

# SENATE BILL 742

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By: **Senator Pugh**

Introduced and read first time: February 4, 2011

Assigned to: Finance

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## A BILL ENTITLED

1 AN ACT concerning

2 **Maryland Cardiovascular Patient Safety Act**

3 FOR the purpose of requiring that certain cardiovascular catheterization laboratories  
4 hold a certain accreditation or certification on or before a certain date; requiring  
5 the Department of Health and Mental Hygiene to adopt certain regulations;  
6 authorizing the Department to use consultants for a certain purpose and set  
7 and impose certain fees; requiring certain accreditation organizations to  
8 accredit certain cardiovascular catheterization laboratories by conducting  
9 certain inspections and surveys and comparing the results to nationally  
10 recognized standards; establishing certain criteria for certain accreditation  
11 organizations and the site visit personnel of certain accreditation organizations;  
12 requiring certain cardiovascular catheterization laboratories to apply for  
13 certification with the Department; requiring certification by the Department to  
14 consist of a certain review and evaluation of certain elements of cardiovascular  
15 catheterization laboratories; requiring the Department to issue a report of  
16 certain deficiencies; requiring the Department to grant full certification or  
17 provisional certification or deny certification under certain circumstances;  
18 requiring certain cardiovascular catheterization laboratories to correct certain  
19 deficiencies; establishing the length of a certain certification; requiring certain  
20 cardiovascular catheterization laboratories to be subject to certain peer review;  
21 establishing the criteria for peer review and requiring peer review to be  
22 performed by certain entities; requiring peer review to be based on certain  
23 cases, address certain issues, and be compared to certain experience and  
24 standards; requiring the Department, the Maryland Health Care Commission,  
25 and the Health Services Cost Review Commission to give certain consideration  
26 to data from a certain registry to determine certain criteria and measures for  
27 hospitals and health care providers using certain cardiovascular procedures;  
28 defining certain terms; and generally relating to the safety of cardiovascular  
29 patients and cardiovascular catheterization laboratories.

30 BY adding to

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Health – General  
2 Section 19–2401 through 19–2404 to be under the new subtitle “Subtitle 24.  
3 Cardiovascular Catheterization Laboratories”  
4 Annotated Code of Maryland  
5 (2009 Replacement Volume and 2010 Supplement)

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

8 **Article – Health – General**

9 **SUBTITLE 24. CARDIOVASCULAR CATHETERIZATION LABORATORIES.**

10 **19–2401.**

11 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
12 INDICATED.

13 (B) “ACCREDITATION” MEANS RECOGNITION THAT A CARDIOVASCULAR  
14 CATHETERIZATION LABORATORY MEETS NATIONALLY RECOGNIZED STANDARDS  
15 FOR QUALITY, SAFETY, COMPETENCY, AND PERFORMANCE OF  
16 CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES.

17 (C) “ACCREDITATION ORGANIZATION” MEANS A PRIVATE ENTITY THAT  
18 IS RECOGNIZED NATIONALLY FOR ITS DEDICATION TO ACCREDITING  
19 CARDIOVASCULAR CATHETERIZATION LABORATORIES.

20 (D) “CARDIOVASCULAR CATHETERIZATION LABORATORY” MEANS A  
21 HOSPITAL–BASED LABORATORY THAT PERFORMS CARDIOVASCULAR  
22 DIAGNOSTIC OR PCI PROCEDURES TO DIAGNOSE AND TREAT CORONARY  
23 ARTERY DISEASE.

24 (E) (1) “CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES”  
25 MEANS PROCEDURES USED IN A CARDIOVASCULAR CATHETERIZATION  
26 LABORATORY TO DIAGNOSE AND TREAT CORONARY ARTERY DISEASE.

27 (2) “CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES”  
28 INCLUDES:

29 (I) LEFT AND RIGHT HEART CATHETERIZATION;

30 (II) PERCUTANEOUS TRANSLUMINAL CORONARY  
31 ANGIOGRAPHY; AND

32 (III) CORONARY STENT PLACEMENT.

