# Chapter 418

#### (House Bill 1141)

#### AN ACT concerning

#### Maryland Health Care Commission – Cardiac Surgery and Percutaneous Coronary Intervention Services

FOR the purpose of requiring, with a certain exception, a certificate of need for the establishment of percutaneous coronary intervention (PCI) services; requiring, beginning on a certain date, an acute general hospital to have a certificate of conformance before the hospital may establish primary emergency PCI services or <del>nonprimary</del> elective PCI services; prohibiting the Maryland Health Care Commission from issuing a certificate of conformance unless the Commission finds that the proposed primary emergency PCI services or proposed nonprimary elective PCI services meet certain standards; providing that a certificate of conformance is not required, notwithstanding certain provisions of this Act, for an acute general hospital to establish <del>primary</del> emergency PCI services or elective PCI services under certain circumstances; requiring an acute <del>care</del> general hospital that provides cardiac surgery or PCI services under certain authorization to obtain and maintain a certificate of ongoing performance to continue to provide cardiac surgery services, <del>primary</del> emergency PCI services, or <del>nonprimary</del> elective PCI services; requiring an acute general hospital that is providing <del>nonprimary</del> elective PCI services under a research waiver issued by the Commission and does not meet certain requirements to obtain a certificate of conformance for its nonprimary elective PCI services before it may obtain a certificate of ongoing performance to provide the <del>nonprimary</del> elective PCI services; requiring the Commission to adopt certain regulations; requiring the regulations to include certain items; requiring the Commission to establish a clinical advisory group for a certain purpose; requiring the Commission to develop certain recommended regulations, post the recommended regulations on its Web site, and submit the recommended regulations to the Governor and certain legislative committees for review and comment; establishing certain parameters for the process established by the Commission for issuing a certificate of conformance; authorizing a certain hospital, notwithstanding certain provisions of this Act, to provide <del>nonprimary</del> elective PCI services until the Commission takes <del>certain actions</del> a certain action; requiring the Commission to consider a certain factor in issuing a certificate of conformance; requiring a certain process and a certain requirement established in regulation to operate and be implemented in certain manners; providing that certain requirements of this Act do not apply to a hospital that provided cardiac surgery services and PCI services on a certain date until the Commission takes certain actions; defining certain terms; and generally relating to the regulation of cardiac surgery and percutaneous coronary intervention services by the Maryland Health Care Commission.

BY repealing and reenacting, without amendments,

Article – Health – General Section 19–120(j)(1) Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments, Article – Health – General Section 19–120(j)(2) Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)

BY adding to Article – Health – General Section 19–120.1 Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

## Article – Health – General

#### 19 - 120.

(j) (1) A certificate of need is required before the type or scope of any health care service is changed if the health care service is offered:

- (i) By a health care facility;
- (ii) In space that is leased from a health care facility; or
- (iii) In space that is on land leased from a health care facility.
- (2) This subsection does not apply if:

(i) The Commission adopts limits for changes in health care services and the proposed change would not exceed those limits;

(ii) The proposed change and the annual operating revenue that would result from the addition is entirely associated with the use of medical equipment;

(iii) The proposed change would establish, increase, or decrease a health care service and the change would not result in the:

1. Establishment of a new medical service or elimination of an existing medical service;

2. Establishment of [an open heart] A CARDIAC surgery, organ transplant surgery, or burn or neonatal intensive health care service;

# **3.** EXCEPT AS PROVIDED IN § 19–120.1 OF THIS SUBTITLE, ESTABLISHMENT OF PERCUTANEOUS CORONARY INTERVENTION SERVICES;

[3.] 4. Establishment of a home health program, hospice program, or freestanding ambulatory surgical center or facility; or

[4.] 5. Expansion of a comprehensive care, extended care, intermediate care, residential treatment, psychiatry, or rehabilitation medical service, except for an expansion related to an increase in total bed capacity in accordance with subsection (h)(2)(i) of this section; or

(iv) 1. At least 45 days before increasing or decreasing the volume of one or more health care services, written notice of intent to change the volume of health care services is filed with the Commission;

2. The Commission in its sole discretion finds that the proposed change:

A. Is pursuant to the consolidation or merger of two or more health care facilities, the conversion of a health care facility or part of a facility to a nonhealth–related use, or the conversion of a hospital to a limited service hospital;

B. Is not inconsistent with the State health plan or the institution–specific plan developed and adopted by the Commission;

C. Will result in the delivery of more efficient and effective health care services; and

D. Is in the public interest; and

3. Within 45 days of receiving notice under item 1 of this item, the Commission notifies the health care facility of its finding.

