MARYLAND
HEALTH CARE
COMMISSION

DRAFT FOR INFORMAL PUBLIC COMMENT

STATE HEALTH PLAN FOR FACILITIES AND SERVICES: SPECIALIZED CARDIOVASCULAR SERVICES COMAR 10.24.17

Written Public Comments
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At 5:00 p.m.
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State Health Plan for Facilities and Services: Cardiac Surgery and Percutaneous Coronary Intervention Services

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

.02 Introduction.

A. Purposes of the State Health Plan.

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

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources; and

(2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in services for health care facilities are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, methodologies, standards, and criteria that the Commission uses in making decisions on applications for Certificates of Need, Certificates of Conformance, and Certificates of Ongoing Performance.

B. Legal Authority of the State Health Plan.

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

(1) The methodologies, standards, and criteria for CON review; and

(2) Priority for conversion of acute capacity to alternative uses where appropriate.

Health-General §19-120.1, which was enacted in 2012, directs the Commission to update to the State Health Plan to establish a process and adopt standards for the granting of Certificates of Conformance and Certificates of Ongoing Performance. A Certificate of Conformance is an approval issued by the Commission that allows an acute general hospital to establish emergency percutaneous coronary intervention (PCI) services or elective PCI services and provide those services for a specified period of time. At the end of that period of time, the hospital must renew its authorization to provide the specific PCI service or services by obtaining a Certificate of Ongoing Performance. A Certificate of Ongoing Performance is an approval issued by the Commission that renews the authorization of the hospital to continue to provide cardiac surgery services, emergency PCI services, or emergency and elective PCI services for a specified period of time, based on the hospital's record in providing the involved service at an acceptable level of performance and quality. Before the end of the specified time period, the hospital must obtain a renewal of its Certificate of Ongoing Performance for the service.

C. Organizational Setting of the Commission.

The Commission is an independent agency located within the Department of Health and Mental Hygiene for budgetary purposes. The purposes of the Commission, as enumerated at Health-General §19-103(c), include responsibilities to:

(1) Develop 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) Promote 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 has only allowed hospitals to perform percutaneous coronary intervention, a treatment for obstructed coronary arteries, at hospitals with cardiac surgery on-site. Beginning in 2006, the Commission permitted a hospital 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), but emergency cardiac surgery may be required for a complication of, or inability to satisfactorily complete, PCI. As cardiologists gained experience with primary PCI and better techniques evolved, the risks of the procedure declined and results improved. Multiple, well-structured, multi-site clinical trials have validated the safety and efficacy of performing primary PCI for the treatment of STEMI in hospitals without on-site cardiac surgery.[1] In 2012, a team led by Dr. Thomas Aversano,

[1] Aversano, T, Aversano, L, Passamani, E, Knatterud, G., Terrin, M., Williams, D., Forman, S. "Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery." *New England Journal of Medicine.* 2002 April 17; 287(15):1943-51. Jacobs AK, Normand SLT, Massaro JM, Cutlip DE, Carrozza JP Jr, Marks AD, Murphy N, Romm IK, Biondolillo M, Mauri L; MASS COMM Investigators. "Non-emergency PCI at Hospitals with or without On-site Cardiac Surgery." *New England Journal of Medicine.* 2013 April 18;368:1498-508; Ting HH, Raveendran G, Lennon RJ, et

Associate Professor of Medicine, Johns Hopkins School of Medicine presented new research from a second multi-site clinical trial (C-PORT E), which found that elective (non-primary) PCI could be performed safely and effectively under certain circumstances and conditions at hospitals without on-site cardiac surgery.[2] Ten Maryland hospitals participated in one or more of these research studies.

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

This chapter of the State Health Plan is applicable to the establishment of a new adult or pediatric cardiac surgery program, the establishment of emergency 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 programs.

