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To: Commissioners

From : Paul Parker, Director
Center for Hospital Services

Date: January 17, 2013

Re: **Final Action**
Amendments to COMAR 10.24.05
Continuation of Authority to Provide Non-Primary PCI Through Participation in the Follow-on C-PORT E Registry

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Staff recommends adoption of amendments to the Commission's regulations that govern the oversight of non-primary percutaneous coronary intervention ("PCI") programs at the eight hospitals currently providing this type of PCI service that do not provide cardiac surgery.

These amendments can be accurately characterized as technical in nature rather than substantive because they maintain the same programmatic and practitioner requirements that have been used in the "waiver" renewal process but bring the regulations into conformance with the 2012 legislation that replaced the "waiver" process used by the Maryland Health Care Commission ("MHCC") since 2006 to allow provision of PCI at hospitals that do not provide cardiac surgery. Under this 2012 law, PCI is now "categorically" regulated as a distinct service by MHCC.

The Commission adopted these amendments as proposed permanent regulations in September, 2012. No comments on the proposed amendments were received. These amended rules allow the Commission to continue oversight of non-primary PCI programs at the C-PORT E Registry hospitals while the Commission is in the process of revising the State Health Plan Chapter on Cardiac Surgery and PCI Services, consistent with the new law. As such, they serve as a bridge during the transition period while the oversight regulations are being updated.

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Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

Chapter 05 Continuation of Authority to Provide Non-primary PCI Through Participation in the Follow-On C-PORT E Registry

Authority: Health-General Article, §§19-101, 19-118, and 19-120, Annotated Code of Maryland

.01 Definitions.

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

B. Terms Defined.

(1) "Commission" means the Maryland Health Care Commission.

(2) "C-PORT study" means the randomized clinical research trial that was conducted by the Atlantic Cardiovascular Patient Outcomes Team (C-PORT) to determine whether nonprimary PCI performed in hospitals without on-site cardiac surgery services is as safe and effective as nonprimary PCI performed in hospitals with on-site cardiac surgery services.

(3) "Nonprimary percutaneous coronary intervention" means PCI capable of relieving coronary vessel narrowing associated with coronary artery disease unrelated to ST-segment elevation myocardial infarction and includes elective PCI.

(4) "Percutaneous coronary intervention (PCI)" means a variety of catheter-based techniques, including balloon angioplasty, capable of relieving coronary vessel narrowing.

(5) "Primary PCI" means PCI capable of relieving coronary vessel narrowing associated with ST-segment elevation myocardial infarction (STEMI) and is also known as emergency PCI.

(6) "Regional service area" means the area used for planning for cardiac surgery and PCI services, as provided in the State Health Plan, COMAR 10.24.17.

(7) “Registry” means the C-PORT E Registry of Non-Primary PCI that follows-on the C-PORT E Study of Non-Primary PCI and that is:

(a) Maintained by the Principal Investigator in the C-PORT E Study of Non-Primary PCI;

(b) Overseen by the Johns Hopkins Institutional Review Board;

(c) Overseen by a Data and Safety Monitoring Board.

(8) "STEMI" means coronary vessel narrowing associated with ST-segment elevation myocardial infarction.

(9) "Waiver to perform nonprimary PCI" means a time-limited exemption from the requirements of COMAR 10.24.17.04E, Policy 5.0, by which the Commission permitted an acute care hospital without on-site cardiac surgery services to perform nonprimary PCI services within the C-PORT study.

(10) "Waiver to perform primary PCI" means a time-limited exemption from the requirements of COMAR 10.24.17.04E, Policy 5.0, by which the Commission permits an acute care hospital without on-site cardiac surgery services to perform primary PCI services.

.02 Purpose and Scope.

A. In 2007, the Commission established a one-time process by which certain licensed acute general hospitals without on-site cardiac surgery services were awarded time-limited research waivers from the requirements of COMAR 10.24.17.04E, Policy 5.0, and were permitted to provide non-primary PCI services as part of the C-PORT E study to assess the safety and efficacy of providing non-primary PCI services for certain patient groups without on-site cardiac surgery, as provided in COMAR 10.24.17.04E, Policy 5.3.

B. In 2007, the Commission determined that the C-PORT E study offered a means of acquiring information to support future evidence-based State health care policy and planning with regard to cardiovascular services.

C. In 2011, after the C-PORT E research study concluded active enrollment, the Commission continued the research waiver of each hospital that was in good standing, thereby permitting each such hospital to continue to offer nonprimary PCI services while the required follow-up data on C-PORT E patients was collected and analyzed, provided that the hospital continued to perform non-primary PCI under the limitations and for the Registry term provided in prior regulations until such time as the Commission has the information from the research study that is needed to guide State policy about the regulation of non-primary PCI.