1           **(F) (1) “CATHPCI REGISTRY” MEANS THE NATIONAL**  
2 **CARDIOVASCULAR DATA REGISTRY THAT ASSESSES THE CHARACTERISTICS,**  
3 **TREATMENTS, AND OUTCOMES OF CARDIAC DISEASE PATIENTS WHO RECEIVE**  
4 **CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES.**

5                   **(2) “CATHPCI REGISTRY” INCLUDES BENCHMARK REPORTS**  
6 **THAT:**

7                           **(I) COMPARE THE PERFORMANCE OF A CARDIOVASCULAR**  
8 **CATHETERIZATION LABORATORY WITH LIKE-SIZED LABORATORIES AND**  
9 **NATIONAL STANDARDS; AND**

10                           **(II) MAY BE USED TO SET ACHIEVABLE PERFORMANCE**  
11 **GOALS AND DEVELOP QUALITY IMPROVEMENT PLANS FOR A CARDIOVASCULAR**  
12 **CATHETERIZATION LABORATORY.**

13           **(G) “CERTIFICATION” MEANS RECOGNITION BY THE DEPARTMENT**  
14 **THAT A CARDIOVASCULAR CATHETERIZATION LABORATORY MEETS SPECIFIED**  
15 **STANDARDS.**

16           **(H) “HOSPITAL” HAS THE MEANING STATED IN § 19-301 OF THIS TITLE.**

17           **(I) “NATIONAL CARDIOVASCULAR DATA REGISTRY” MEANS THE**  
18 **INITIATIVE OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION IN**  
19 **PARTNERSHIP WITH OTHER CARDIOVASCULAR SOCIETIES.**

20           **(J) “PCI” MEANS PERCUTANEOUS CORONARY INTERVENTION.**

21           **(K) “PEER REVIEW” MEANS A ROUTINE OR UNANNOUNCED**  
22 **EXAMINATION OF THE CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES OF**  
23 **A CARDIOVASCULAR CATHETERIZATION LABORATORY.**

24 **19-2402.**

25           **(A) (1) ON OR BEFORE MAY 31, 2014, EACH CARDIOVASCULAR**  
26 **CATHETERIZATION LABORATORY SHALL HOLD A CURRENT:**

27                           **(I) ACCREDITATION WITH AN ACCREDITATION**  
28 **ORGANIZATION IN ACCORDANCE WITH SUBSECTION (B) OF THIS SECTION; OR**

29                           **(II) CERTIFICATION WITH THE DEPARTMENT IN**  
30 **ACCORDANCE WITH SUBSECTION (C) OF THIS SECTION.**

1           **(2) THE DEPARTMENT MAY USE CONSULTANTS TO MEET THE**  
2 **REQUIREMENTS OF THIS SECTION.**

3           **(3) THE DEPARTMENT MAY SET AND IMPOSE ON CARDIAC**  
4 **CATHETERIZATION LABORATORIES REASONABLE FEES TO COVER THE COSTS OF**  
5 **CARRYING OUT THIS SECTION.**

6           **(B) (1) AN ACCREDITATION ORGANIZATION SHALL ACCREDIT A**  
7 **CARDIOVASCULAR CATHETERIZATION LABORATORY BY CONDUCTING**  
8 **INSPECTIONS OF AND SURVEYS ON CARDIOVASCULAR DIAGNOSTIC OR PCI**  
9 **PROCEDURES PERFORMED AT THE CARDIOVASCULAR CATHETERIZATION**  
10 **LABORATORY AND COMPARING THE RESULTS TO NATIONALLY RECOGNIZED**  
11 **STANDARDS.**

12           **(2) AN ACCREDITATION ORGANIZATION SHALL:**

13           **(I) BE INDEPENDENT OF:**

14                   **1. THE CARDIOVASCULAR CATHETERIZATION**  
15 **LABORATORY THAT THE ACCREDITATION ORGANIZATION IS ACCREDITING;**

16                   **2. THE HOSPITAL IN WHICH THE CARDIOVASCULAR**  
17 **CATHETERIZATION LABORATORY IS BASED; AND**

18                   **3. THE STAFF OF THE CARDIOVASCULAR**  
19 **CATHETERIZATION LABORATORY OR HOSPITAL;**

20           **(II) HAVE AN OVERSIGHT BOARD AND SITE VISIT**  
21 **PERSONNEL THAT ARE INDEPENDENT OF:**

22                   **1. THE CARDIOVASCULAR CATHETERIZATION**  
23 **LABORATORY THAT THE ACCREDITATION ORGANIZATION IS ACCREDITING;**