E. Effective Date.

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

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al. "A Total of 1,007 Percutaneous Coronary Interventions without On-site Cardiac Surgery: Acute and Long-term Outcomes." *Journal of the American College of Cardiology.* 2006 April 18; 47:1713-21.

[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.* 2012 May 10; 366(19):1792-802.

.03 Issues and Policies.

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

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

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

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

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

Policy 5: A provider of cardiac surgery and PCI services, as well as a provider of 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 utilization patterns, geographic proximity, and the volume of cardiac surgeries for the population in each jurisdiction in the

region. Each health planning region is defined by the jurisdictions included. 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, Wicomico, Worcester, and Somerset Counties.

Western Region: Garrett, Allegany, and Washington Counties.

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

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

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 cost of inpatient and outpatient hospital care. This system was established through the Medicare waiver in §1814(b) of the Social Security Act. Under this waiver, Maryland has been allowed to regulate rates for all payers, including Medicare, as long as its regulatory system kept the rate of growth in Medicare cost-per-discharge below the national average rate of growth. Recently, it has been projected that Maryland could fail to meet the conditions required for maintaining the all-payer system under this waiver test.[4] As a result, the Health Services Cost Review Commission, the Maryland state agency that governs the State's all-payer system has been negotiating with the Centers for Medicare and Medicaid Services on how to reform its all-payer system.[5]

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[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>

[4] Redmon, P.D. "The Health Services Cost Review Commission FY 2014 Budget: Presentation to the Budget Committees of the Maryland General Assembly" <http://www.dbm.maryland.gov/agencies/operbudget/FY2013Testimony/M00R0102.pdf>

[5] Ibid.

In September 2013,the Maryland Department of Health and Mental Hygiene released for public comment an updated draft application for modernization of Maryland's all-payer model to the Centers for Medicare and Medicaid Services.[6] If the proposal is implemented, this proposal would move the Maryland hospital rate setting system away from a focus on the costs of inpatient discharges to a focus on the overall per capita health care expenditures of Marylanders. Growth in inpatient and outpatient expenditures would be limited by growth in the State's long-term gross state product. Given the uncertainty regarding reform of the all-payer system in Maryland at the time of this writing in the Fall of 2013, the approval of new cardiac surgery or new PCI programs that require capital investment by hospitals should be delayed until more certainty is assured concerning how hospitals will be reimbursed for services. Delaying decisions on these types of projects will facilitate informed decision-making by the Maryland Health Care Commission by making it easier to estimate how changes in the utilization of services will affect revenue and costs for individual hospitals and the health care system.

Quality of Care

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

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[6] Maryland Department of Health and Mental Hygiene. "Maryland's All-Payor Model Proposal to the Center for Medicare and Medicaid Innovation." September 27, 2013. <http://dhmh.maryland.gov/docs/Maryland%20Model%20Design,%20Waiver%20Application,%20Revised%20September%202013%20with%20cover%20letter.pdf>

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

Regarding percutaneous coronary intervention, numerous studies support that a relationship exists between volume and patient outcomes, with lower volume predicting a greater need for CABG and higher in-hospital mortality.[9] One meta-analysis that examined the outcome

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

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

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

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 patient 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.[10] This finding was considered by the CAG in its recommendations regarding the target volumes that should be achieved for hospitals that provide emergency or emergency and elective PCI services without on-site cardiac surgery.

Access to Care

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

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

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

Talbot).[13] Cardiac interventional centers are hospitals that have authorization from MHCC to provide primary PCI and that accept STEMI patients who meet specific criteria determined by the *Maryland Medical Protocols for EMS Providers.*[14]

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 System, and representatives of the Maryland Chapter of the American College of Cardiology and the Maryland Chapter of the Society of Thoracic Surgeons, and others as appropriate. Representatives of providers of cardiac surgery and PCI services will be selected to cover a wide geographic range and multiple health care systems. The Commission shall designate a Chair and Vice-Chair of the Committee and may form subcommittees of the CSAC as needed.

