

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 14-078)**

Overview and Legal and Fiscal Impact

The regulations implement Chapter 418 of 2012 and Chapter 73 of 2014, establishing policies and standards for cardiac services, including certificates of need for cardiac surgery services, certificates of conformance for primary and elective percutaneous coronary intervention (PCI) services, and certificates of ongoing performance for cardiac surgery and primary and elective PCI services.

The regulation presents no legal issue of concern.

Special fund expenditures increase for Maryland Health Care Commission (MHCC) by an estimated \$420,000 annually beginning in fiscal 2015 for costs associated with regulation of hospitals performing cardiac surgery and emergency and elective PCI services. Expenditures can be handled with existing budgeted resources.

Regulation of COMAR Affected

Department of Health and Mental Hygiene:

Maryland Health Care Commission: State Health Plan for Facilities and Services:
Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary
Intervention Services: COMAR 10.24.17.01

Legal Analysis

Background

Regulation of cardiac services, including open heart surgery and PCI (also known as angioplasty), at Maryland hospitals has generated controversy for many years. Until 2012, cardiac services were regulated under the certificate of need (CON) program administered by MHCC. A hospital was required to have CON to perform cardiac surgery in order to provide PCI services. MHCC regulations authorized hospitals to provide emergency and, in some cases, elective PCI services by obtaining a waiver from CON.

Chapter 418 of 2012 made fundamental changes to the regulation of cardiac services. The law required, beginning July 1, 2012, an acute general hospital, except under specified circumstances, to obtain a certificate of conformance from MHCC before establishing emergency or elective PCI services. Emergency, also known as “primary” PCI, treats certain types of heart attacks. Elective, also known as “secondary” PCI, treats certain heart conditions

that are not considered emergencies. A CON is still required to establish cardiac surgery services.

Chapter 418 also required an acute general hospital to obtain and maintain a certificate of ongoing performance to continue to provide cardiac surgery services or emergency or elective PCI services. The law required MHCC to adopt regulations for certificates of conformance and certificates of ongoing performance and establish a clinical advisory group to recommend standards for inclusion in the regulations. MHCC was required to submit its proposed regulations to the Senate Finance Committee and the House Health and Government Operations Committee for a 60-day review and comment period.

In October 2013, MHCC provided a draft of proposed regulations regarding specialized cardiovascular services for public comment. The draft regulations required acute general hospitals to agree to the voluntary relinquishment of a cardiac surgery services CON. Both the Senate Finance and House Health and Government Operations committees sent correspondence to MHCC questioning the authority of MHCC to require voluntary relinquishment of the authority to provide cardiac surgery services as Chapter 418 of 2012 only authorized MHCC to require voluntary relinquishment of the authority to provide emergency or elective PCI services. The committees noted that “there should be specific legislative statutory authorization in order for the commission to have the authority to revoke or require voluntary relinquishment of a CON for cardiac surgery services.”

Chapter 73 of 2014 was enacted to address the committees’ concern. Chapter 73 required regulations adopted by MHCC to require, as a condition of the issuance of a certificate of conformance or a certificate of ongoing performance, that an acute general hospital agree to voluntarily relinquish its authority to provide cardiac surgery services if the hospital fails to meet the applicable standards established by MHCC. Chapter 73 took effect June 1, 2014.

Summary of Regulation

The proposed regulations implement Chapter 418 of 2012 and Chapter 73 of 2014. The regulations establish a new chapter of the State Health Plan for Facilities and Services – Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services. The chapter lays out several policies that serve as a foundation for specific standards relating to cardiac surgery and primary and elective PCI services. The chapter also defines four health planning regions for the purpose of planning and regulating cardiac services: eastern region, western region, Baltimore/upper shore region, and metropolitan Washington region (which includes the District of Columbia). The chapter notes that the volume of both cardiac surgery and PCI has steadily declined over the past several years and that geographic access to cardiac surgery and elective PCI is not a problem in the State, with respect to patient travel time or survival. Access to primary PCI remains a problem in some areas of the State, however, with Southern Maryland and the mid-Eastern Shore being the largest geographic regions beyond a 30-minute drive time to PCI in an emergency situation.

Commission Program Policies

In the new cardiac services chapter, the regulations establish policies for consideration of new cardiac surgery, elective PCI, and primary PCI programs. As in the past, a CON is required to establish cardiac surgery services. A hospital must 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. For both elective and primary PCI, a certificate of conformance is required to establish a program, unless a hospital is exempt from this requirement under the law. The law provides for exemptions for hospitals that were providing elective or primary PCI as of January 1, 2012 and met other requirements. Under the regulations, 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 the State that does not have sufficient access to emergency PCI services.

The regulations also establish policies for closure of cardiac surgery and PCI programs. The policies require closure of a program that fails to meet volume or quality standards and also fails to adequately correct deficiencies through an approved plan of correction.

