
By: Senator Bromwell

Introduced and read first time: January 13, 1997

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Experimental Medical Care Disclosure Act**

3 FOR the purpose of requiring certain insurers, nonprofit health service plans, and health
4 maintenance organizations to establish and follow a certain process when evaluating
5 emerging medical and surgical treatments for the purpose of making certain
6 coverage decisions; requiring certain insurers, nonprofit health service plans, and
7 health maintenance organizations to make certain disclosures to certain providers,
8 enrollees, and prospective enrollees under certain circumstances; specifying the
9 provisions of the process; requiring certain insurers, nonprofit health service plans,
10 and health maintenance organizations to file a certain report with the Insurance
11 Commissioner; specifying the contents of the report; authorizing the Commissioner
12 to grant certain waivers under certain circumstances; authorizing the Commissioner
13 to issue certain orders; authorizing the Commissioner to adopt regulations;
14 providing for the application of this Act; providing a certain immunity from liability
15 for certain individuals; defining certain terms; and generally relating to requiring
16 certain insurers, nonprofit health service plans, and health maintenance
17 organizations to establish and follow a certain process when evaluating emerging
18 medical and surgical treatments for the purpose of making certain coverage
19 decisions.

20 BY adding to

21 Article - Insurance

22 Section 15-121

23 Annotated Code of Maryland

24 (1995 Volume and 1996 Supplement)

25 (As enacted by Chapter _____ (H.B. 11) of the Acts of the General Assembly of 1997)

26 BY adding to

27 Article - Courts and Judicial Proceedings

28 Section 5-399.8

29 Annotated Code of Maryland

30 (1995 Replacement Volume and 1996 Supplement)

31 BY adding to

32 Article - Health - General

2

1 Section 19-706(n)
2 Annotated Code of Maryland
3 (1996 Replacement Volume and 1996 Supplement)

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

6 **Article - Insurance**

7 15-121.

8 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
9 INDICATED.

10 (2) "CARRIER" MEANS:

11 (I) AN INSURER;

12 (II) A NONPROFIT HEALTH SERVICE PLAN;

13 (III) A HEALTH MAINTENANCE ORGANIZATION;

14 (IV) A DENTAL PLAN ORGANIZATION; OR

15 (V) ANY PERSON OR ENTITY ACTING AS A THIRD PARTY
16 ADMINISTRATOR.

17 (3) "CONTRACT" MEANS ANY WRITTEN AGREEMENT BETWEEN A
18 PROVIDER AND A CARRIER FOR THE PROVIDER TO RENDER HEALTH CARE
19 SERVICES TO ENROLLEES OF THE CARRIER.

20 (4) "DIAGNOSTIC SERVICES" MEANS ANY MEDICAL OR SURGICAL
21 SERVICE OR PROCEDURE THAT ALLOWS A PROVIDER TO IDENTIFY OR DIAGNOSE A
22 HUMAN DISEASE OR DISORDER.

23 (5) "ENROLLEE" MEANS ANY PERSON ENTITLED TO HEALTH CARE
24 BENEFITS FROM A CARRIER.

25 (6) "HEALTH CARE SERVICES" MEANS A HEALTH OR MEDICAL CARE
26 PROCEDURE OR SERVICE RENDERED BY A PROVIDER THAT:

27 (I) PROVIDES TESTING, DIAGNOSIS, OR TREATMENT OF A HUMAN
28 DISEASE OR DYSFUNCTION; OR

29 (II) DISPENSES DRUGS, MEDICAL DEVICES, MEDICAL APPLIANCES,
30 OR MEDICAL GOODS FOR THE TREATMENT OF A HUMAN DISEASE OR
31 DYSFUNCTION.

32 (7) (I) "PROVIDER" MEANS A PERSON OR ENTITY LICENSED,
33 CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE HEALTH OCCUPATIONS
34 ARTICLE OR THE HEALTH - GENERAL ARTICLE TO PROVIDE HEALTH CARE
35 SERVICES.

36 (II) "PROVIDER" INCLUDES:

3

- 1 1. A HEALTH CARE FACILITY;
- 2 2. A PHARMACY;
- 3 3. A PROFESSIONAL SERVICES CORPORATION;
- 4 4. A PARTNERSHIP;
- 5 5. A LIMITED LIABILITY COMPANY;
- 6 6. A PROFESSIONAL OFFICE; OR
- 7 7. ANY OTHER ENTITY LICENSED OR AUTHORIZED BY LAW
- 8 TO PROVIDE OR DELIVER PROFESSIONAL HEALTH CARE SERVICES THROUGH OR
- 9 ON BEHALF OF A PROVIDER.

