

**HB1141/726686/3**

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 1141  
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in lines 7, 10, 13, and 16, in each instance, strike “primary” and substitute “emergency”; in lines 8, 10, 17, 18, 19, 20, and 25, in each instance, strike “nonprimary” and substitute “elective”; in line 13, after “services” insert “or elective PCI services”; in line 14, strike “care” and substitute “general”; in line 18, after “Commission” insert “and does not meet certain requirements”; in line 22, after “items;” insert “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;”; and in line 25, strike “certain actions” and substitute “a certain action”; and in the same line, after the semicolon insert “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;”.

AMENDMENT NO. 2

On page 4 in lines 1, 5, 25, and 30, on page 5 in lines 6, 7, and 9, on page 6 in line 16, in each instance, strike “PRIMARY” and substitute “EMERGENCY”.

On page 4 in lines 1, 5, 25, and 30, on page 5 in lines 25, 27, and 29, and on page 6 in line 16, in each instance, strike “NONPRIMARY” and substitute “ELECTIVE”.

(Over)

On page 4, in line 8, strike “(I)”; in line 8, strike “NONPRIMARY” and substitute “ELECTIVE”; strike beginning with “MEANS” in line 8 down through “INFARCTION” in line 11 and substitute “(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”; strike line 12 in its entirety; after line 12, insert:

“(5) “EMERGENCY PCI” (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.”;

in lines 13 and 14, strike “(5)” and “(6)”, respectively, and substitute “(6)” and “(7)”, respectively; and strike in their entirety lines 21 through 23, inclusive, and substitute:

“(8) “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.”.

On page 5, in line 12, strike “CARE” and substitute “GENERAL”; in line 23, strike “PRIMARY” and substitute “EMERGENCY”; and in line 24, strike “NONPRIMARY” and substitute “ELECTIVE”.

On page 6 in lines 29 and 31 and on page 7 in line 4, in each instance, strike “nonprimary” and substitute “elective”.

AMENDMENT NO. 3

On page 5, after line 11, insert:

“(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) THE REQUIREMENTS OF THE C-PORT E REGISTRY;  
AND

(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.”;

in lines 12 and 25, strike “(D)” and “(E)”, respectively, and substitute “(E)” and “(F)”, respectively; in line 19, after “(C)” insert “OR (D)”; and in line 26, after “COMMISSION” insert “AND DOES NOT MEET THE REQUIREMENTS OF SUBSECTION (D) OF THIS SECTION”.

(Over)

On page 6, in line 27, strike “, notwithstanding” and substitute “:

(a) Notwithstanding”;

and in line 31, after “services” insert “under the authorization that existed on January 1, 2012.”.

On pages 6 and 7, strike beginning with “one” in line 32 on page 6 down through “B,” in line 2 on page 7 and substitute “a determination under § 19-120.1(d)(3) of the Health – General Article, as enacted by Section 1 of this Act;

(2)”.

On page 7, in line 5, after “services” insert “; 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 E registry under authority of a research waiver issued by the Commission, whether the conditions of § 19-120.1(d)(3) of the Health – General Article are satisfied”.

AMENDMENT NO. 4

On page 6, in line 1, strike “(F)” and substitute “(G)”; in line 11, strike “AND”; in line 14, after “PERFORMANCE” insert “TO AN ACUTE GENERAL HOSPITAL WITHOUT ON-SITE CARDIAC SURGERY SERVICES”; in the same line, strike “AN” and substitute “THE”; in line 15, strike “CARDIAC SURGERY SERVICES,”; in line 16, strike the comma; and in line 18, after “COMMISSION” insert “;

(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) (I) 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:

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

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

3. OTHER PERSONS WITH NEEDED EXPERTISE FROM INSIDE AND OUTSIDE THE STATE.

(4) (I) ON OR BEFORE SEPTEMBER 30, 2013, AFTER OBTAINING ADVICE FROM THE CLINICAL ADVISORY GROUP AND OTHER APPROPRIATE STAKEHOLDERS, THE COMMISSION SHALL:

1. DEVELOP RECOMMENDED REGULATIONS UNDER THIS SUBSECTION;
2. POST THE RECOMMENDED REGULATIONS ON ITS WEB SITE FOR PUBLIC COMMENT; AND
3. SUBMIT THE RECOMMENDED REGULATIONS TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE.

(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”.

AMENDMENT NO. 5

On page 6, in line 25, strike “and”; in line 26, after “status” insert “; and”

(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.

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

and in line 27, strike “3.” and substitute “4.”

(Over)

AMENDMENT NO. 6

On page 7, after line 5, insert:

“SECTION 5. AND BE IT FURTHER ENACTED 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.

SECTION 6. AND BE IT FURTHER ENACTED, 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) be implemented in a manner consistent with the regulations and underlying principles of the Commission in its oversight of hospitals providing emergency PCI services and elective PCI services under a waiver and a research waiver, respectively; and

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

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

(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) reports its recommendations to the Governor and, in 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) a mechanism for an acute general hospital with on-site cardiac surgery services that is out of compliance with performance standards for cardiac surgery services or PCI services to return to good standing; and

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

and in line 6, strike “4.” and substitute “8.”.