24                   **2. THE HOSPITAL IN WHICH THE CARDIOVASCULAR**  
25 **CATHETERIZATION LABORATORY IS BASED; AND**

26                   **3. THE STAFF OF THE CARDIOVASCULAR**  
27 **CATHETERIZATION LABORATORY OR HOSPITAL; AND**

28           **(III) BE APPROVED BY THE DEPARTMENT.**

29           **(3) THE SITE VISIT PERSONNEL OF AN ACCREDITATION**  
30 **ORGANIZATION SHALL INCLUDE NURSE AND PHYSICIAN REVIEWERS WHO:**

1                   **(I) ARE TRAINED AND EXPERIENCED IN THE STANDARDS**  
2 **OF THE ACCREDITATION ORGANIZATION IN ORDER TO PROVIDE CONSISTENT**  
3 **REVIEW THROUGHOUT THE STATE; AND**

4                   **(II) DO NOT HAVE A CONFLICT OF INTEREST WITH:**

5                   1.   **THE CARDIOVASCULAR CATHETERIZATION**  
6 **LABORATORY THAT THE ACCREDITATION ORGANIZATION IS ACCREDITING;**

7                   2.   **THE HOSPITAL IN WHICH THE CARDIOVASCULAR**  
8 **CATHETERIZATION LABORATORY IS BASED; AND**

9                   3.   **THE STAFF OF THE CARDIOVASCULAR**  
10 **CATHETERIZATION LABORATORY OR HOSPITAL.**

11           **(C) (1) A CARDIOVASCULAR CATHETERIZATION LABORATORY THAT**  
12 **DOES NOT HOLD AN ACCREDITATION SHALL APPLY FOR CERTIFICATION WITH**  
13 **THE DEPARTMENT.**

14                   **(2) CERTIFICATION BY THE DEPARTMENT SHALL CONSIST OF**  
15 **PERIODIC REVIEW AND EVALUATION OF THE FOLLOWING ELEMENTS OF A**  
16 **CARDIOVASCULAR CATHETERIZATION LABORATORY:**

17                   **(I) FACILITIES, INCLUDING:**

18                   1.   **SCOPE OF SERVICE;**

19                   2.   **WHERE APPROPRIATE, TRANSFER POLICIES;**

20                   3.   **PROCEDURAL VOLUMES;**

21                   4.   **EQUIPMENT; AND**

22                   5.   **SPACE;**

23                   **(II) HEALTH CARE PROVIDERS, INCLUDING:**

24                   1.   **PHYSICIANS;**

25                   2.   **MEDICAL DIRECTORS;**

26                   3.   **TECHNICAL DIRECTORS;**

27                   4.   **PHYSICIAN EXTENDERS;**

- 1                   **5. NURSES; AND**
- 2                   **6. TECHNICAL PERSONNEL;**
- 3                   **(III) HEALTH CARE PROVIDER PRIVILEGES, INCLUDING:**
- 4                    1. INITIAL PRIVILEGES; AND
- 5                    2. MAINTENANCE OF PRIVILEGES;
- 6                   **(IV) INDICATIONS FOR PROCEDURE, INCLUDING:**
- 7                    1. CONSISTENCY IN THE APPROPRIATE USE OF
- 8 **CRITERIA FOR CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES;**
- 9                    2. VALIDATION OF REPORTED DATA; AND
- 10                  3. INFORMED CONSENT;
- 11                  **(V) PROCEDURAL CONDUCT;**
- 12                  **(VI) PATIENT OUTCOMES, INCLUDING OUTCOMES:**
- 13                    1. IN THE LABORATORY;
- 14                    2. IN THE HOSPITAL; AND
- 15                    3. FOR 30 DAYS AFTER THE PROCEDURE;
- 16                  **(VII) RADIATION SAFETY AND EXPOSURE;**
- 17                  **(VIII) REPORTING OF RESULTS, INCLUDING:**
- 18                    1. PROCEDURE REPORTS;
- 19                    2. REPORTS TO THE NATIONAL CARDIOVASCULAR
- 20 **DATA REGISTRY; AND**
- 21                    3. VALIDATION OF REPORTED DATA; AND
- 22                  **(IX) QUALITY ASSURANCE, INCLUDING:**