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

.04 Commission Program Policies

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

[14] Maryland Emergency Medical Services System. "Statewide STEMI Map Narrative." <http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/Map_narrative_STEMI.pdf>

A. Consideration of New Programs

(1) Cardiac Surgery

(a) A Certificate of Need is required to establish a cardiac surgery program.

(b) At least one full year of reporting on the quality measures recommended the CSAC and approved by the Commission for the evaluation of Maryland cardiac surgery programs must be publically available, before the Commission will consider an application for a CON to establish cardiac surgery services. In addition, at least five percent of the data on which these quality measures are based must have been audited externally for accuracy.

(c) The hospital rate setting system established by the Health Services Cost Review Commission must be adequately stable to allow for an evaluation of the future costs and benefits of a new cardiac surgery program. This determination will be made in consultation with the Health Services Cost Review Commission.

(d) A hospital must have provided both primary and elective PCI services for at least three years before filing a application for a CON to establish cardiac surgery services.

(e) A new cardiac surgery program will not be considered in a health planning region, if the most recently approved program in the health planning region has been in operation less than three years.

(f) 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 conditions in .04A(1)(a)-(e) are met.

(2) Elective PCI

(a) A hospital must 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 must 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.

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 shows that the population in the primary service area of the proposed program is receiving suboptimal therapy for STEMI. This review must 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. A proposal 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 PCI

(a) A hospital must 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 periodically in the *Maryland Register*. All proposals will be considered in accordance with the published review schedule, except when an applicant proposes to establish both primary and non-primary PCI services pursuant to .04(2)(c).

B. Closure of Programs

(1) Cardiac Surgery

Closure of a cardiac surgery program will be evaluated by the Commission under the following circumstances:

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

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

(c) A new cardiac surgery program fails to achieve a volume of at least 200 cardiac surgery cases in the second year of operation.

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

(2) Primary and Elective PCI

(a) Closure of a primary or elective PCI program will be evaluated by the Commission when a program fails to comply with standards of ongoing performance after the program has been given an opportunity to address deficiencies identified by the Commission through an approved plan of correction.

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

C. Relocation of Programs

(1) Cardiac Surgery

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

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

(2) Elective and Primary PCI Services

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

.05 Certificate of Need Review Standards for Cardiac Surgery Programs

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

A. Cardiac Surgery Standards

(1) Minimum Volume Standard

An applicant must 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 250 cardiac surgery cases in the second full year of operation; the program must 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 must 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 must attain a minimum annual volume of each type of cardiac surgery cases by the end of the second year of operation.

(d) The applicant's demonstration of compliance with the Minimum Volume and Impact standards of this Chapter shall address the most recent published utilization projection of cardiac surgery cases in Regulation Part .08 for the health planning region in which the applicant hospital is located and any other health planning regions from which it projects drawing 20 percent of more of its patients. The applicant shall demonstrate that its volume projections and impact analysis are consistent with the projection in Regulation .08 or, alternatively, demonstrate

why the methods and assumptions employed in the Part .08 projections are not reasonable as a basis for forecasting case volume.

(2) Impact

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

(a) Compromise the financial viability of the cardiac surgery services at an affected hospital; or
(b) Result in an existing cardiac surgery program with an overlapping service area dropping below an annual volume of 200 cardiac surgery cases; or
(c) Result in the loss of additional volume at an existing cardiac surgery program that has an annual volume of less than 200 cardiac surgery cases and that has an overlapping service area .

(3) Quality

An applicant must demonstrate its commitment to provide high quality health care.

(a) 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) 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;

(v) Establish mechanisms for monitoring long-term outcomes of discharged patients.

(b) An applicant must demonstrate that the quality of care for cardiac surgery patients at an existing cardiac surgery hospital in its health planning region or an adjacent health planning region is unlikely to be negatively affected by the addition of the proposed new program.

