
By: **Delegates Dewberry, Guns, Weir, McHale, Elliott, Stull, Malone, D. Murphy, and Sophocleus**

Introduced and read first time: February 12, 1999

Assigned to: Environmental Matters

A BILL ENTITLED

1 AN ACT concerning

2 **Open Heart Surgery Services - Demonstration Program For New Services**

3 FOR the purpose of exempting certain open heart surgery services from a certain
4 certificate of need requirement under certain circumstances; creating a
5 demonstration program; requiring the Secretary of Health and Mental Hygiene,
6 by a certain date, to adopt certain quality-of-care standards for certain new
7 open heart surgery services; requiring the Secretary to develop a certain
8 reporting system and model for expected mortality rates; authorizing the
9 Secretary to request and collect certain statistical or other information from
10 accredited and nonaccredited hospitals; authorizing the Secretary to take
11 certain enforcement action if certain hospitals do not provide certain
12 information; requiring certain hospitals to be subject to a certain inspection by
13 the Department of Health and Mental Hygiene to review compliance with
14 certain standards; requiring the Department in conducting certain
15 investigations to use certain standards adopted by the Secretary; authorizing
16 the Secretary to take certain enforcement action if certain hospitals do not
17 comply with certain regulations; providing for the confidentiality and
18 evidentiary in admissibility of certain statistical or other information submitted
19 by a certain hospital to the Secretary; requiring a hospital to be licensed by the
20 Secretary to provide a new open heart surgery service before the hospital
21 provides that service; prohibiting a hospital from applying for a certain license
22 before a certain date; requiring a certain hospital to obtain a certain license
23 before a certain date unless the termination date for this Act is extended;
24 providing for the acquisition of a certain license if the termination date of this
25 Act is extended; requiring the Secretary to submit a report to the Senate
26 Finance Committee and the House Environmental Matters Committee on or
27 before a certain date; making certain legislative findings; providing for the
28 termination of this Act; defining a certain term; and generally relating to certain
29 open heart surgery services.

30 BY repealing and reenacting, without amendments,
31 Article - Health - General
32 Section 1-101(a) and (i)
33 Annotated Code of Maryland

1 (1994 Replacement Volume and 1998 Supplement)

2 BY repealing and reenacting, without amendments,

3 Article - Health - General

4 Section 19-101(a) and (d) and 19-115(a)(1)

5 Annotated Code of Maryland

6 (1996 Replacement Volume and 1998 Supplement)

7 BY adding to

8 Article - Health - General

9 Section 19-115(a)(4)

10 Annotated Code of Maryland

11 (1996 Replacement Volume and 1998 Supplement)

12 BY repealing and reenacting, with amendments,

13 Article - Health - General

14 Section 19-115(i), 19-308, 19-309, and 19-318

15 Annotated Code of Maryland

16 (1996 Replacement Volume and 1998 Supplement)

17 Preamble

18 WHEREAS, Open heart surgery has developed to the point where it can safely

19 be provided in large community hospitals, and quality-of-care standards for open

20 heart surgery are now well defined by standards such as those approved by the

21 American College of Cardiology and the American College of Surgeons; and

22 WHEREAS, Regulatory oversight of new open heart surgery services is more

23 appropriately focused on establishing and enforcing appropriate standards for quality

24 of care; and

25 WHEREAS, There should be a demonstration program that regulates quality of

26 care in new open heart surgery services and that provides a limited exemption from

27 certificate of need for new open heart surgery services, to be approved only if the

28 Health Services Cost Review Commission determines that the new service will result

29 in a net saving to the health care system; now, therefore,

30 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

31 MARYLAND, That the Laws of Maryland read as follows:

32 **Article - Health - General**

33 1-101.

34 (a) In this article the following words have the meanings indicated.

35 (i) "Secretary" means the Secretary of Health and Mental Hygiene.

1 19-101.

2 (a) In Part I of this subtitle the following words have the meanings indicated.

3 (d) "Commission" means the State Health Resources Planning Commission.

4 19-115.

5 (a) (1) In this section the following words have the meanings indicated.