1                   **1. THE ADEQUACY, COMPLETENESS, FAIRNESS, AND**  
2 **CONSISTENCY OF FACILITY-BASED PROCESSES; AND**

3                   **2. EXTERNAL VALIDATION OF ANGIOGRAPHIC**  
4 **FINDINGS.**

5                   **(3) REVIEW AND EVALUATION FOR CERTIFICATION BY THE**  
6 **DEPARTMENT SHALL INCLUDE SPOT AUDITS AND ANNOUNCED OR**  
7 **UNANNOUNCED SITE VISITS.**

8                   **(4) (I) AFTER EACH REVIEW AND EVALUATION, THE**  
9 **DEPARTMENT SHALL ISSUE A REPORT THAT IDENTIFIES DEFICIENCIES FOUND**  
10 **DURING THE REVIEW AND EVALUATION.**

11                   **(II) AFTER A CARDIOVASCULAR CATHETERIZATION**  
12 **LABORATORY RECEIVES A REPORT OF DEFICIENCIES, THE LABORATORY SHALL**  
13 **DEVELOP A CORRECTIVE ACTION PLAN THAT ADDRESSES THE IDENTIFIED**  
14 **DEFICIENCIES.**

15                   **(III) ONGOING SURVEILLANCE OF A CARDIOVASCULAR**  
16 **CATHETERIZATION LABORATORY SHALL DOCUMENT ACTION TAKEN TO CARRY**  
17 **OUT A CORRECTIVE ACTION PLAN.**

18                   **(5) (I) BASED ON THE REVIEW AND EVALUATION OF A**  
19 **CARDIOVASCULAR CATHETERIZATION LABORATORY, THE DEPARTMENT SHALL:**

20                   **1. GRANT THE CARDIOVASCULAR**  
21 **CATHETERIZATION LABORATORY A FULL CERTIFICATION OR PROVISIONAL**  
22 **CERTIFICATION; OR**

23                   **2. DENY THE CARDIOVASCULAR CATHETERIZATION**  
24 **LABORATORY CERTIFICATION.**

25                   **(II) FULL CERTIFICATION SHALL BE GRANTED TO A**  
26 **CARDIOVASCULAR CATHETERIZATION LABORATORY THAT MEETS ALL OF THE**  
27 **STANDARDS ESTABLISHED BY THE DEPARTMENT.**

28                   **(III) 1. A CARDIOVASCULAR CATHETERIZATION**  
29 **LABORATORY THAT IS GRANTED PROVISIONAL CERTIFICATION SHALL MAKE**  
30 **SUBSTANTIVE CORRECTIONS OF DEFICIENCIES IN ACCORDANCE WITH A**  
31 **CORRECTIVE ACTION PLAN WITHIN 6 MONTHS AFTER THE PROVISIONAL**  
32 **CERTIFICATION IS GRANTED.**

1                   **2. A REPEAT REVIEW AND EVALUATION SHALL BE**  
2 **CONDUCTED NOT MORE THAN 6 MONTHS AFTER THE PROVISIONAL**  
3 **CERTIFICATION IS GRANTED.**

4                   **3. IF THE REPEAT REVIEW AND EVALUATION DOES**  
5 **NOT SHOW THAT THE CARDIOVASCULAR CATHETERIZATION LABORATORY HAS**  
6 **MADE SUBSTANTIVE CORRECTIONS TO THE IDENTIFIED DEFICIENCIES, THE**  
7 **LABORATORY SHALL BE DENIED CERTIFICATION AND REQUIRED TO RESUBMIT**  
8 **ALL DATA AT A LATER TIME FOR RECONSIDERATION.**

9                   **(6) (I) FULL CERTIFICATION OF A CARDIOVASCULAR**  
10 **CATHETERIZATION LABORATORY SHALL BE VALID FOR 2 YEARS.**

11                   **(II) FULL CERTIFICATION IS NOT VALID AFTER 2 YEARS**  
12 **UNLESS THE CERTIFICATION IS RENEWED BY THE DEPARTMENT.**