10 (8) "THERAPEUTIC SERVICES" MEANS ANY MEDICAL OR SURGICAL
11 SERVICE OR PROCEDURE THAT A PROVIDER CAN USE TO TREAT A HUMAN DISEASE
12 OR DISORDER.

13 (B) THIS SECTION APPLIES TO ANY CARRIER THAT PROVIDES HEALTH CARE
14 SERVICES TO ENROLLEES OR OTHERWISE MAKES HEALTH CARE SERVICES
15 AVAILABLE TO ENROLLEES THROUGH CONTRACTS WITH PROVIDERS.

16 (C) THE SECTION DOES NOT:

17 (1) APPLY TO ANY COSMETIC OR MEDICALLY UNNECESSARY SERVICE
18 OR PROCEDURE THAT TYPICALLY WOULD BE EXCLUDED FROM COVERAGE BY ANY
19 CARRIER THAT ISSUES OR DELIVERS CONTRACTS OR POLICIES OF HEALTH
20 INSURANCE IN THE STATE; AND

21 (2) AFFECT THE RIGHT OF AN ENROLLEE TO APPEAL ANY ADVERSE
22 DECISION BY A CARRIER THROUGH THE CARRIER'S APPEAL PROCESS.

23 (D) (1) EACH CARRIER SHALL DISCLOSE TO PROVIDERS, ENROLLEES, AND
24 PROSPECTIVE ENROLLEES THE CARRIER'S DEFINITION OF "EXPERIMENTAL
25 MEDICAL CARE".

26 (2) THE CARRIER SHALL DISCLOSE THE DEFINITION IN:

27 (I) CONTRACTS OFFERED TO PROVIDERS THAT MAY RENDER
28 DIRECT HEALTH CARE SERVICES TO THE ENROLLEES OF THE CARRIER; AND

29 (II) MARKETING MATERIALS AND ENROLLMENT MATERIALS OF
30 THE CARRIER THAT ARE PROVIDED TO CURRENT ENROLLEES AND PROSPECTIVE
31 ENROLLEES.

32 (3) THE DEFINITION:

33 (I) SHALL INCLUDE THE GENERAL CRITERIA AND PROCESS THAT
34 THE CARRIER FOLLOWS FOR INDIVIDUAL ENROLLEES OR FOR THE ENTIRE
35 ENROLLED POPULATION IN EVALUATING WHETHER AN EMERGING MEDICAL OR
36 SURGICAL TREATMENT WILL BE COVERED BY THE CARRIER; AND

4

1 (II) SHALL BE BINDING ON THE CARRIER, ENROLLEES, AND
2 PROVIDERS FOR THE PURPOSE OF RESOLVING DISPUTES THAT ARISE OVER
3 WHETHER A MEDICAL OR SURGICAL TREATMENT IS OR IS NOT EXPERIMENTAL,
4 AND THEREFORE, COVERED BY THE CARRIER.

5 (E) (1) EACH CARRIER SHALL ESTABLISH A SYSTEMATIC, SCIENTIFIC
6 PROCESS TO FOLLOW FOR EVALUATING EMERGING MEDICAL AND SURGICAL
7 TREATMENTS TO ENSURE THAT PROVIDERS AND ENROLLEES HAVE ACCESS TO THE
8 LATEST APPROPRIATE TREATMENTS.

9 (2) THE PROCESS SHALL INCLUDE:

10 (I) ONGOING ANALYSES BY THE MEDICAL DIRECTOR OF THE
11 CARRIER AND THE MEDICAL POLICY STAFF OF THE CARRIER OF PUBLISHED,
12 PEER-REVIEWED MEDICAL LITERATURE, AND THE FINDINGS AND PUBLICATIONS
13 OF STATE AND FEDERAL AGENCIES; AND

14 (II) ONGOING DIALOGUE WITH OTHER CLINICAL EXPERTS IN THE
15 MEDICAL COMMUNITY FOR THE PURPOSE OF EVALUATING WHETHER EMERGING
16 MEDICAL OR SURGICAL TREATMENTS HAVE BECOME AN APPROPRIATE STANDARD
17 OF CARE FOR SPECIFIED HUMAN DISEASES OR DISORDERS.

18 (3) THE CARRIER SHALL IDENTIFY LEADING CLINICAL EXPERTS IN
19 RECOGNIZED MEDICAL AND SURGICAL SPECIALITIES AND SUBSPECIALTIES FOR
20 THE PURPOSE OF HAVING THE CLINICAL EXPERTS PROVIDE THE CARRIER WITH
21 DIALOGUE ON AND ANALYSES OF THE STATUS OF EMERGING MEDICAL AND
22 SURGICAL TREATMENTS.