(4) Cost Effectiveness

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

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

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

(5) Access

(a)An applicant that justifies a new program, in whole or in part, based on inadequate access to cardiac surgery services in a health planning region shall:

(i) Demonstrate that access barriers exist; and

(ii) Present a detailed plan for addressing such barriers.

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

(6) Need

(a) An applicant must demonstrate that a new program is needed based on projected demand for cardiac surgery by the population to be served.

(b) The applicant's need analysis must account for 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 20 percent of more of its patients.

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

(7) Preference in Comparative Reviews

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

(a) the applicant whose proposal is the most cost effective for the health care system.

(b) the applicant with an established record of cardiovascular disease prevention and early diagnosis programming, that includes provisions for educating patients about treatment options.

(c) the 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.

.06 Certificate of Conformance Criteria

A. Primary PCI Services

(1) General Standards

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

(2) Need

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

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

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

(ii) Is receiving suboptimal therapy for STEMI.

(4) Institutional Resources

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

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

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

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

(f) A hospital must 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 must include protocols for both routine and usual emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency coronary artery bypass graft (CABG) surgery, and primary angioplasty system failure. In addition, there must be an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMIs occur at the hospital.

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

(i) The hospital must 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 must have a formal written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

(5) Quality

(a) A hospital must 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 primary PCI patients.

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

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

(i) Include a review of angiographic images; and

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

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

(6) Physician Resources

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

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

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

(b) Cases performed during fellowship training cannot be counted in calculating a physician's compliance with this standard.

(7) Patient Selection

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

(a) A patient 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) A patient 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) A patient 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) A patient 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

An applicant seeking to establish elective PCI services must meet all applicable criteria for a Certificate of Conformance for a primary PCI program, and must meet the following additional requirements:

(1) Need

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

(3) Financial Viability

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

(4) Quality

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

.07 Certificate of Ongoing Performance

A. Cardiac Surgery

(1) Schedule of Reviews

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

(2) Focused Reviews

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

(3) Data Collection

Each cardiac surgery program shall participate in uniform data collection and reporting. This requirement is met through participation in the STS-ACSD registry, with submission of duplicate information to the Maryland Health Care Commission. Each cardiac surgery programs 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 must develop a formal, regularly scheduled (meetings every other month) cardiac surgery case reviews that requires attendance by physicians, nurses, and technicians who care for cardiac surgery patients.

(b) The hospital shall conduct an annual external review of five percent of randomly selected cardiac surgery cases.

(c) The hospital shall evaluate the performance of each cardiac surgeon through an annual review of:

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

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

(d) The performance review shall:

(i) Include a review of angiographic images; and

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

(e) 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 must meet all performance standards established in statute or in State regulations. Applicable performance measures include:

(i) The hospital shall maintain a composite score of two stars or higher; if the composite score from the STS-ACSD registry is one star for four consecutive six-month reporting periods then the program may be closed due to concerns regarding the quality of care.

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

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

(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 must submit an acceptable plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff.

(d) The Commission may require the successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its cardiac surgery program.

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

(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 target volume of 100 cardiac surgery cases may be subject to a focused review.

(c) If the focused review indicates that the hospital's cardiac surgery services do not meet acceptable quality standards, the Commission may require the submission and successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its cardiac surgery program.

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

B. Elective PCI Program

(1) Schedule of Reviews

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

(2) Focused Reviews

Commission staff may review a program's clinical records at any time for the purpose of auditing data. In addition, reported patient safety concerns or aberrations in data identified by Commission staff may lead to a focused review that investigates the quality of patient care or the

accuracy of the data. A hospital must cooperate with Commission staff, and other persons acting on behalf of the Commission, and must timely provide all information and data requested.

(3) Data Collection

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

(4) Quality

(a) The hospital must 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 primary PCI patients.

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

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

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

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

(e) The performance review shall:

(i) Include a review of angiographic images; 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 must meet all performance standards established in statute or in State regulations. Applicable performance measures include that a hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

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

(c) A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance following a focused review must submit an acceptable plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff.

