.

(8) *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 (9th Revision) procedure codes: 36.10-36.19 or the corresponding International Classification of Diseases (10th 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.

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

(10) *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.

(11) *External review* means an independent review conducted in accordance with this Chapter by one or more physicians who meet the minimum qualifications in Section .08E for an external reviewer and who are not affiliated with the hospital or health care system associated with the cases being reviewed. A physician licensed in Maryland may not perform an external review for a Maryland hospital unless the physician is performing external review through a Commission-approved external review organization that involves four or more hospitals and two or more health systems and uses a Commission-approved blinded system.

(12) *External review organization* means an organization that has contracted with a hospital to provide external review of PCI cases and that maintains appropriate oversight of each external reviewer who evaluates PCI cases for a hospital. The term includes an organization that has been approved by the Commission, as provided in Section .08D, that uses a Commission-approved blinded system for external review.

(13) *External reviewer* means a physician who meets the minimum qualifications in Regulation .08E and has agreed to conduct an external review of PCI cases for a hospital.

(14) *Focused review* means an investigation of limited scope that is undertaken by one or more independent auditors with clinical expertise in order 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. A nurse auditor may evaluate the accuracy of data reporting; a physician auditor shall evaluate the quality of clinical care.

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

(16) *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.

(17) *Minority* means a person who has one or more of the following ethnic heritages: American Indian or Alaskan Native; Asian or Pacific Islander; African American; 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.

(18) *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 (9th Revision) procedure codes: 36.01; 36.02; 36.05-36.07 or the corresponding International Classification of Diseases (10th Revision) procedure codes.

(19) *Plain balloon angioplasty* 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 through inflating a balloon, without insertion of a stent.

(20) *Plan of correction.* A plan submitted by a hospital to Commission staff that details how the hospital will address deficiencies in its compliance with the standards and policies in this chapter, including a timeline for the hospital's proposed actions.

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

(22) *Proposed service area* means the zip code areas from which the applicant expects to draw patients for cardiac surgery, when a new cardiac surgery program is proposed, or the zip code areas from which the applicant expects to draw patients for percutaneous coronary intervention procedures, when an applicant proposes to add an elective or primary PCI program.

(23) *Rating cycle* means the time period used by the Society of Thoracic Surgeons to assign a star rating to hospitals participating in the STS-ACSD. Currently, the STS-ACSD composite rating for CABG for a cardiac surgery program is based on rolling 12-month periods that overlap by six months with the prior rating cycle.

(24) *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).

(25) *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 a specific type of cardiovascular services at a hospital, either cardiac surgery, primary PCI, or elective PCI services, for the most recent 12 month period of data available.

(26) *ST-segment elevation myocardial infarction (STEMI)* means a heart attack in which there is cardiac muscle damage resulting from an acute interruption of blood supply to a part of the heart and can be demonstrated by a change of ST-segment elevation on an electrocardiogram.

(27) *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.

(28) *Thrombolysis in myocardial infarction (TIMI) flow* means the scoring system from zero to three referring to levels of coronary blood flow assessed during percutaneous coronary angioplasty. TIMI 0 flow (no perfusion) refers to the absence of any antegrade flow beyond a coronary occlusion. TIMI 1 flow (penetration without perfusion) is faint antegrade coronary flow beyond the occlusion, with incomplete filling of the distal coronary bed. TIMI 2 flow (partial reperfusion) is delayed or sluggish antegrade flow with complete filling of the distal territory. TIMI 3 flow is normal flow which fills the distal coronary bed completely.