6 (4) "NEW OPEN HEART SURGERY SERVICE" MEANS AN OPEN HEART
7 SURGERY SERVICE THAT IS INITIATED ON OR AFTER JANUARY 1, 2000, IN
8 ACCORDANCE WITH SUBSECTION (I)(2)(IV) OF THIS SECTION.

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

11 (i) By a health care facility;

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

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

14 (2) This subsection does not apply if:

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

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

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

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

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

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

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

1 (IV) 1. THE PROPOSED CHANGE WOULD ESTABLISH A NEW OPEN
2 HEART SURGERY SERVICE AT A MEDICAL-SURGICAL HOSPITAL THAT HAD AT LEAST
3 300 LICENSED BEDS ON JANUARY 1, 1999;

4 2. THE HOSPITAL AT WHICH THE NEW OPEN HEART
5 SURGERY SERVICE WOULD BE ESTABLISHED IS NOT PART OF A MERGED OR
6 CONSOLIDATED HEALTH CARE SYSTEM IN WHICH ONE OR MORE HOSPITALS
7 ALREADY PROVIDE OPEN HEART SURGERY SERVICES;

8 3. AFTER TAKING INTO ACCOUNT ANY VOLUNTARY OR
9 MANDATORY ADJUSTMENTS TO HOSPITAL RATES, THE HEALTH SERVICES COST
10 REVIEW COMMISSION DETERMINES THAT THERE WILL BE A NET SAVINGS TO THE
11 HEALTH CARE SYSTEM AS A RESULT OF THE PROPOSED CHANGE IN SERVICE; AND

12 4. THE NEW OPEN HEART SURGERY SERVICE COMPLIES
13 WITH QUALITY-OF-CARE STANDARDS ESTABLISHED BY THE SECRETARY; OR

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

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

19 A. Is pursuant to the consolidation or merger of 2 or more
20 health care facilities, or conversion of a health care facility or part of a facility to a
21 nonhealth-related use;

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

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

26 D. Is in the public interest; and

27 3. Within 45 days of receiving notice under item 1 of this
28 subparagraph, the Commission shall notify the health care facility of its finding.

29 (3) Notwithstanding the provisions of paragraph (2) of this subsection, a
30 certificate of need is required:

31 (i) Before an additional home health agency, branch office, or home
32 health care service is established by an existing health care agency or facility;

33 (ii) Before an existing home health agency or health care facility
34 establishes a home health agency or home health care service at a location in the
35 service area not included under a previous certificate of need or license;

1 (iii) Before a transfer of ownership of any branch office of a home
2 health agency or home health care service of an existing health care facility that
3 separates the ownership of the branch office from the home health agency or home
4 health care service of an existing health care facility which established the branch
5 office; or

6 (iv) Before the expansion of a home health service or program by a
7 health care facility that:

8 1. Established the home health service or program without a
9 certificate of need between January 1, 1984 and July 1, 1984; and

10 2. During a 1-year period, the annual operating revenue of
11 the home health service or program would be greater than \$333,000 after an annual
12 adjustment for inflation, based on an appropriate index specified by the Commission.
13 19-308.

14 (a) The Secretary shall adopt reasonable rules and regulations that set
15 standards of services for related institutions, nonaccredited hospitals, and
16 nonaccredited residential treatment centers in the following areas:

- 17 (1) The care of patients;
- 18 (2) The medical supervision of patients;
- 19 (3) The physical environment;
- 20 (4) Disease control;
- 21 (5) Sanitation;
- 22 (6) Safety; and
- 23 (7) Dietary matters.

24 (B) (1) IN THIS SUBSECTION, "NEW OPEN HEART SURGERY SERVICE" HAS
25 THE MEANING STATED IN § 19-115(A) OF THIS ARTICLE.

26 (2) (I) ON OR BEFORE JANUARY 1, 2000, THE SECRETARY SHALL
27 ADOPT QUALITY-OF-CARE STANDARDS FOR NEW OPEN HEART SURGERY SERVICES.

