

SENATE BILL 735

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2001 Regular Session  
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CF 11r1536

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By: **Senators Della and Miller**

Introduced and read first time: February 2, 2001

Assigned to: Finance

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A BILL ENTITLED

1 AN ACT concerning

2 **Cardiac Surgery - Licensing**

3 FOR the purpose of repealing a provision of the State health planning law requiring  
4 the granting of a certificate of need to establish a cardiac surgery program in the  
5 State; requiring the Department of Health and Mental Hygiene to license, on  
6 and after a certain date, cardiac surgery programs; providing for the issuance  
7 and renewal of licenses; prohibiting the Department from issuing a license  
8 under certain circumstances; requiring an applicant for a license or license  
9 renewal to meet certain conditions; requiring a licensed program to attain and  
10 maintain certain minimum caseload levels; requiring the Secretary of Health  
11 and Mental Hygiene to adopt certain regulations on or before a certain date;  
12 requiring the regulations to contain certain items and requirements;  
13 authorizing the Secretary to incorporate certain existing standards and  
14 providing for the effect of those existing standards; authorizing the Department  
15 to collect certain information; requiring the Secretary to develop and adopt by  
16 regulation, on or before a certain date, a data set relating to interhospital  
17 transports and providing for the use of that data set; requiring the Maryland  
18 Institute for Emergency Medical Services Systems to adopt, on or before a  
19 certain date, certain protocols; requiring the Secretary and the Maryland Health  
20 Care Commission to submit a certain report to the Governor and certain  
21 committees of the General Assembly on or before a certain date and providing  
22 for the contents of that report; defining cardiac surgery; requiring the  
23 Department to grant a waiver until a certain date of certain requirements under  
24 this Act to certain cardiac surgery programs under certain circumstances; and  
25 generally relating to the licensing of cardiac surgery programs in the State.

26 BY repealing and reenacting, with amendments,  
27 Article - Health - General  
28 Section 19-123(j)  
29 Annotated Code of Maryland  
30 (2000 Replacement Volume)

31 BY adding to  
32 Article - Health - General

1 Section 19-601 to be under the new subtitle "Subtitle 6. Cardiac Services"  
2 Annotated Code of Maryland  
3 (2000 Replacement Volume)

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

6 **Article - Health - General**

7 19-123.

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

10 (i) By a health care facility;

11 (ii) In space that is leased from a health care facility; or

12 (iii) In space that is on land leased from a health care facility.

13 (2) This subsection does not apply if:

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

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

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

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

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

25 3. Establishment of a home health program, hospice  
26 program, or freestanding ambulatory surgical center or facility; or

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

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

- 1                                        2.        The Commission in its sole discretion finds that the  
2 proposed change:
- 3                                        A.        Is pursuant to the consolidation or merger of 2 or more  
4 health care facilities, the conversion of a health care facility or part of a facility to a  
5 nonhealth-related use, or the conversion of a hospital to a limited service hospital;
- 6                                        B.        Is not inconsistent with the State health plan or the  
7 institution-specific plan developed and adopted by the Commission;
- 8                                        C.        Will result in the delivery of more efficient and effective  
9 health care services; and
- 10                                       D.        Is in the public interest; and
- 11                                       3.        Within 45 days of receiving notice under item 1 of this  
12 subparagraph, the Commission shall notify the health care facility of its finding.
- 13                                       (3)       Notwithstanding the provisions of paragraph (2) of this subsection, a  
14 certificate of need is required:
- 15                                       (i)       Before an additional home health agency, branch office, or home  
16 health care service is established by an existing health care agency or facility;
- 17                                       (ii)      Before an existing home health agency or health care facility  
18 establishes a home health agency or home health care service at a location in the  
19 service area not included under a previous certificate of need or license;
- 20                                       (iii)     Before a transfer of ownership of any branch office of a home  
21 health agency or home health care service of an existing health care facility that  
22 separates the ownership of the branch office from the home health agency or home  
23 health care service of an existing health care facility which established the branch  
24 office; or
- 25                                       (iv)     Before the expansion of a home health service or program by a  
26 health care facility that:
- 27                                       1.        Established the home health service or program without a  
28 certificate of need between January 1, 1984 and July 1, 1984; and
- 29                                       2.        During a 1-year period, the annual operating revenue of  
30 the home health service or program would be greater than \$333,000 after an annual  
31 adjustment for inflation, based on an appropriate index specified by the Commission.