#### 19–120.1.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "CERTIFICATE OF CONFORMANCE" MEANS AN APPROVAL ISSUED BY THE COMMISSION THAT ALLOWS AN ACUTE GENERAL HOSPITAL TO ESTABLISH <u>PRIMARY</u> <u>EMERGENCY</u> PCI SERVICES OR <del>NONPRIMARY</del> <u>ELECTIVE</u> PCI SERVICES WITHOUT A CERTIFICATE OF NEED.

(3) "CERTIFICATE OF ONGOING PERFORMANCE" MEANS AN APPROVAL ISSUED BY THE COMMISSION THAT THE CARDIAC SURGERY SERVICES, <del>PRIMARY</del> <u>EMERGENCY</u> PCI SERVICES, OR <del>NONPRIMARY</del> <u>ELECTIVE</u> PCI SERVICES PROVIDED BY AN ACUTE GENERAL HOSPITAL MEET STANDARDS EVIDENCING CONTINUED QUALITY.

(4) (1) "Nonprimary <u>Elective</u> PCI" <u>means PCI capable</u> of relieving coronary-vessel narrowing associated with coronary artery disease unrelated to <u>ST-segment-elevation</u> <u>Myocardial</u> infarction (also known as "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 based on regulations established by the Commission.

## (II) "Nonprimary PCI" includes elective PCI.

(5) <u>"EMERGENCY PCI"</u> (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.

(5) (6) "PCI" MEANS PERCUTANEOUS CORONARY INTERVENTION.

(6) (7) (I) "PERCUTANEOUS CORONARY INTERVENTION" 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 TO RELIEVE CORONARY NARROWING.

(II) "PERCUTANEOUS CORONARY INTERVENTION" INCLUDES A VARIETY OF CATHETER–BASED TECHNIQUES, INCLUDING BALLOON ANGIOPLASTY. (7) "PRIMARY PCI" MEANS PCI CAPABLE OF RELIEVING CORONARY VESSEL NARROWING ASSOCIATED WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION.

(8) <u>"STEMI"</u> (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.

(B) (1) BEGINNING JULY 1, 2012, BEFORE AN ACUTE GENERAL HOSPITAL MAY ESTABLISH **PRIMARY** <u>EMERGENCY</u> PCI SERVICES OR **NONPRIMARY** <u>ELECTIVE</u> PCI SERVICES, THE HOSPITAL SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FROM THE COMMISSION.

(2) THE COMMISSION MAY NOT ISSUE A CERTIFICATE OF CONFORMANCE UNLESS THE COMMISSION FINDS THAT THE PROPOSED **PRIMARY** <u>EMERGENCY</u> PCI SERVICES OR PROPOSED <del>NONPRIMARY</del> <u>ELECTIVE</u> PCI SERVICES:

(I) ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES;

(II) WILL RESULT IN THE DELIVERY OF MORE EFFICIENT AND EFFECTIVE HEALTH CARE SERVICES; AND

(III) ARE IN THE PUBLIC INTEREST.

(C) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL HOSPITAL TO ESTABLISH <del>PRIMARY</del> <u>EMERGENCY</u> PCI SERVICES IF:

(1) THE ACUTE GENERAL HOSPITAL WAS PROVIDING **PRIMARY** <u>EMERGENCY</u> PCI SERVICES ON JANUARY 1, 2012; AND

(2) THE COMMISSION DETERMINES THAT THE **PRIMARY** <u>EMERGENCY</u> PCI SERVICES ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES.

(D) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL HOSPITAL TO ESTABLISH ELECTIVE PCI SERVICES IF: (1) ON JANUARY 1, 2012, THE ACUTE GENERAL HOSPITAL WAS PROVIDING ELECTIVE PCI SERVICES THROUGH THE C-PORT E REGISTRY UNDER AUTHORITY OF A RESEARCH WAIVER ISSUED BY THE COMMISSION;

(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 ACUTE GENERAL HOSPITAL CONTINUE TO BE CONSISTENT WITH:

(I) <u>The requirements of the C-PORT E registry;</u> <u>AND</u>

(II) EXCEPT FOR THE REQUIREMENTS UNDER COMAR 10.24.05.05, THE REQUIREMENTS FOR MAINTAINING A RESEARCH WAIVER UNDER COMAR 10.24.05 AND 10.24.17, TABLE A-1.