28 (II) FOR ADULTS, THE QUALITY-OF-CARE STANDARDS SHALL
29 INCLUDE:

30 1. WITHIN 2 YEARS AFTER INITIATION OF THE OPEN HEART
31 SURGERY SERVICE, A MINIMUM ANNUAL CASELOAD OF 200 OPEN HEART SURGERY
32 CASES FOR EACH HOSPITAL;

33 2. GUIDELINES CONCERNING PERSONNEL AND FACILITIES,
34 SUCH AS THOSE CONTAINED IN:

1 A. THE GUIDELINES AND INDICATIONS FOR CORONARY
2 ARTERY BYPASS GRAFT SURGERY, APPROVED BY THE AMERICAN COLLEGE OF
3 CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION; AND

4 B. THE GUIDELINES FOR STANDARDS IN CARDIAC SURGERY,
5 APPROVED BY THE AMERICAN COLLEGE OF SURGEONS; AND

6 3. A REQUIREMENT THAT A PATIENT UNDERGOING
7 SURGERY AT AN OPEN HEART SURGERY PROGRAM SHALL NOT EXPERIENCE A
8 MORTALITY RATE THAT SIGNIFICANTLY EXCEEDS THE EXPECTED MORTALITY RATE
9 FOR ALL OPEN HEART SURGERY PATIENTS IN THE STATE AFTER ADJUSTING FOR
10 RECOGNIZED PATIENT SPECIFIC RISK FACTORS.

11 (III) IN DEVELOPING QUALITY-OF-CARE STANDARDS FOR NEW
12 OPEN HEART SURGERY SERVICES, THE SECRETARY SHALL CONSIDER:

13 1. THE GUIDELINES AND INDICATIONS FOR CORONARY
14 ARTERY BYPASS GRAFT SURGERY, APPROVED BY THE AMERICAN COLLEGE OF
15 CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION;

16 2. THE GUIDELINES FOR STANDARDS IN CARDIAC SURGERY,
17 APPROVED BY THE AMERICAN COLLEGE OF SURGEONS; AND

18 3. ANY REVISIONS AND UPDATES OF THE GUIDELINES
19 SPECIFIED IN SUBPARAGRAPHS (I) AND (II) OF THIS PARAGRAPH.

20 (IV) THE SECRETARY SHALL DEVELOP A REPORTING SYSTEM AND A
21 MODEL FOR EXPECTED MORTALITY RATES BASED ON GENERALLY ACCEPTED
22 STATISTICAL AND CLINICAL PRINCIPLES.

23 (V) THE SECRETARY MAY REQUEST AND COLLECT ANY
24 STATISTICAL OR OTHER INFORMATION FROM ACCREDITED AND NONACCREDITED
25 HOSPITALS THAT THE SECRETARY DEEMS TO BE NECESSARY FOR THE
26 DEVELOPMENT OF STANDARDS FOR OPEN HEART SURGERY OR THE MONITORING OF
27 THE DELIVERY OF OPEN HEART SURGERY.

28 (VI) IF AN ACCREDITED OR NONACCREDITED HOSPITAL DOES NOT
29 PROVIDE THE INFORMATION SPECIFIED IN SUBPARAGRAPH (V) OF THIS PARAGRAPH,
30 THE SECRETARY MAY:

31 1. IMPOSE A PENALTY OF NOT MORE THAN \$1,000 A DAY FOR
32 EACH DAY THE VIOLATION CONTINUES AFTER CONSIDERATION OF THE
33 WILLFULNESS AND SERIOUSNESS OF THE WITHHOLDING OF THE INFORMATION AND
34 ANY PAST HISTORY OF WITHHOLDING OF THE INFORMATION;

35 2. ISSUE AN ADMINISTRATIVE ORDER THAT REQUIRES THE
36 HOSPITAL TO PROVIDE THE INFORMATION; AND

1 (7) Subject to § 2-1246 of the State Government Article, during each
2 regular session of the General Assembly, the Department shall submit to the General
3 Assembly a report on the inspections.

4 (8) (i) An employee of the Department may not inform a hospital,
5 residential treatment center, or related institution of any proposed inspection activity,
6 unless the chief of the employee's division directs the employee to do so.

7 (ii) An employee who violates any provision of this paragraph is
8 guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 or
9 imprisonment not exceeding 1 year or both.

