Maryland Health Care Commission

HEALTH CARE FACILITIES PLANNING AND DEVELOPMENT

MHCC HISTORICAL OVERSIGHT OF CARDIAC SERVICES

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MARYLAND
Health Care
Commission

Statutory and Regulatory Authority of Maryland State Agencies Oversight of Cardiac Services in Maryland

Maryland State Agency Regulatory Oversight

- The ***MHCC*** is the primary State agency that has direct oversight of Cardiac Surgery and PCI by hospitals through its statutory authority found in Health General 19-120(j)(2)(iii) and 19-120.1. Regulatory oversight of cardiac services is shared with several other State agencies:
- ***Office of Health Care Quality***, Maryland Department of Health (MDH) provides oversight of health care facilities through Health General Article §19-319 – 19-324 through the licensure process. PCI oversight is complaint driven, and to qualify for a license, a hospital must have a Certificate of Need
- ***Health Services Cost Review Commission*** (HSCRC) is authorized by Health General 19-201, *et. seq* to review, approve and sets hospital rates, including those for cardiac services
- ***Maryland Institute for Emergency Medical Services Systems*** (MIEMSS) is responsible for the Emergency Medical System that coordinates emergency medical services in Maryland, the designation of trauma and specialty referral centers and establishes criteria for designation and evaluation of Cardiac Interventional, Comprehensive Stroke, Primary Stroke, and Thrombectomy-Capable Primary Stroke Centers. Education Article 13-504 and 13-509 and COMAR 30.08.16.

About Cardiac Surgery and Coronary Artery Bypass Graft (CABG)*

- **CABG** involves making a large incision in the chest and temporarily stopping the heart from beating. To open the chest, the surgeon will cut the breastbone (sternum) in half lengthwise and spread it apart to access the heart. Then, the surgeon will place tubes in the heart so blood can continue to be pumped throughout the body with the assistance of a heart-lung bypass machine.
- Federal law created CON programs in 1974 to eliminate unnecessary duplication in facilities and equipment, however, Maryland continued to support and operate the health planning and CON programs.
- In Maryland, as of July 1, 1988, a CON is required before the establishment of a new open heart surgery program. Approvals new cardiac surgery programs have evolved from the initial four to eleven programs.
- Recent approvals (Suburban and Luminis Health) have been competitive and resulted in judicial review of MHCC's decision.
- Factors that may impact the decision to add a new cardiac surgery program include clinical advances, technological, and demographic changes that affect volume and which translates into future need.
- Suburban and Luminis applications identified hospital initiatives to reduce health disparities in access to advanced cardiac services.

*SB 750/HB 1141 in the 2012 General Assembly Session changed the words "open heart surgery" in Health General §19-120(j)(2)(iii) to cardiac surgery to reflect current terminology.

About Percutaneous Coronary Intervention (PCI) primary and elective

- PCI is the treatment of occlusion or narrowing (also known as stenosis) of coronary arteries, through use of catheter-based techniques.
- ***Primary or Emergency PCI*** is the intervention during a heart attack (acute ST-segment elevation myocardial infarction, or STEMI) and is currently performed in 23 of Maryland's 43 general acute care hospitals
- ***Elective PCI*** is the intervention to treat occlusion of coronary arteries to restore blood supply to the heart muscle and help prevent heart attack, heart failure and other forms of heart disease. PCI (Emergency) is used to open a blocked artery while a heart attack is in progress. Elective PCI enables cardiologists to perform the procedure proactively to prevent heart attacks before they occur.
- Eleven of the 23 hospitals providing PCI also provide cardiac surgery.
- A principal commitment of MHCC, post the clinical trials of the 2000's has been to ensure Marylanders have access to ***primary PCI***, which is usually the first choice treatment for patients suffering from a STEMI.