(D) (E) (1) This subsection applies to an acute care <u>General</u> hospital that provides cardiac surgery or PCI services under:

(I) A CERTIFICATE OF NEED ISSUED UNDER § 19–120 OF THIS SUBTITLE;

(II) A CERTIFICATE OF CONFORMANCE ISSUED UNDER THIS SECTION; OR

(III) AN EXCEPTION FROM THE CERTIFICATE OF CONFORMANCE REQUIREMENTS UNDER SUBSECTION (C) <u>OR (D)</u> OF THIS SECTION.

(2) AN ACUTE GENERAL HOSPITAL SHALL OBTAIN AND MAINTAIN A CERTIFICATE OF ONGOING PERFORMANCE TO CONTINUE TO PROVIDE:

- (I) CARDIAC SURGERY SERVICES;
- (II) **PRIMARY** <u>Emergency</u> PCI services; or
- (III) NONPRIMARY ELECTIVE PCI SERVICES.

(E) (F) AN ACUTE GENERAL HOSPITAL THAT IS PROVIDING NONPRIMARY ELECTIVE PCI SERVICES UNDER A RESEARCH WAIVER ISSUED BY THE COMMISSION AND DOES NOT MEET THE REQUIREMENTS OF SUBSECTION (D) OF THIS SECTION SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FOR ITS NONPRIMARY ELECTIVE PCI SERVICES BEFORE THE ACUTE GENERAL HOSPITAL MAY OBTAIN A CERTIFICATE OF ONGOING PERFORMANCE TO PROVIDE THE NONPRIMARY ELECTIVE PCI SERVICES.

(F) (G) (1) THE COMMISSION SHALL ADOPT REGULATIONS THROUGH AN UPDATE TO THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES TO IMPLEMENT THIS SECTION.

(2) THE REGULATIONS SHALL:

(I) ADDRESS QUALITY, ACCESS, AND COST;

(II) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR OBTAINING A CERTIFICATE OF CONFORMANCE;

(III) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR OBTAINING AND MAINTAINING A CERTIFICATE OF ONGOING PERFORMANCE;

(IV) SET AN APPROPRIATE TIME PERIOD FOR THE EXPIRATION OF A CERTIFICATE OF ONGOING PERFORMANCE; AND

**REQUIRE, AS A CONDITION OF THE ISSUANCE OF A** (V) CERTIFICATE CONFORMANCE OR Α CERTIFICATE OF OF **ONGOING** PERFORMANCE TO AN ACUTE GENERAL HOSPITAL WITHOUT ON-SITE CARDIAC SURGERY SERVICES, THAT AN THE ACUTE GENERAL HOSPITAL AGREE TO VOLUNTARILY RELINQUISH ITS AUTHORITY TO PROVIDE CARDIAC SURGERY SERVICES, PRIMARY EMERGENCY PCI SERVICES, OR NONPRIMARY ELECTIVE **PCI** SERVICES IF THE HOSPITAL FAILS TO MEET THE APPLICABLE STANDARDS ESTABLISHED BY THE COMMISSION;

(VI) ESTABLISH A PROCESS FOR AN ACUTE GENERAL HOSPITAL THAT IS OUT OF COMPLIANCE WITH MINIMUM STANDARDS FOR A CERTIFICATE OF ONGOING PERFORMANCE TO RETURN TO GOOD STANDING;

(VII) REQUIRE THAT AN ACUTE GENERAL HOSPITAL, EXCEPT FOR AN ACUTE GENERAL HOSPITAL LOCATED IN A PART OF THE STATE THAT DOES NOT HAVE SUFFICIENT ACCESS TO EMERGENCY PCI SERVICES, HAVE PROVIDED EMERGENCY PCI SERVICES IN ACCORDANCE WITH ESTABLISHED STANDARDS BEFORE SEEKING A CERTIFICATE OF CONFORMANCE FOR ELECTIVE PCI SERVICES;

## (VIII) PROHIBIT AN ACUTE GENERAL HOSPITAL FROM PROVIDING ELECTIVE PCI SERVICES UNLESS THE ACUTE GENERAL HOSPITAL ALSO PROVIDES EMERGENCY PCI SERVICES;

(IX) INCORPORATE, TO THE EXTENT APPROPRIATE, THE STANDARDS FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES, AND ELECTIVE PCI SERVICES RECOMMENDED BY THE CLINICAL ADVISORY GROUP ESTABLISHED UNDER PARAGRAPH (3) OF THIS SUBSECTION;

