
By: **Senators Kelley, Della, Gladden, Lawlah, and Miller**
Introduced and read first time: January 31, 2003
Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Cardiac Services - 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 services program in
5 the State; requiring the Department of Health and Mental Hygiene to license,
6 on and after a certain date, cardiac services programs; providing for the
7 issuance and renewal of licenses; prohibiting the Department from issuing a
8 license under certain circumstances; requiring an applicant for a license or
9 license renewal to meet certain conditions; requiring a licensed program to
10 attain and maintain certain 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 certain terms; requiring the Department
23 to grant a waiver until a certain date of certain requirements under this Act to
24 certain cardiac services programs under certain circumstances; and generally
25 relating to the licensing of cardiac services programs in the State.

26 BY repealing and reenacting, with amendments,
27 Article - Health - General
28 Section 19-120(j)
29 Annotated Code of Maryland
30 (2000 Replacement Volume and 2002 Supplement)

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 and 2002 Supplement)

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 19-120.

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) "CARDIAC-RELATED PROCEDURES" INCLUDES:

2 (I) CARDIAC PROCEDURES THAT DO NOT REQUIRE THE USE OF
3 CARDIOPULMONARY BYPASS SUPPORT; AND

4 (II) CATHETER-BASED CORONARY REVASCULARIZATION
5 PROCEDURES, INCLUDING CONVENTIONAL BALLOON ANGIOPLASTY AND CORONARY
6 STENTING.

7 (3) "CARDIAC SERVICES" INCLUDES CARDIAC-RELATED PROCEDURES
8 AND CARDIAC SURGERY.

9 (4) "CARDIAC SURGERY" MEANS SURGERY DURING WHICH
10 CARDIOPULMONARY BYPASS SUPPORT MAY TEMPORARILY ASSUME THE FUNCTIONS
11 OF THE PATIENT'S HEART AND LUNGS.

12 (B) (1) ON AND AFTER JANUARY 1, 2004, THE DEPARTMENT SHALL LICENSE
13 EACH CARDIAC SERVICES PROGRAM OPERATED BY A HOSPITAL WITHIN THE STATE
14 THAT MEETS THE REQUIREMENTS OF THIS SUBTITLE AND REGULATIONS ADOPTED
15 UNDER THIS SUBTITLE.

16 (2) THE TERM OF A LICENSE IS 3 YEARS.

17 (3) (I) UNLESS A LICENSE IS RENEWED FOR A 3-YEAR TERM AS
18 PROVIDED UNDER THIS PARAGRAPH, THE LICENSE EXPIRES ON THE THIRD
19 DECEMBER 31 AFTER ITS EFFECTIVE DATE.

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

22 1. A RENEWAL FORM; AND

23 2. A NOTICE THAT STATES THE DATE ON WHICH THE
24 LICENSE EXPIRES, THE DATE BY WHICH THE DEPARTMENT MUST RECEIVE THE
25 RENEWAL APPLICATION FOR A RENEWAL LICENSE TO BE ISSUED AND MAILED
26 BEFORE THE LICENSE EXPIRES, AND THE AMOUNT OF THE RENEWAL FEE.

27 (III) A LICENSED PROGRAM MAY RENEW A LICENSE FOR AN
28 ADDITIONAL TERM IF THE LICENSED PROGRAM MEETS THE CONDITIONS OF THIS
29 SUBTITLE.

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

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

1 (I) A PLAN TO STAFF AND OPERATE A CARDIAC SERVICES
2 PROGRAM;

3 (II) ADEQUATE OPERATING ROOM CAPACITY AS DEFINED BY THE
4 REGULATIONS IN SUBSECTION (C) OF THIS SECTION;

5 (III) COMPLIANCE WITH REGULATIONS ADOPTED BY THE
6 SECRETARY; AND

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

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

11 (I) ATTAIN, AND SUBSEQUENTLY MAINTAIN, 350 CARDIAC
12 SURGERY CASES ANNUALLY;

13 (II) ATTAIN, AND SUBSEQUENTLY MAINTAIN, A MINIMUM OF 200
14 CARDIAC-RELATED PROCEDURES PERFORMED ANNUALLY; AND

15 (III) DEVELOP OR ESTABLISH A CARDIOVASCULAR DISEASE
16 PREVENTION AND EARLY DIAGNOSTIC PROGRAM THAT:

17 1. PROVIDES PATIENT EDUCATION ABOUT TREATMENT
18 OPTIONS; AND

19 2. INCLUDES OUTREACH TO THE MINORITY AND INDIGENT
20 POPULATIONS IN THE REGIONAL SERVICE AREA OF THE HOSPITAL OPERATING THE
21 PROGRAM.

22 (C) (1) ON OR BEFORE NOVEMBER 30, 2003, THE SECRETARY SHALL ADOPT
23 REGULATIONS TO IMPLEMENT THIS SUBTITLE.