D. Health-General §19-120.1(d), effective July 1, 2012, provides that a certificate of conformance to establish a nonprimary PCI service is not required for a Registry hospital that the Commission determines, on or before December 31, 2012, that the hospital continues to be in compliance with

(1) Commission regulations, including COMAR 10.24.17 Table A-1; and

(2) The requirements of the Registry.

E. The Commission has convened a clinical advisory group, in accordance with Health-General §19-120.1(g)(3), that will offer advice to the Commission on the update of COMAR 10.24.17, the Cardiac Surgery and PCI Services Chapter of the State Health Plan. The analysis conducted as part of this update will review the C-PORT E study results, which were published in a peer-reviewed journal in March 2012 and will consider the system impact, including access, cost-effectiveness, and quality implications, of non-primary PCI being performed in hospitals without on-site cardiac surgery.

F. Until the updated COMAR 10.24.17 is effective, each Registry hospital shall continue to meet each requirement in these regulations, including each requirement in the Registry's manual of operations, in order to continue to provide nonprimary PCI.

.03 Conditions for Maintaining Authority to Perform Nonprimary PCI and Participation in Registry.

A. A Registry hospital shall maintain compliance with the following requirements:

(1) A Registry hospital shall meet the criteria established in the manual of operations of the C-PORT E Registry of Non-Primary PCI that follows-on the C-PORT E Study of Non-Primary PCI.

(2) A Registry hospital shall continue to satisfy the following requirements:

(a) For institutional resources:

(i) Maintain a patient prioritization plan that guarantees that a patient who requires primary PCI for STEMI is given immediate preference for care in the cardiac catheterization laboratory;

(ii) Maintain a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution; and

(iii) Maintain its agreement with an advanced cardiac support emergency medical services provider that guarantees arrival of the air or ground ambulance at the applicant hospital within 30 minutes of a request for non-primary PCI patient transport by the applicant;

(b) For physician resources, a Registry hospital shall maintain adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists who:

(i) Meet the requirements in the C-PORT E study research protocol and in COMAR 10.24.17, Table A-1;

(ii) Can be available on-site within 30 minutes when on call; and

(iii) Agree to abide by the Device Selection Criteria in the applicable Manual of Operations;

(c) For minimum volumes, a Registry hospital shall maintain a minimum volume of 200 PCI procedures during each year of its waiver;

(d) For follow-up of patients enrolled in the C-PORT E study, a Registry hospital shall maintain a patient follow-up rate of 98 percent; and

(e) For follow-up of patients enrolled in the Registry, a Registry hospital shall commit to meet and maintain patient follow-up at 6 weeks post-procedure.

(3) A Registry hospital shall notify the Commission in writing within 3 business days of the occurrence of any of the following:

(a) The hospital performs non-primary PCI on a patient not enrolled in the Registry;

(b) The hospital's primary PCI waiver expires, is relinquished, or is withdrawn;

(c) The hospital fails to notify the Commission of death or coronary artery bypass surgery experienced by a patient participating in the Registry;

(4) The hospital fails to perform a minimum of 200 PCI procedures annually each year after it received a non-primary PCI research waiver from the Commission; or

(5) The hospital fails to meet and maintain the criteria required by the Commission for participation in the Registry, or its participation in the Registry ends for any reason.

B. A hospital required to give notice under §A(3) of this regulation, shall, on written notice from the Commission, immediately relinquish its authority to perform nonprimary PCI.

.04 Term.

A. A hospital’s ability to provide non-primary PCI by virtue of participation in the Registry expires on the earlier of:

(1) The date upon which the Commission determines, through implementation in an update to COMAR 10.24.17 or other appropriate regulation, that the results of the C-PORT E study are sufficiently complete to guide public policy;

(2) A finding by the Commission that the C-PORT E study did not produce reliable results to guide public policy; or

(3) A finding by the Commission that the evidence is insufficient to change Policy 5.0 of COMAR 10.24.17.04E that requires non-primary PCI to be performed in hospitals with on-site cardiac surgery services.

.05 Performance and Monitoring.

A. Each Registry hospital shall provide data to the Commission in a form and manner acceptable to the Commission.

B. Each Registry hospital shall submit periodic progress reports in a format specified by the Commission and, at the conclusion of the research project and, if requested, at the end of the Registry, submit final reports in a form and manner acceptable to the Commission, as provided in COMAR 10.24.17.05D(2)(d).

C. Each Registry hospital shall authorize the C-PORT E study principal investigator and the Registry coordinator to provide data requested by the Commission.