(X) INCLUDE REQUIREMENTS FOR PEER OR INDEPENDENT REVIEW, CONSISTENT WITH THE ACCF/AHA/SCAI GUIDELINES FOR PERCUTANEOUS CORONARY INTERVENTION (REPORT OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION TASK FORCE ON PRACTICE GUIDELINES AND THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS), OF DIFFICULT OR COMPLICATED CASES AND FOR RANDOMLY SELECTED CASES; AND

(XI) FOR A CERTIFICATE OF CONFORMANCE FOR ELECTIVE PCI SERVICES, GIVE WEIGHT TO THE EXPERIENCE, PERFORMANCE, INVESTMENT, AND SCOPE OF INTERVENTIONAL CAPABILITIES OF AN APPLICANT HOSPITAL THAT WAS PROVIDING EMERGENCY PCI SERVICES ON JANUARY 1, 2012.

(3) (1) THE COMMISSION SHALL ESTABLISH A CLINICAL ADVISORY GROUP TO ADVISE THE COMMISSION AND RECOMMEND STANDARDS FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES, AND ELECTIVE PCI SERVICES FOR INCLUSION IN REGULATIONS ADOPTED UNDER THIS SUBSECTION.

(II) THE CLINICAL ADVISORY GROUP SHALL BE COMPOSED OF EXPERTS IN CARDIAC SURGERY SERVICES AND PCI SERVICES, INCLUDING:

<u>1.</u> <u>CLINICIANS AND REPRESENTATIVES FROM</u> <u>HOSPITALS IN THE STATE WITH AND WITHOUT ON-SITE CARDIAC SURGERY</u> <u>SERVICES AND WITH AND WITHOUT PCI SERVICES;</u>

2. <u>AT LEAST ONE REPRESENTATIVE OF AN ACUTE</u> <u>GENERAL HOSPITAL THAT IS NOT PART OF A MERGED ASSET SYSTEM AND</u> <u>PROVIDES ONLY EMERGENCY PCI SERVICES; AND</u>

<u>3.</u> <u>OTHER PERSONS WITH NEEDED EXPERTISE FROM</u> INSIDE AND OUTSIDE THE STATE. (4) (1) ON OR BEFORE SEPTEMBER 30, 2013, AFTER OBTAINING ADVICE FROM THE CLINICAL ADVISORY GROUP AND OTHER APPROPRIATE STAKEHOLDERS, THE COMMISSION SHALL:

# **<u>1.</u> DEVELOP RECOMMENDED REGULATIONS UNDER**

#### THIS SUBSECTION;

# 2. <u>POST THE RECOMMENDED REGULATIONS ON ITS</u> WEB SITE FOR PUBLIC COMMENT; AND

# <u>3.</u> <u>Submit the recommended regulations to</u> <u>The Governor and, in accordance with § 2–1246 of the State</u> <u>Government Article, the Senate Finance Committee and the House</u> <u>Health and Government Operations Committee.</u>

# (II) THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE SHALL HAVE 60 DAYS FROM RECEIPT OF THE RECOMMENDED REGULATIONS FOR REVIEW AND COMMENT.

SECTION 2. AND BE IT FURTHER ENACTED, That the process established by the Maryland Health Care Commission for issuing a certificate of conformance, as required under § 19–120.1 of the Health – General Article, as enacted by Section 1 of this Act:

(1) shall be similar to the process through which the Commission grants an exemption from certificate of need requirements for merged asset systems; and

(2) may not allow interested party status<u>; and</u>

(3) shall consider, for a certificate of conformance to establish elective PCI services, applications from acute general hospitals that were providing emergency PCI services on January 1, 2012, before considering applications from other acute general hospitals.

<u>SECTION 3. AND BE IT FURTHER ENACTED, That, in making a decision to</u> <u>issue a certificate of conformance, the Maryland Health Care Commission shall</u> <u>consider the circumstances of a hospital that is the sole hospital in a county</u>.