(d) The Commission may require the successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its cardiac surgery program.

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

(6) Physician Resources

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

(b) A physician who does not perform an annual minimum of 50 PCI procedures averaged over a 24- month period, and who took a leave of absence of less than one year during the 24-month period measured, may resume the provision of primary PCI provided that:

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

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

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

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

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

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

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

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

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

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

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

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

(7) Volume Requirements

(a) The target volume for existing programs with both primary and non-primary PCI services is 200 cases annually

(b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subjected to a focused review.

(c) If the focused review indicates that the hospital's PCI services do not meet acceptable quality standards, the Commission may require the submission and successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its elective PCI services.

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

C. Primary PCI Program

(1) Schedule of Reviews

A review schedule for Certificates of Ongoing Performance will be published in the *Maryland Register*. A Certificates of Ongoing Performance will be granted for a maximum of five years.

The Commission at its discretion may choose to grant a Certificates of Ongoing Performance for a shorter period of time.

(2) Focused Reviews

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

(3) Data Collection

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

(4) Institutional Resources

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

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

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

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

(f) The hospital must 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.

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

(h) The hospital must 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 must have a formal written agreement with an advanced cardiac life support emergency medical services provider that 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 must 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 primary PCI patients.

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

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

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

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

(e) The performance review shall:

(i) Include a review of angiographic images; 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 must meet all performance standards established in statute or in State regulations. Applicable performance measures include that a hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

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

(c) A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance following a focused review must submit an acceptable plan of correction to the Commission within 30 days of receiving notice of the failure from Commission staff.

(d) The Commission may require the successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its cardiac surgery program.

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

(7) Physician Resources

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

(b) A physician who 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.

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

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

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

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

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

(8) Volume

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

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

(c) If the focused review indicates that the hospital's PCI services do not meet acceptable quality standards, the Commission may require the submission and successful and timely completion of an acceptable plan of correction before a hospital is granted a Certificate of Ongoing Performance for its elective PCI services.

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

(8) Patient Selection

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

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

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

(d) A patient who experienced 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.

.08 Utilization Projection Methodology for Cardiac Surgery

A. Period of Time Covered.

(1) The base year from which projections are made is the most recent data for a 12-month period available from the Commission's uniform hospital discharge abstract data set, and from the Washington, D.C. discharge abstract data set.

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

B. Age Groups and Services.

(a) Projection of the utilization of adult cardiac surgery services is made for the age groups 15-44, 45-64, and 65 years and over.

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

(c) Projection of the utilization of pediatric cardiac surgery is made for the age group 0-14 years.

(d) 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 Regional Service Areas:

(a) The migration pattern of patients to Regional Service Areas is assumed to remain the same from the base year to the target year; and

(b) For new programs, no adjustment in patient migration patterns will be made until at least one year after the program has come into operation.

D. Assumptions.

(a) The pediatric cardiac surgery use rate will remain constant from the base year to the target year.

(b) Projected adult cardiac surgery utilization for Maryland residents is estimated by calculating the cardiac surgery use rates by each age group in each Regional Service Area, for each of the most recent six years of reported data.

(c) The average annual percentage change in cardiac surgery use rates in each Regional Service Area for each age group is calculated for the six-year period by adding together the five values calculated for the average annual percentage change and dividing by five.

(d) The estimated use rate of Maryland residents by Regional Service Area is calculated from discharge data for Maryland and Washington, D.C. hospitals.

(e) The target year cardiac surgery use rate for each Regional Service Area is calculated from the use rate in the base year for residents in each age group for each Regional Service Area and the corresponding average annual percentage change in cardiac surgery use rates by age group and Regional Service Area for the six-year period.