32                                       SUBTITLE 6. CARDIAC SERVICES.

33 19-601.

34 (A)        IN THIS SECTION, "CARDIAC SURGERY" MEANS:

1 (1) MINIMALLY INVASIVE PROCEDURES THAT DO NOT REQUIRE THE  
2 USE OF CARDIOPULMONARY BYPASS SUPPORT;

3 (2) CATHETER-BASED REVASCULARIZATION PROCEDURES, INCLUDING  
4 CONVENTIONAL BALLOON ANGIOPLASTY AND CORONARY STENTING; AND

5 (3) SURGERY DURING WHICH CARDIOPULMONARY BYPASS SUPPORT  
6 MAY TEMPORARILY ASSUME THE FUNCTIONS OF THE PATIENT'S HEART AND LUNGS.

7 (B) (1) ON AND AFTER JANUARY 1, 2002, THE DEPARTMENT SHALL LICENSE  
8 EACH CARDIAC SURGERY PROGRAM OPERATED BY A HOSPITAL WITHIN THE STATE  
9 THAT MEETS THE REQUIREMENTS OF THIS SUBTITLE AND REGULATIONS ADOPTED  
10 UNDER THIS SUBTITLE.

11 (2) THE TERM OF A LICENSE IS 2 YEARS.

12 (3) (I) UNLESS A LICENSE IS RENEWED FOR A 2-YEAR TERM AS  
13 PROVIDED UNDER THIS PARAGRAPH, THE LICENSE EXPIRES ON THE SECOND  
14 DECEMBER 31 AFTER ITS EFFECTIVE DATE.

15 (II) AT LEAST 3 MONTHS BEFORE A LICENSE EXPIRES, THE  
16 DEPARTMENT SHALL MAIL TO THE HOSPITAL OPERATING THE LICENSED PROGRAM:

17 1. A RENEWAL FORM; AND

18 2. A NOTICE THAT STATES THE DATE ON WHICH THE  
19 LICENSE EXPIRES, THE DATE BY WHICH THE DEPARTMENT MUST RECEIVE THE  
20 RENEWAL APPLICATION FOR A RENEWAL LICENSE TO BE ISSUED AND MAILED  
21 BEFORE THE LICENSE EXPIRES, AND THE AMOUNT OF THE RENEWAL FEE.

22 (III) A LICENSED PROGRAM MAY RENEW A LICENSE FOR AN  
23 ADDITIONAL TERM IF THE LICENSED PROGRAM MEETS THE CONDITIONS OF THIS  
24 SUBTITLE.

25 (4) THE DEPARTMENT MAY NOT LICENSE A PROGRAM OR RENEW THE  
26 LICENSE OF A PROGRAM IN WHICH, AFTER ADJUSTING FOR RECOGNIZED  
27 PATIENT-SPECIFIC RISK FACTORS, THE MORTALITY AND MORBIDITY RATES FOR ALL  
28 PATIENTS UNDERGOING SURGERY IN THE HOSPITAL SIGNIFICANTLY EXCEED THE  
29 MORTALITY AND MORBIDITY RATES FOR ALL CARDIAC SURGERY PATIENTS IN THE  
30 STATE.

31 (5) EACH APPLICANT FOR A LICENSE OR LICENSE RENEWAL SHALL  
32 DOCUMENT TO THE DEPARTMENT:

33 (I) A PLAN TO STAFF AND OPERATE A CARDIAC SURGERY  
34 PROGRAM AS DEFINED BY THE REGULATIONS IN SUBSECTION (C) OF THIS SECTION;

35 (II) ADEQUATE OPERATING ROOM CAPACITY;

1 (III) COMPLIANCE WITH REGULATIONS ADOPTED BY THE  
2 SECRETARY; AND

3 (IV) THE PRESENT ABILITY TO MAINTAIN THE CASELOAD PROVIDED  
4 IN ITEM (6) OF THIS SUBSECTION.