SECTION 3. 4. AND BE IT FURTHER ENACTED, That, notwithstanding:

(a) <u>Notwithstanding</u> any other provision of this Act, an acute general hospital whose research waiver for <del>nonprimary</del> <u>elective</u> PCI services was extended by the Maryland Health Care Commission under COMAR 10.24.05 and that continues to

meet the requirements under COMAR 10.24.05 may provide <del>nonprimary</del> <u>elective</u> PCI services <u>under the authorization that existed on January 1, 2012</u>, until the Commission:

(1) makes <del>one of the determinations or findings provided under</del> <del>COMAR 10.24.05.05; and</del>

(2) depending on the results of the C-PORT E study and the Commission's actions taken under COMAR 10.24.05.05A(1) and B, a determination under § 19–120.1(d)(3) of the Health – General Article, as enacted by Section 1 of this <u>Act</u>;

(2) considers the hospital's application under § 19-120.1(b) of the Health – General Article, as enacted by Section 1 of this Act, for a certificate of conformance for its nonprimary elective PCI services; or

(3) makes a determination under COMAR 10.24.05 to terminate the hospital's authority to provide elective PCI services.

(b) On or before December 31, 2012, the Commission shall determine for each hospital providing elective PCI services on January 1, 2012, through the C–PORT <u>E registry under authority of a research waiver issued by the Commission, whether</u> the conditions of § 19–120.1(d)(3) of the Health – General Article are satisfied.

<u>SECTION 5. AND BE IT FURTHER ENACTED.</u> That the process established in regulation under § 19–120.1(g)(2)(vi) of the Health – General Article, as enacted by Section 1 of this Act, for an acute general hospital that is out of compliance with minimum standards for a certificate of ongoing performance to return to good standing shall operate in a manner consistent with the process and underlying principles that:

(1) guided the Maryland Health Care Commission in its oversight of hospitals providing emergency PCI services and elective PCI services under a waiver and a research waiver, respectively; and

(2) provided a reasonable opportunity for an acute general hospital that was out of compliance with performance standards to come into compliance.

<u>SECTION 6. AND BE IT FURTHER ENACTED</u>, That the requirement established in regulation under § 19–120.1(g)(2)(v) of the Health – General Article, as enacted by Section 1 of this Act, as a condition of the issuance of a certificate of conformance or a certificate of ongoing performance for an acute general hospital without on-site cardiac surgery services to agree to voluntarily relinquish its authority to provide emergency PCI services or elective PCI services if the hospital fails to meet the applicable standards established by the Maryland Health Care Commission, shall: (1) <u>be implemented in a manner consistent with the regulations and</u> <u>underlying principles of the Commission in its oversight of hospitals providing</u> <u>emergency PCI services and elective PCI services under a waiver and a research</u> <u>waiver, respectively; and</u>

(2) require an acute general hospital without on-site cardiac surgery services to:

and

(i) notify the Commission of the occurrence of specified events;

(ii) subject to Section 5 of this Act, on written notice from the Commission, immediately relinquish its authority to provide PCI services.

#### SECTION 7. AND BE IT FURTHER ENACTED, That:

(a) The requirements of § 19–120.1(e) of the Health – General Article, as enacted by Section 1 of this Act, do not apply to a hospital that provided cardiac surgery services and PCI services on January 1, 2012, until:

(1) the Maryland Health Care Commission consults with the clinical advisory group established under § 19–120.1(g)(3) of the Health – General Article, as enacted by Section 1 of this Act, and other appropriate stakeholders on appropriate standards for ongoing performance for cardiac surgery services and PCI services at acute general hospitals with on-site cardiac surgery services;

(2) the Commission develops recommendations for actions, including any changes in State law, that are necessary to enhance the Commission's ability to monitor ongoing performance and compliance with quality standards related to cardiac surgery services and PCI services at hospitals with on-site cardiac surgery services;

(3) the Commission:

(i) <u>reports its recommendations to the Governor and, in</u> accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee; and

(ii) posts the report on its Web site for a 60-day review and comment period; and

(4) the Commission adopts regulations to implement the recommendations.

(b) The Commission shall report its recommendations and post its report under subsection (a)(3) of this section on or before December 1, 2013. (c) The report, recommendations, and regulations under subsection (a) of this section shall include:

(1) <u>a mechanism for an acute general hospital with on-site cardiac</u> <u>surgery services that is out of compliance with performance standards for cardiac</u> <u>surgery services or PCI services to return to good standing; and</u>

(2) <u>a process through which the authority for an acute general hospital</u> <u>with on-site cardiac surgery services to provide cardiac surgery services and PCI</u> <u>services may be revoked for failure to meet performance standards.</u>

SECTION 4. 8. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2012.

Approved by the Governor, May 2, 2012.