10 (D) IF AN ACCREDITED OR NONACCREDITED HOSPITAL DOES NOT COMPLY
11 WITH A REGULATION ADOPTED UNDER SUBSECTION (B) OF THIS SECTION, THE
12 SECRETARY MAY, IN ADDITION TO ANY OTHER PENALTY IMPOSED UNDER THIS
13 SUBTITLE:

14 (1) AFTER CONSIDERATION OF THE WILLFULNESS AND SERIOUSNESS
15 OF THE VIOLATION AS WELL AS ANY PAST HISTORY OF VIOLATIONS, IMPOSE A
16 PENALTY OF NOT MORE THAN \$10,000 A DAY FOR EACH DAY THE VIOLATION
17 CONTINUES;

18 (2) ISSUE AN ADMINISTRATIVE ORDER THAT PROHIBITS THE HOSPITAL
19 FROM:

20 (I) ADMITTING DESIGNATED TYPES OF PATIENTS WHO, IN THE
21 JUDGMENT OF THE SECRETARY, ARE ADVERSELY AFFECTED BY THE FAILURE OF
22 THE HOSPITAL TO COMPLY WITH THE REGULATION; OR

23 (II) PROVIDING DESIGNATED TYPES OF SERVICES WHICH, IN THE
24 JUDGMENT OF THE SECRETARY, ARE ADVERSELY AFFECTED BY THE FAILURE OF
25 THE HOSPITAL TO COMPLY WITH THE REGULATION; OR

26 (III) OR BOTH; OR

27 (3) APPLY TO THE CIRCUIT COURT FOR THE COUNTY IN WHICH THE
28 HOSPITAL IS LOCATED FOR LEGAL RELIEF THAT THE SECRETARY CONSIDERS
29 APPROPRIATE.

30 [(c)] (E) (1) An accredited hospital or accredited residential treatment
31 center shall submit the survey findings of the Joint Commission on Accreditation of
32 Healthcare Organizations within 30 days of receipt by the hospital or the residential
33 treatment center to the Department.

34 (2) Except as provided in paragraph (5) of this subsection, an accredited
35 hospital's or accredited residential treatment center's official accreditation report and
36 any summary of the report, written progress reports, or plans of correction which are
37 submitted to the Secretary are confidential and are not discoverable or admissible as
38 evidence in any civil action.

1 (3) ANY STATISTICAL OR OTHER INFORMATION A HOSPITAL SUBMITS
2 UNDER SUBSECTION (B)(2)(V) OF THIS SECTION CONCERNING STANDARDS FOR NEW
3 OPEN HEART SURGERY SERVICES IS CONFIDENTIAL AND NOT DISCOVERABLE OR
4 ADMISSIBLE AS EVIDENCE IN ANY CIVIL ACTION.

5 [(3)] (4) The Secretary shall refer any request for public inspection of a
6 survey report made by the Joint Commission on Accreditation of Healthcare
7 Organizations for an accredited hospital or accredited residential treatment center
8 directly to the hospital or residential treatment center.

9 [(4)] (5) Upon the written request of any person, within 15 working
10 days, the accredited hospital or accredited residential treatment center shall make
11 available for public inspection the most recent accreditation letter and any Type I
12 recommendations if the Joint Commission on Accreditation of Healthcare
13 Organizations has made a final decision on any appeal by the hospital or residential
14 treatment center of the Type I recommendations.

15 [(5)] (6) If information is released in accordance with paragraph (4) of
16 this subsection, that information is no longer confidential, but is not discoverable or
17 admissible in any civil action.

18 [(6)] (7) An accreditation report, including any summary of the report
19 and any information contained in the report, disclosed by a hospital or residential
20 treatment center, the Joint Commission on the Accreditation of Healthcare
21 Organizations, or the Department is not admissible or discoverable in any civil action.

22 [(7)] (8) If an accredited hospital or accredited residential treatment
23 center willfully fails to comply with the provisions of this subsection, the Secretary
24 may impose a penalty not to exceed \$1,000 a day for each day the violation continues.
25 19-309.

26 (a) Notwithstanding any other provisions of this subtitle, each hospital or
27 residential treatment center shall be open to inspections by the Department to
28 investigate and resolve any complaint concerning patient care, safety, medical and
29 nursing supervision, physical environment, sanitation or dietary matters.

