

Department of Legislative Services
Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 750
Finance

(Senators Middleton and Pugh)

**Maryland Health Care Commission - Cardiac Surgery and Percutaneous
Coronary Intervention Services**

This bill specifically requires a certificate of need for the establishment of percutaneous coronary intervention (PCI) services, except as specified by the bill. The bill also requires, beginning July 1, 2012, an acute general hospital, except under specified circumstances, to obtain a certificate of conformance from the Maryland Health Care Commission (MHCC) before establishing emergency or elective PCI services. MHCC may issue a certificate of conformance only if specified conditions are met. The bill also requires an acute general hospital to obtain and maintain a certificate of ongoing performance in order to continue to provide cardiac surgery services or emergency or elective PCI services. MHCC must adopt specified regulations to implement the bill and must establish a clinical advisory group to recommend standards for inclusion in the regulations.

The bill takes effect July 1, 2012.

Fiscal Summary

State Effect: MHCC can likely handle the bill's requirements with existing resources.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: Under the bill, “PCI” means a procedure in which a catheter is inserted into a blood vessel and guided to the site of the narrowing of a coronary artery in order to relieve coronary narrowing. “STEMI” (ST-segment-elevation myocardial infarction) means a type of heart attack or myocardial infarction that is caused by a prolonged period of blocked blood supply, which affects a large area of the heart muscle and causes changes on an electrocardiogram and in the blood levels of key chemical markers. “Emergency PCI” (or “primary PCI”) includes PCI capable of relieving coronary vessel narrowing associated with STEMI or its equivalent, whereas “elective PCI” (or “nonprimary PCI”) includes PCI provided to a patient who is not suffering from an acute coronary syndrome but whose condition is appropriately treated with PCI.

MHCC may not issue a certificate of conformance unless the commission finds that the proposed emergency or elective PCI services (1) are consistent with the State Health Plan for Facilities and Services; (2) will result in the delivery of more efficient and effective health care services; and (3) are in the public interest. A certificate of conformance is not required for an acute general hospital to establish *emergency* PCI services if (1) the acute general hospital was providing emergency PCI services on January 1, 2012; and (2) MHCC determines that the emergency PCI services are consistent with the State Health Plan for Facilities and Services. A certificate of conformance is not required for an acute general hospital to establish *elective* PCI services if (1) on January 1, 2012, the hospital was providing elective PCI services through the C-PORT E study (a multistate, controlled clinical trial to study the safety and efficacy of elective angioplasty in hospitals without on-site cardiac surgery programs) registry under authority of a research waiver issued by MHCC; (2) the commission finds that the C-PORT E study produced results that should guide public policy; and (3) the commission determines that the elective PCI services provided by the hospital continue to be consistent with specified requirements.

An acute general hospital that provides cardiac surgery or PCI services – whether under a certificate of need, a certificate of conformance, or an exception to certificate of conformance requirements – must obtain and maintain a certificate of ongoing performance to continue to provide cardiac surgery services or emergency or elective PCI services. An acute general hospital that is providing elective PCI services under a research waiver issued by MHCC must obtain a certificate of conformance for its elective PCI services before obtaining a certificate of ongoing performance to provide the elective PCI services.

To implement the bill, MHCC must adopt regulations, through an update to the State Health Plan for Facilities and Services – that establish specified standards and requirements with regard to PCI services and the issuance of certificates of conformance and ongoing performance, as specified by the bill. The process established by MHCC for

issuing a certificate of conformance (1) may not allow interested party status; (2) must be similar to the process through which the commission grants an exemption from certificate of need requirements for merged asset systems; and (3) must, for a certificate of conformance to establish PCI services, consider applications from hospitals that were providing emergency PCI services on January 1, 2012, before considering applications from other hospitals. In deciding whether to issue a certificate of conformance, MHCC must also consider the circumstances of a hospital that is the sole hospital in a county.

An acute general hospital whose research waiver for elective PCI services was extended by MHCC and that continues to meet specified requirements may provide elective PCI services until the commission (1) makes a specified determination regarding the C-PORT E study; (2) considers the hospital's application for a certificate of conformance for its elective PCI services; or (3) makes a specified determination to terminate the hospital's authority to provide elective PCI services. MHCC must determine – by December 31, 2012, and with respect to each hospital that provided services through the research waiver on January 1, 2012 – whether specified conditions are satisfied.