The Evolution of Cardiac Services in Maryland

- 1980 – The first State Health Plan was adopted, open heart surgery services were available at four Maryland hospitals
- 1995 – MHCC regulations required co-location of PCI programs at hospitals with cardiac surgery
- 1996 - Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) study approved
- 1999 – Nine Maryland hospitals offered or had CON approval for OHS with addition of UPMC Western Maryland in that year
- 2000 – Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) study results
- 2004 - ACC and AHA guidelines revised in response to C-PORT to allow primary PCI at hospitals without cardiac surgery on site
- 2006 - MHCC began issuing waivers to primary PCI programs at non-cardiac surgery hospitals
- 2009 MHCC initiated a non-primary PCI research program to enable Maryland hospitals participation in C-PORT-E (Elective PCI without surgical backup) clinical trial

The Evolution of Cardiac Services in Maryland

- 2012 C-PORT-E concludes with publication of "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery" NEJM, March 25, 2012….

  "We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months."

- End of C-PORT-E meant Maryland hospitals without cardiac surgery on site could no longer perform PCI without new legislation
- 2012 legislation (HB 1141) directed the MHCC to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI
  - Establishing MHCC's authority over PCI at hospitals with and without cardiac surgery backup generally supported
  - Hospitals with cardiac surgery initially opposed on-going oversight of cardiac surgery
  - The Commission to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI. The legislation required the Commission to establish a Clinical Advisory Group (CAG) to advise MHCC on development of regulations to implement the new

Details of 2012 Legislation

- HB 1141, MHCC- Cardiac Surgery and PCI Services was triggered by:
  - Two high-profile stenting cases in Maryland hospitals in 2011 deemed to be the result of inadequate internal review generated a call to establish rigorous internal and external review of stenting practices in hospitals, combined with regular audits through external peer review, and
  - The C-PORT clinical research trials concluded in 2012 finding that elective (non-emergency) PCI could be performed safely in a hospital without on-site cardiac surgery, in combination with a 1999 study, that emergency PCI for certain heart attack patients performed in community hospitals was superior to traditional drug therapy research.
- MHCC was tasked to establish a new framework for oversight of PCI services that provided consistency for all hospitals
- Specifically, MHCC was to develop:
  - New mechanisms for oversight of services through certificates of conformance and certificates of ongoing performance;
  - New requirements for peer or independent review of randomly selected and difficult or complicated PCI cases ; and
  - A clinical advisory group to provide guidance to the Commission on appropriate standards for PCI and cardiac surgery oversight
- Hospital PCI programs were subject to ongoing performance review in order to maintain authority to offer the service
- Any hospital proposing to provide elective PCI for the first time needed to obtain a certificate of conformance and, thereafter, will be subject to review of ongoing performance to maintain authorization to operate. The continuing quality and performance oversight was a departure from the traditional approach used in certificate of need regulation of hospital and other health care facility projects.

The State Health Plan: COMAR 10.24.17 Cardiac Surgery CON standards and PCI Services (cont)

- The Cardiac Surgery Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance
- A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or elective or both PCI services, for a specified time, that cannot exceed five years
- At the end of the approved time period, the hospital must demonstrate that it continues to meet the regulatory requirements for a Certificate of Ongoing Performance for renewal of the authorization to provide PCI services
- In between Certificate of Ongoing Performance renewals, if a hospital is not in compliance with certain standards, a focused review must be conducted. MHCC has the authority to conduct a focused review based on reported patient safety concerns, aberrations in data, or failure to meet quality standards established in State and federal regulations
- If the focused review identifies the hospital as failing to meet one or more of the requirements for a Certificate of Ongoing Performance, the hospital must receive a detailed list of deficiencies identified in the focused review and submit a plan of correction within 30 days of receipt of the list of deficiencies
- If a hospital does not submit a plan of correction that addresses deficiencies cited or does not successfully complete a plan of correction, upon notice of the Executive Director of the Commission, the hospital shall voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.