24 (2) THE REGULATIONS SHALL INCLUDE:

25 (I) QUALITY OF CARE STANDARDS, INCLUDING:

26 1. GUIDELINES FOR PERSONNEL AND FACILITIES, SUCH AS
27 THOSE CONTAINED IN:

28 A. THE GUIDELINES AND INDICATIONS FOR CORONARY
29 ARTERY BYPASS GRAFT SURGERY, APPROVED BY THE AMERICAN COLLEGE OF
30 CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION;

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

33 C. THE PHYSICIAN MINIMUM VOLUME GUIDELINES
34 RECOMMENDED BY THE AMERICAN COLLEGE OF CARDIOLOGY, THE AMERICAN
35 COLLEGE OF SURGEONS, OR OTHER APPROPRIATE PROFESSIONAL ORGANIZATIONS;

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

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

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

8 C. ESTABLISH A PROGRAM TO EDUCATE PATIENTS ABOUT
9 TREATMENT OPTIONS;

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

13 E. REVIEW MORBIDITY AND MORTALITY RATES AND OTHER
14 INDICATORS OF PATIENT OUTCOMES USING REGIONAL AND NATIONAL AVERAGES
15 FOR COMPARISON; AND

16 F. ESTABLISH MECHANISMS FOR MONITORING LONG-TERM
17 OUTCOMES OF DISCHARGED PATIENTS;

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

21 4. THE REQUIREMENT THAT EACH PROGRAM LICENSED
22 UNDER THIS SUBTITLE SHALL ESTABLISH AND MAINTAIN ANCILLARY AND SUPPORT
23 SERVICES AT LEVELS ESTABLISHED BY THE SECRETARY IN REGULATION,
24 INCLUDING:

25 A. A CARDIAC INTENSIVE CARE UNIT;

26 B. A CARDIAC CATHETERIZATION LABORATORY; AND

27 C. AN APPROPRIATE NUMBER OF OPERATING ROOMS; AND

28 (II) LICENSING AND RENEWAL PROCEDURES AND FEES.

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

32 (II) IF THE STANDARDS OF THE JOINT COMMISSION ON
33 ACCREDITATION OF HEALTH CARE ORGANIZATIONS ARE LESS STRICT THAN, OR ARE
34 IN CONFLICT WITH, THE STANDARDS ADOPTED BY THE DEPARTMENT, THE
35 DEPARTMENTAL STANDARDS SHALL PREVAIL.

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

4 (I) DEVELOP STANDARDS FOR CARDIAC SERVICES PROGRAMS;

5 (II) MONITOR THE DELIVERY OF CARDIAC SERVICES, INCLUDING:

6 1. MORTALITY AND MORBIDITY RATES;

7 2. INFECTIONS AND COMPLICATIONS; AND

8 3. PATIENT RISK FACTORS; AND

9 (III) MONITOR THE NUMBER OF CARDIAC SURGERIES PERFORMED
10 IN THE STATE.

11 (2) IN MONITORING MORTALITY AND MORBIDITY RATES, THE
12 DEPARTMENT SHALL COMPARE THE MORTALITY AND MORBIDITY RATES OF EACH
13 HOSPITAL WITH:

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

15 (II) REGIONAL OR NATIONAL AVERAGE MORTALITY AND
16 MORBIDITY RATES.

17 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before November
18 30, 2003, the Secretary of Health and Mental Hygiene shall develop and adopt by
19 regulation a standard data set for the volume and characteristics of interhospital
20 transports, to be collected by the Maryland Institute for Emergency Medical Services
21 Systems. The data set shall be used to benchmark current system performance,
22 provide continuous feedback to sending and receiving hospitals, and set goals for
23 improving interhospital transport response times.

24 SECTION 3. AND BE IT FURTHER ENACTED, That, on or before November
25 30, 2003, the Maryland Institute for Emergency Medical Services Systems, with the
26 assistance of the Secretary of Health and Mental Hygiene and the hospitals providing
27 specialized cardiac care or referring patients for cardiac services, shall adopt by
28 regulation protocols to guide the rapid interhospital transport of cardiac patients.

29 SECTION 4. AND BE IT FURTHER ENACTED, That, on or before December
30 31, 2007, the Secretary of Health and Mental Hygiene and the Maryland Health Care
31 Commission shall submit a report to the Governor and, subject to § 2-1246 of the
32 State Government Article, to the Senate Finance and House Health and Government
33 Operations committees concerning:

34 (1) the impact on health care costs in the State of discontinuing the
35 granting of certificates of need for, and instead licensing, cardiac services programs;

1 (2) the impact on the quality of medical care in cardiac services programs
2 by discontinuing the granting of certificates of need for, and instead licensing, those
3 programs;

4 (3) the impact on access to cardiac services by discontinuing the granting
5 of certificates of need for, and instead licensing, those programs;

6 (4) the impact on bed capacity and caseload in cardiac services programs
7 by discontinuing the granting of certificates of need for, and instead licensing, those
8 programs; and

9 (5) the impact on the number of interhospital transports for cardiac
10 services by discontinuing the granting of certificates of need for, and instead
11 licensing, those programs.

12 SECTION 5. AND BE IT FURTHER ENACTED, That, until September 30,
13 2008, the Department shall grant a waiver of the conditions for licensure under this
14 Act to any cardiac services program that:

15 (1) holds a certificate of need granted on or before June 30, 2003 by the
16 Maryland Health Care Commission; and

17 (2) applies for licensure under this Act.

18 SECTION 6. AND BE IT FURTHER ENACTED, That this Act shall take effect
19 July 1, 2003.