13                   **(D) THE DEPARTMENT SHALL ADOPT REGULATIONS TO CARRY OUT**  
14 **THIS SECTION.**

15 **19-2403.**

16                   **(A) EACH CARDIOVASCULAR CATHETERIZATION LABORATORY SHALL**  
17 **BE SUBJECT TO PERIODIC PEER REVIEW.**

18                   **(B) PEER REVIEW SHALL BE PERFORMED BY AN ACCREDITATION**  
19 **ORGANIZATION.**

20                   **(C) PEER REVIEW SHALL BE BASED ON CASES:**

21                   **(1) SELECTED AT RANDOM;**

22                   **(2) SELECTED FOR APPROPRIATENESS OF INDICATIONS FOR A**  
23 **PARTICULAR CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURE; OR**

24                   **(3) INVOLVING COMPLICATIONS OR UNEXPECTED OUTCOMES.**

25                   **(D) THE PEER REVIEW PROCESS SHALL ADDRESS:**

26                   **(1) ADHERENCE TO INTERNALLY APPROVED PROCESSES;**

27                   **(2) COMPLIANCE WITH NATIONAL STANDARDS FOR APPROPRIATE**  
28 **USE CRITERIA FOR CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES;**



1           (3)    **VALIDATION OF ANGIOGRAPHIC FINDINGS AND PATIENT**  
2 **OUTCOMES;**

3           (4)    **MEDICAL DATA REPORTING PROCEDURES AS MANDATED BY**  
4 **THE STATE;**

5           (5)    **EFFECTIVENESS OF INTERNAL EVALUATIONS;**

6           (6)    **CAPABILITY TO CORRECT DEFICIENCIES FOUND BY AN**  
7 **ACCREDITATION ORGANIZATION OR THROUGH CERTIFICATION BY THE**  
8 **DEPARTMENT; AND**

9           (7)    **QUALITY ASSURANCE.**

10          **(E)    FINDINGS FROM PEER REVIEW SHALL BE COMPARED TO:**

11               (1)    **PREVIOUS STATE EXPERIENCE; AND**

12               (2)    **APPROPRIATE NATIONAL STANDARDS.**

13          **(F)    THE DEPARTMENT SHALL ADOPT REGULATIONS TO CARRY OUT**  
14 **THIS SECTION.**

15    **19-2404.**

16          **(A)    THE DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION,**  
17 **AND THE HEALTH SERVICES COST REVIEW COMMISSION SHALL GIVE THE**  
18 **SAME CONSIDERATION TO DATA FROM THE CATHPCI REGISTRY AS GIVEN TO**  
19 **DATA FROM OTHER SOURCES TO DETERMINE APPROPRIATE USE CRITERIA AND**  
20 **QUALITY AND PERFORMANCE MEASURES FOR HOSPITALS AND HEALTH CARE**  
21 **PROVIDERS USING CARDIOVASCULAR DIAGNOSTIC OR PCI PROCEDURES.**

22          **(B)    DATA TO BE CONSIDERED UNDER SUBSECTION (A) OF THIS SECTION**  
23 **INCLUDES:**

24               (1)    **PATIENT OUTCOMES;**

25               (2)    **PATIENT DEMOGRAPHICS;**

26               (3)    **HOSPITAL PERFORMANCE;**

27               (4)    **PHYSICIAN PERFORMANCE;**

28               (5)    **RISK ADJUSTMENT OUTCOMES;**

1                   **(6) BENCHMARKING CAPABILITY FOR COMPARISON OF LIKE**  
2 **FACILITIES;**

3                   **(7) COST-EFFECTIVE TREATMENTS;**

4                   **(8) QUALITY MEASUREMENTS;**

5                   **(9) COMORBIDITIES OF POPULATIONS BEING STUDIED;**

6                   **(10) USE CRITERIA FOR PATIENT SELECTION;**

7                   **(11) REFERRAL PATTERNS TO STATE HOSPITALS;**

8                   **(12) DEVICE SURVEILLANCE; AND**

9                   **(13) CHANGING STANDARDS OF MEDICAL PRACTICE.**

10           **(C) THE DEPARTMENT SHALL ADOPT REGULATIONS TO CARRY OUT**  
11 **THIS SECTION.**

12           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
13 June 1, 2011.