(f) The projected utilization by out-of-state adult patients, including residents of Washington, D.C., and patients of foreign or unknown origin, is assumed to be equal to the number of discharges for patients who underwent cardiac surgery in the base year, for each of the Regional Service Areas. Discharges identified as Maryland residents, from an unknown jurisdiction, will be counted as patients of unknown origin in calculations of projected utilization.

(g) Projected utilization by out-of-state pediatric patients in the Baltimore Upper Shore and Metropolitan Washington Regions is the same as the actual volume of these patients who underwent cardiac surgery in each Regional Service Area in the base year.

E. Publication and Re-computation of Utilization Projections

(a) 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.

(b)Updated utilization projections are published as notices in the *Maryland Register* prior to use in Certificate of Need decisions.

(c) The most recently published utilization projections supersede any previously published projections.

(d) Published utilization projections remain in effect until the Commission publishes updated projections.

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

Use Rate Calculations

(a) Calculate the rate of cardiac surgery for Maryland residents for each of the six most recent years of available data for each age group, in each Regional Service Area by dividing the total number of surgery cases performed for each age group, in each Regional Service Area, by the corresponding Maryland population for each Regional Service Area.

(b) Calculate the average annual percentage change in cardiac surgery use rates in each 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 each age group, in each Regional Service Area, by multiplying the average annual percentage change in the cardiac surgery use rate for each group by the use rate in the previous year, beginning with the use rate in the base year.

Projection of Total Utilization

(a) Calculate the projected utilization of cardiac surgery in the target year for Maryland residents in each age group for each Regional Service Area by multiplying the projected target year cardiac surgery use rate by the corresponding projected target year population for each age group and Regional Service Area.

(b) The projected utilization of cardiac surgery for residents of Washington, D.C. is the same number of cases in the base year.

Adjustments to Projections Due to Migration Patterns

(a) Calculate the base year number of cardiac surgery cases for each age group and Regional Service Area from the hospital discharge abstracts for Washington, D.C. and Maryland hospitals.

(b) Calculate the proportion of patients in each age group and each Regional Service Area who underwent cardiac surgery in each Regional Service Area by dividing for each age group the number of patients who had cardiac surgery in each Regional Service Area by the corresponding total number of cardiac surgery patients for each age group and Regional Service Area who are residents of the Regional Service Area.

Allocation of Additional Utilization by Out-of-State Patients

Allocate to each Region the actual number of adult patients from other states, foreign countries, or of unknown residence, including those from an unknown county or city in Maryland, who underwent cardiac surgery in each Regional Service Area in the base year.

G. Projection of Cardiac Surgery Utilization by the Pediatric Population

Use Rate Calculations

(a) Calculate the rate of cardiac surgery for Maryland residents for each of the six most recent years of available data for the age group 14 years and under, in each Regional Service Area by dividing the total number of surgery cases performed in each Regional Service Area, by the corresponding Maryland population for each Regional Service Area.

(b) Calculate the average annual percentage change in open heart surgery use rates for the age group 14 years and under 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 age group 14 years and under, in each Regional Service Area, by multiplying the average annual percentage change in the cardiac surgery use rate by the use rate in the previous year, beginning with the use rate in the base year.

Projection of Total Utilization

(a) Calculate the projected utilization of cardiac surgery in the target year for Maryland residents age 14 years and under for each Regional Service Area by multiplying the projected target year cardiac surgery use rate by the corresponding projected target year population for the Regional Service Area.

(b) The projected utilization of cardiac surgery for residents of Washington, D.C. is the same number of cases in the base year.

Adjustments to Projections Due to Migration Patterns

(a) Calculate the base year number of cardiac surgery cases for the age group 14 years and under in each Regional Service Area from the hospital discharge abstracts for Washington, D.C. and Maryland hospitals.

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

Allocation of Additional Utilization by Out-of-State Patients

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

.09 Definitions

Acceptable Margin of Error means the 95 percent confidence interval calculated for a given data set.

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.

Cardiac Surgery means surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery.

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.

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

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

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

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

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

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

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

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