5 (6) WITHIN 3 YEARS AFTER A HOSPITAL INITIATES A LICENSED CARDIAC  
6 SURGERY PROGRAM, THE PROGRAM SHALL:

7 (I) ATTAIN, AND SHALL SUBSEQUENTLY MAINTAIN, A MINIMUM  
8 CASELOAD EACH YEAR OF 350 CARDIAC SURGERY CASES; AND

9 (II) DEVELOP OR ESTABLISH A CARDIOVASCULAR DISEASE  
10 PREVENTION AND EARLY DIAGNOSTIC PROGRAM THAT:

11 1. PROVIDES PATIENT EDUCATION ABOUT TREATMENT  
12 OPTIONS; AND

13 2. INCLUDES OUTREACH TO THE MINORITY AND INDIGENT  
14 POPULATIONS IN THE REGIONAL SERVICE AREA OF THE HOSPITAL OPERATING THE  
15 PROGRAM.

16 (C) (1) ON OR BEFORE NOVEMBER 30, 2001, THE SECRETARY SHALL ADOPT  
17 REGULATIONS TO IMPLEMENT THIS SUBTITLE.

18 (2) THE REGULATIONS SHALL INCLUDE:

19 (I) QUALITY OF CARE STANDARDS, INCLUDING:

20 1. GUIDELINES FOR PERSONNEL AND FACILITIES, SUCH AS  
21 THOSE CONTAINED IN:

22 A. THE GUIDELINES AND INDICATIONS FOR CORONARY  
23 ARTERY BYPASS GRAFT SURGERY, APPROVED BY THE AMERICAN COLLEGE OF  
24 CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION;

25 B. THE GUIDELINES FOR STANDARDS IN CARDIAC SURGERY  
26 APPROVED BY THE AMERICAN COLLEGE OF SURGEONS; AND

27 C. THE PHYSICIAN MINIMUM VOLUME GUIDELINES  
28 RECOMMENDED BY THE AMERICAN COLLEGE OF CARDIOLOGY, THE AMERICAN  
29 COLLEGE OF SURGEONS, OR OTHER APPROPRIATE PROFESSIONAL ORGANIZATIONS;

30 2. THE REQUIREMENT THAT PROGRAMS LICENSED UNDER  
31 THIS SUBTITLE SHALL HAVE UTILIZATION OR PEER REVIEW AND CONTROL  
32 PROGRAMS, WITH REGULARLY SCHEDULED CONFERENCES TO:

33 A. ESTABLISH AND REVIEW PROTOCOLS THAT GOVERN THE  
34 REFERRAL, ADMISSION, AND DISCHARGE OF CARDIAC SURGERY PATIENTS;

1 B. ESTABLISH AND REVIEW A LIST OF INDICATIONS AND  
2 CONTRAINDICATIONS TO GOVERN PATIENT SELECTION FOR CARDIAC SURGERY;

3 C. ESTABLISH A PROGRAM TO EDUCATE PATIENTS ABOUT  
4 TREATMENT OPTIONS;

5 D. ESTABLISH AND REVIEW GUIDELINES GOVERNING THE  
6 ADMISSION OF CARDIAC SURGERY PATIENTS TO INTENSIVE CARE, CORONARY, OR  
7 PROGRESSIVE CARE UNITS AND DISCHARGE FROM THOSE UNITS;

8 E. REVIEW MORBIDITY AND MORTALITY RATES AND OTHER  
9 INDICATORS OF PATIENT OUTCOMES USING REGIONAL AND NATIONAL AVERAGES  
10 FOR COMPARISON; AND

11 F. ESTABLISH MECHANISMS FOR MONITORING LONG-TERM  
12 OUTCOMES OF DISCHARGED PATIENTS;

13 3. THE REQUIREMENT THAT EACH PROGRAM LICENSED  
14 UNDER THIS SUBTITLE SHALL MAKE ITS CARDIAC SURGERY SERVICES AVAILABLE  
15 ON AN EMERGENCY BASIS, 24 HOURS EACH DAY AND 7 DAYS EACH WEEK;

16 4. THE REQUIREMENT THAT EACH PROGRAM LICENSED  
17 UNDER THIS SUBTITLE SHALL ESTABLISH AND MAINTAIN ANCILLARY AND SUPPORT  
18 SERVICES AT LEVELS ESTABLISHED BY THE SECRETARY IN REGULATION,  
19 INCLUDING:

20 A. A CARDIAC INTENSIVE CARE UNIT;

21 B. A CARDIAC CATHETERIZATION LABORATORY;

22 C. A CHEST PAIN CENTER; AND

23 D. AN APPROPRIATE NUMBER OF OPERATING ROOMS; AND

24 (II) LICENSING AND RENEWAL PROCEDURES AND FEES.