Maryland Acute Care Hospitals Participation in Cardiac Surgery and PCI programs

Health Planning Region	Acute Care Hospitals	Cardiac Surgery	Primary PCI	Elective PCI	Cardiac Interventional Center
Baltimore/ Upper Shore	24	6	13	13	13
Eastern/ Lower Shore	2	1	1	1	1
Metropolitan Washington	14	3	7	6	7
Western	3	1	2	2	2
Total	**43**	**11**	**24**	**23**	**24**

What is Next?

Issue 1: Volume Requirements

- Hospitals must maintain volume requirements to receive Certificates of Ongoing Performance
  - PCI volume standards exist for hospitals and for interventionalists. Separate standards exist for emergency and elective PCI
  - Volume standards exist for cardiac surgery programs, but not for surgeons.
- New cardiac surgery programs must commit to delivering 200 CABGs by the second year
- CABG volumes have declined due to improved treatment of hyperlipidemia, expanded access to PCI, and development of new cardiac procedures such as Transcatheter aortic valve replacement (TAVR).
  - Procedures that are not defined as cardiac surgery but are recommended for performance only at hospitals with cardiac surgery programs do not count toward volume thresholds.
- Regulatory changes will be needed

Issue 2: PCI in the ASC Setting?

- Centers for Medicare & Medicaid Services (CMS) pays for certain angioplasty and stenting procedures performed outside the hospital outpatient setting starting in calendar year 2020
- In November 2019 CMS issued a final rule on PCI in the ambulatory surgical center (ASC) setting by approving six CPT codes to the ASC-covered procedures list for calendar year (CY) 2020
- CMS considers these procedures clinically similar to those that do not require an overnight stay and are currently covered under the Medicare Outpatient Prospective Payment System (OPPS), but at ASCs would be covered by the Medicare ASC Fee Schedule
- Some hospital interest in offering elective PCI in ASC settings
- Could compromise PCI volumes at certain hospitals
- Statutory changes will be needed

Issues Moving Forward:

Migration of Certain PCI Patients from Hospital to Ambulatory Surgical Center Setting

Factors to Consider

- **Patient Selection**: Patients suitable for ambulatory PCI should be carefully selected based on clinical criteria, including stability, absence of significant comorbidities, and ability to tolerate the procedure without the need for prolonged hospitalization.
- **Safety and Monitoring**: Ensuring the ambulatory setting has appropriate facilities and equipment to monitor patients during and after the procedure is crucial. This includes access to emergency medications, defibrillation equipment, and personnel trained in advanced cardiac life support.
- **Procedural Logistics**: Efficient scheduling and coordination of procedures to minimize patient wait times and optimize resource utilization. Should there be dedicated outpatient catheterization labs and streamlined patient admission processes, preparation, and discharge.
- **Clinical Pathways**: Developing standardized clinical pathways for ambulatory PCI can help ensure consistency in patient care and outcomes. Including protocols for pre-procedural evaluation, peri-procedural management, and post-procedure follow-up.
- **Patient Education and Consent**: Comprehensive education about the procedure, potential risks, and post-procedure instructions. Informed consent should be obtained, and patients should understand the need for close monitoring following the procedure.

Factors to Consider (cont.)

- **Transportation and Access**: Adequate arrangements for patient transportation to and from the ambulatory facility, particularly for patients requiring sedation or anesthesia. Accessibility to patients from diverse geographic areas should also be considered.
- **Regulatory and Reimbursement Considerations**: Regulatory requirements, including accreditation standards, licensure requirements, and reimbursement policies and guidelines.
- **Quality Assurance and Outcomes Monitoring**: Implementing systems for quality assurance and outcomes monitoring to ensure the safety and effectiveness. This may involve tracking procedural complications, patient satisfaction, and long-term clinical outcomes.
- **Interdisciplinary Collaboration**: Collaboration, communication and coordination among team members, such as cardiologists, interventionalists, nurses, anesthesiologists, and other healthcare providers to deliver comprehensive care for optimal patient outcomes.
- **Cost-effectiveness**: Assessing the cost-effectiveness of ambulatory PCI compared to traditional inpatient procedures including procedure volumes, resource utilization, and reimbursement rates.