Certificate of Need Review Standards for Cardiac Surgery Programs

The regulations require an applicant for a CON to establish or relocate cardiac surgery services to address and meet specific standards relating to minimum volume, impact on other providers of cardiac surgery services, quality, cost effectiveness, access, need, and financial feasibility. An applicant's demonstration of compliance with the minimum volume and impact standards must address the utilization projections of cardiac surgery cases adopted by MHCC for the health planning region in which the applicant hospital is located and any other health planning regions from which the hospital projects drawing 20% or more of its patients. The regulations also establish preference criteria that MHCC must use in the case of a comparative review of applications in which all policies and standards have been met by all applicants.

Certificate of Conformance Criteria

The regulations require an applicant for a certificate of conformance to establish primary PCI services to address criteria relating to need, access, institutional resources, quality, physician resources, and patient selection. An applicant for a certificate of conformance to establish elective PCI services must address criteria relating to need, volume, financial viability, quality, and patient selection. A hospital issued a certificate of conformance to establish either primary or elective PCI services must agree to voluntarily relinquish its authority to provide the service if it fails to meet the applicable standards for a certificate of conformance.

Certificate of Ongoing Performance

With certain exceptions, a hospital may not provide cardiac surgery services or PCI services without a certificate of ongoing performance. The regulations establish specific standards that a hospital must meet to obtain a certificate of ongoing performance. A hospital that, before the effective date of the regulations, has a pending application for a CON to relocate the hospital and its cardiac surgery and PCI services is exempt from the requirement to have a certificate of ongoing performance for 36 months following the relocation.¹ The regulations require MHCC to publish a separate review schedule for certificates of ongoing performance for cardiac surgery, elective PCI, and primary PCI. A certificate of ongoing performance may be granted for a maximum of five years. The regulations also provide for focused reviews at any

¹This provision addresses a particular concern of the University of Maryland Medical System relating to the proposed relocation of Prince George's Hospital Center and provides time for the relocated hospital to come into compliance with criteria for a certificate of ongoing performance.

time for the purpose of auditing data or in response to identified concerns. If a focused review finds that a hospital fails to meet a requirement for a certificate of ongoing performance, the hospital must submit a plan of correction. If the hospital does not successfully and timely complete an approved plan of correction, the hospital must, upon notice from MHCC, voluntarily relinquish its authority and close its cardiac surgery, elective PCI, or primary PCI services.

Legal Issue

The regulation presents no legal issue of concern.

Statutory Authority and Legislative Intent

MHCC cites §§ 19-109(a)(1) and 19-118 of the Health – General Article as authority for the regulation. Section 19-109(a)(1) authorizes MHCC to adopt rules and regulations to carry out the provisions of the Health Care Planning and Systems Regulation subtitle. Section 19-118 requires MHCC to adopt a State health plan at least every five years. The plan must include the methodologies, standards, and criteria for CON review.

MHCC also should have cited §§ 19-120(j) and 19-120.1 as authority for the regulation. Section 19-120(j) requires a health care facility to obtain a CON to establish a cardiac surgery program and, unless the health care facility meets statutory requirements for certificate of conformance and certificate of ongoing performance, PCI services. Section 19-120.1 requires an acute general hospital, beginning on July 1, 2012, to obtain a certificate of conformance before the hospital establishes PCI services. The section provides for exceptions from the certificate of conformance requirement. Section 19-120.1 also requires an acute general hospital to obtain and maintain a certificate of ongoing performance to continue to provide cardiac surgery, emergency PCI, or elective PCI services.

With these additions, the statutory authority is correct and complete. The proposed regulation complies with legislative intent.

Fiscal Analysis

Special fund expenditures increase for MHCC by an estimated \$420,000 annually beginning in fiscal 2015 for costs associated with regulation of hospitals performing cardiac surgery and emergency and elective PCI services. Expenditures can be handled with existing budgeted resources.

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapter 418 of 2012 and Chapter 73 of 2014, by updating the chapter of the State Health Plan for Facilities and Services that addresses quality, access, and cost for cardiac surgery and emergency and elective PCI services. The department advises that MHCC special fund expenditures increase by approximately \$420,000 annually beginning in fiscal 2015 to conduct routine audits of hospitals with both cardiac surgery and PCI services, obtain certain data analyses from the Society of Thoracic Surgeons or from vendors, and conduct independent focused reviews triggered by noncompliance issues related to specific standards in

the regulations. Expenditures can be handled with existing budgeted resources. The Department of Legislative Services concurs.

Impact on Budget

Special fund expenditures increase by an estimated \$420,000 annually for MHCC beginning in fiscal 2015 for costs associated with regulation of hospitals performing cardiac surgery and emergency and elective PCI services. Expenditures can be handled with existing budgeted resources.

Agency Estimate of Projected Small Business Impact

The department advises that the regulation has minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

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