25 (3) (I) THE SECRETARY MAY INCORPORATE BY REFERENCE INTO THE  
26 REGULATIONS ADOPTED UNDER THIS SUBTITLE THE STANDARDS OF THE JOINT  
27 COMMISSION ON ACCREDITATION OF HEALTH CARE ORGANIZATIONS.

28 (II) IF THE STANDARDS OF THE JOINT COMMISSION ON  
29 ACCREDITATION OF HEALTH CARE ORGANIZATIONS ARE LESS STRICT THAN, OR ARE  
30 IN CONFLICT WITH, THE STANDARDS ADOPTED BY THE DEPARTMENT, THE  
31 DEPARTMENTAL STANDARDS SHALL PREVAIL.

32 (D) (1) THE DEPARTMENT MAY REQUEST AND COLLECT FROM HOSPITALS  
33 IN THE STATE ANY STATISTICAL OR OTHER INFORMATION THAT THE DEPARTMENT  
34 CONSIDERS NECESSARY TO:

35 (I) DEVELOP STANDARDS FOR CARDIAC SURGERY PROGRAMS; AND

- 1 (II) MONITOR THE DELIVERY OF CARDIAC SURGERY SERVICES,  
2 INCLUDING:
- 3 1. MORTALITY AND MORBIDITY RATES;  
4 2. INFECTIONS AND COMPLICATIONS; AND  
5 3. PATIENT RISK FACTORS; AND

6 (III) MONITOR THE NUMBER OF CARDIAC SURGERIES PERFORMED  
7 IN THE STATE.

8 (2) IN MONITORING MORTALITY AND MORBIDITY RATES, THE  
9 DEPARTMENT SHALL COMPARE THE MORTALITY AND MORBIDITY RATES OF EACH  
10 HOSPITAL WITH:

11 (I) THE RATES OF OTHER HOSPITALS IN THE STATE; AND

12 (II) REGIONAL OR NATIONAL AVERAGE MORTALITY AND  
13 MORBIDITY RATES.

14 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before November  
15 30, 2001, the Secretary of Health and Mental Hygiene shall develop and adopt by  
16 regulation a standard data set for the volume and characteristics of interhospital  
17 transports, to be collected by the Maryland Institute for Emergency Medical Services  
18 Systems. The data set shall be used to benchmark current system performance,  
19 provide continuous feedback to sending and receiving hospitals, and set goals for  
20 improving interhospital transport response times.

21 SECTION 3. AND BE IT FURTHER ENACTED, That, on or before November  
22 30, 2001, the Maryland Institute for Emergency Medical Services Systems, with the  
23 assistance of the Secretary of Health and Mental Hygiene and the hospitals providing  
24 specialized cardiac care or referring patients for cardiac surgery services, shall adopt  
25 by regulation protocols to guide the rapid interhospital transport of cardiac patients.

26 SECTION 4. AND BE IT FURTHER ENACTED, That, on or before December  
27 31, 2005, the Secretary of Health and Mental Hygiene and the Maryland Health Care  
28 Commission shall submit a report to the Governor and, subject to § 2-1246 of the  
29 State Government Article, to the Senate Finance and House Environmental Matters  
30 committees concerning:

31 (1) the impact on health care costs in the State of discontinuing the  
32 granting of certificates of need for, and instead licensing, cardiac surgery licensing  
33 programs;

34 (2) the impact on quality of medical care in cardiac surgery licensing  
35 programs of discontinuing the granting of certificates of need for, and instead  
36 licensing, those programs;

1           (3)       the impact on access to cardiac surgery services of discontinuing the  
2 granting of certificates of need for, and instead licensing, those programs;

3           (4)       the impact on bed capacity and caseload in cardiac surgery services  
4 programs of discontinuing the granting of certificates of need for, and instead  
5 licensing, those programs; and

6           (5)       the impact on the number of interhospital transports for cardiac  
7 surgery services of discontinuing the granting of certificates of need for, and instead  
8 licensing, those programs.

9       SECTION 5. AND BE IT FURTHER ENACTED, That, until September 30,  
10 2003, the Department shall grant a waiver of the conditions for licensure under this  
11 Act to any cardiac surgery program that:

12           (1)       holds a certificate of need granted on or before June 30, 2001 by the  
13 Maryland Health Care Commission; and

14           (2)       applies for licensure under this Act.

15       SECTION 6. AND BE IT FURTHER ENACTED, That this Act shall take effect  
16 July 1, 2001.