30 (b) (1) To resolve expeditiously a complaint that alleges the existence of any
31 nonlife-threatening deficiency, the Department may refer the complaint directly to
32 the hospital or residential treatment center.

33 (2) If appropriate, issues relating to the practice of medicine or the
34 licensure or conduct of a health professional shall be referred to the hospital or the
35 residential treatment center and may be referred to the appropriate licensure board
36 for resolution.

37 (3) If the Department determines that the hospital or residential
38 treatment center has not satisfactorily addressed the referred complaint or where the
39 complaint alleges the existence of a life-threatening deficiency, the Department shall

1 conduct an independent investigation. When conducting its independent
2 investigation, the Department shall use:

3 (i) For an accredited hospital or accredited residential treatment
4 center, the current applicable standards of review of the Joint Commission on
5 Accreditation of Healthcare Organizations AND ANY APPLICABLE STANDARDS FOR
6 NEW OPEN HEART SURGERY SERVICES THE SECRETARY ADOPTS UNDER § 19-308(B)
7 OF THIS SUBTITLE;

8 (ii) For a nonaccredited hospital or nonaccredited residential
9 treatment center, the standards adopted by the Secretary under this subtitle;

10 (iii) For an accredited or nonaccredited hospital that is a facility as
11 defined under § 19-319.2 of this subtitle, the requirements of §§ 10-701 through
12 10-709 of this article; and

13 (iv) For an accredited or nonaccredited residential treatment center,
14 the requirements of §§ 10-701 through 10-709 of this article.

15 19-318.

16 (a) A person shall be licensed by the Secretary before the person may operate
17 a hospital or related institution in this State.

18 (b) A hospital shall be classified as a special rehabilitation hospital before the
19 hospital may provide or hold itself out as providing comprehensive physical
20 rehabilitation services, as defined in § 19-1201 of this title.

21 (C) (1) IN THIS SUBSECTION, "NEW OPEN HEART SURGERY SERVICE" HAS
22 THE MEANING STATED IN § 19-115(A) OF THIS ARTICLE.

23 (2) A HOSPITAL:

24 (I) SHALL BE LICENSED BY THE SECRETARY TO PROVIDE A NEW
25 OPEN HEART SURGERY SERVICE BEFORE THE HOSPITAL PROVIDES A NEW OPEN
26 HEART SURGERY SERVICE UNDER § 19-115(I)(2)(IV) OF THIS ARTICLE; AND

27 (II) MAY NOT APPLY FOR A LICENSE TO PROVIDE A NEW OPEN
28 HEART SURGERY SERVICE BEFORE JANUARY 1, 2000.

29 SECTION 2. AND BE IT FURTHER ENACTED, That:

30 (1) unless the General Assembly extends the termination date of this
31 Act, as specified in Section 4 of this Act, any medical-surgical hospital that seeks to
32 establish a new open heart surgery service in accordance with Section 1 of this Act
33 shall, before January 1, 2003, obtain a license from the Secretary of Health and
34 Mental Hygiene for the new open heart surgery service; and

1 (2) if the General Assembly extends the termination date of this Act, the
2 medical-surgical hospital has until the new termination date specified by the General
3 Assembly to obtain a license for a new open heart surgery service.

4 SECTION 3. AND BE IT FURTHER ENACTED, That on or before July 1, 2002,
5 the Secretary of Health and Mental Hygiene shall submit a report to the Senate
6 Finance Committee and the House Environmental Matters Committee concerning:

7 (1) the cost to the health care system of the State concerning new open
8 heart surgery services established in accordance with this Act;

9 (2) the quality of medical care delivered by new open heart surgery
10 services established in accordance with this Act;

11 (3) access to open heart surgery in the health care system of the State;
12 and

13 (4) the number of open heart surgery procedures performed at hospitals
14 with open heart surgery services that existed before July 1, 1999.

15 SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect
16 July 1, 1999. It shall remain effective for a period of 3 1/2 years and, at the end of
17 December 31, 2003, with no further action required by the General Assembly, this Act
18 shall be abrogated and of no further force and effect.