With respect to a hospital that provided cardiac surgery and PCI services on January 1, 2012, requirements for certificates of ongoing performance do not apply until MHCC adopts regulations and fulfills related requirements, including (1) developing and reporting on specified recommendations by December 1, 2013; and (2) posting its report on the commission's website for a 60-day review and comment period.

Current Law/Background: PCI services at noncardiac surgery hospitals have been regulated by MHCC or its predecessor since 1990. State law and regulations require hospitals to obtain a certificate of need to provide cardiac surgery; MHCC regulations also prohibit hospitals from performing PCI without on-site cardiac surgery. Ten hospitals with on-site cardiac surgery programs are currently approved by MHCC to perform PCI:

- Johns Hopkins Hospital (Baltimore City);
- Peninsula Regional Medical Center (Wicomico County);
- Prince George's Hospital Center (Prince George's County);
- St. Joseph Medical Center (Baltimore County);
- Sinai Hospital of Baltimore (Baltimore City);
- Suburban Hospital (Montgomery County);
- Union Memorial Hospital (Baltimore City);
- University of Maryland Medical Center (Baltimore City);
- Washington Adventist Hospital (Montgomery County); and
- Western Maryland Regional Medical Center (Allegany County).

Approximately 80% of the 12,000 PCIs performed in 2010 were performed at the 10 cardiac surgery hospitals.

In 2006, MHCC initiated a waiver program under the State Health Plan that allowed community hospitals without on-site cardiac surgery programs to perform emergency angioplasty for patients experiencing certain types of heart attacks. Thirteen hospitals currently participate in this “primary PCI waiver program”:

- Anne Arundel Medical Center (Anne Arundel County);
- Baltimore Washington Medical Center (Anne Arundel County);
- Carroll Hospital Center (Carroll County);
- Franklin Square Hospital Center (Baltimore County);
- Frederick Memorial County (Frederick County);
- Holy Cross Hospital (Montgomery County);
- Howard County General Hospital (Howard County);
- Johns Hopkins Bayview Medical Center (Baltimore City);
- Saint Agnes Hospital (Baltimore City);
- Shady Grove Adventist Hospital (Montgomery County);
- Southern Maryland Hospital Center (Prince George’s County);
- Upper Chesapeake Medical Center (Harford County); and
- Washington County Hospital (Washington County).

The hospitals participating in the primary PCI waiver program are subject to a two-year waiver renewal and must demonstrate adherence to performance requirements.

In 2007, MHCC initiated a nonprimary PCI research waiver program under the State Health Plan. Under this program, 8 of the 13 hospitals in the primary PCI waiver program are also allowed to perform *elective* angioplasties. These 8 hospitals (Anne Arundel Medical Center, Baltimore Washington Medical Center, Frederick Memorial Hospital, Johns Hopkins Bayview Medical Center, Saint Agnes Hospital, Shady Grove Adventist Hospital, Southern Maryland Hospital Center, and Washington County Hospital) are participating in the C-PORT E study.

Chapter 616 of 2011 prohibited a hospital from establishing a nonprimary PCI program or providing nonprimary PCI services unless the hospital was operating a PCI program on January 1, 2011, through (1) a certificate of need for an open heart surgery program; or (2) a nonprimary waiver issued by MHCC. Chapter 616 also required MHCC to develop and report on recommendations for statutory changes needed to provide appropriate oversight of PCI services. Recommendations consequently developed by MHCC included that (1) PCI be identified as a service regulated by MHCC and, when provided in hospitals without cardiac surgical backup, require an exemption from

certificate of need; and (2) MHCC be given statutory authority to oversee PCI and cardiac surgery, including in existing cardiac surgery hospitals, on an ongoing basis after the issuance of a certificate of need or an exemption from a certificate of need. MHCC advised that this ongoing regulatory authority would require PCI and cardiac surgery programs to meet minimum performance standards as a condition of continuing to provide PCI and cardiac surgery services.

Additional Information

Prior Introductions: None.

Cross File: HB 1141 (Delegate Pendergrass, *et al.*) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - February 29, 2012
ncs/mwc Revised - Senate Third Reader - April 5, 2012

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