23 (4) THE CLINICAL EXPERTS IDENTIFIED BY THE CARRIER:

24 (I) SHALL BE ACTIVELY INVOLVED IN THE PROVISION OF DIRECT
25 HEALTH CARE SERVICES TO PATIENTS WITH THE HUMAN DISEASES OR DISORDERS
26 BEING EVALUATED, WHETHER OR NOT THE PATIENTS ROUTINELY TREATED BY
27 THE PROVIDER ARE ENROLLEES OF THE CARRIER;

28 (II) MAY NOT BE AN EMPLOYEE OF THE CARRIER;

29 (III) SHALL BE BOARD-CERTIFIED IN THE PERTINENT OR
30 APPROPRIATE SPECIALTY OR SUBSPECIALTY AREA; AND

31 (IV) SHALL BE GENERALLY RECOGNIZED BY THEIR PEERS TO BE
32 AUTHORITATIVE RESOURCES IN THE CLINICAL AREA BEING EVALUATED, AS
33 EVIDENCED BY:

34 1. FACULTY APPOINTMENTS;

35 2. AUTHORSHIP OF A SIGNIFICANT BODY OF
36 PEER-REVIEWED CLINICAL LITERATURE IN THE RELEVANT SPECIALTY AREA; AND

37 3. A DEMONSTRATED HISTORY OF LEADERSHIP IN LOCAL,
38 STATE, AND NATIONAL PROFESSIONAL ASSOCIATIONS AND NONPROFIT PATIENT
39 AND COMMUNITY ADVOCACY ORGANIZATIONS THAT ADDRESS THE DISEASES AND
40 SPECIALTY AREAS IN QUESTION.

1 (5) EACH CARRIER SHALL FILE ANNUALLY WITH THE COMMISSIONER
2 THE CREDENTIALING CRITERIA THE CARRIER HAS UTILIZED IN SELECTING THE
3 CLINICAL EXPERTS AND OTHER SOURCES UTILIZED BY THE CARRIER IN
4 EVALUATING A DIAGNOSTIC OR THERAPEUTIC SERVICE THAT IS PART OF AN
5 EMERGING MEDICAL OR SURGICAL TREATMENT.

6 (F) A CARRIER'S DECISION TO PROVIDE COVERAGE FOR AN EMERGING
7 MEDICAL OR SURGICAL TREATMENT SHALL RESULT FROM THE CONSENSUS OF
8 OPINION FROM ITS OWN ANALYSIS AND THE KNOWLEDGE PROVIDED TO THE
9 CARRIER FROM THE CLINICAL EXPERTS IDENTIFIED BY THE CARRIER UNDER
10 SUBSECTION (E)(3) OF THIS SECTION.

11 (G) (1) EACH CARRIER, IN CONSULTATION WITH THE CLINICAL EXPERTS
12 IDENTIFIED BY THE CARRIER UNDER SUBSECTION (E)(3) OF THIS SECTION, SHALL
13 DECIDE THE APPROPRIATE PATIENT SELECTION CRITERIA FOR AN EMERGING
14 MEDICAL OR SURGICAL TREATMENT FOR THE CARRIER'S AND THE CLINICAL
15 EXPERT'S REVIEW AND FOR WHICH COVERAGE BY THE CARRIER IS TO BE
16 EXTENDED.

17 (2) A CARRIER MAY USE THE PATIENT SELECTION CRITERIA AND
18 OTHER GUIDELINES AGREED ON WITH THE CLINICAL EXPERTS TO APPROVE OR
19 DENY COVERAGE FOR EMERGING MEDICAL AND SURGICAL TREATMENTS FOR ITS
20 ENROLLEES.

21 (H) (1) A CARRIER'S MEDICAL DIRECTOR AND MEDICAL POLICY STAFF
22 MAY NOT MAKE COVERAGE DECISIONS ON LIFESAVING EMERGING MEDICAL OR
23 SURGICAL TREATMENTS WITHOUT FIRST CONSULTING THE CLINICAL EXPERTS
24 IDENTIFIED BY THE CARRIER UNDER SUBSECTION (E)(3) OF THIS SECTION.

25 (2) A CARRIER SHALL HAVE THE RIGHT TO REEVALUATE AREAS OF
26 DISPUTE BETWEEN THE CARRIER AND THE CLINICAL EXPERTS ANNUALLY TO
27 DETERMINE WHETHER SCIENTIFIC ADVANCES WARRANT A CHANGE IN THE
28 CARRIER'S COVERAGE AND PAYMENT POLICY FOR EMERGING MEDICAL AND
29 SURGICAL TREATMENTS.

30 (I) (1) EACH CARRIER SHALL FILE ANNUALLY WITH THE COMMISSIONER A
31 DETAILED REPORT ON ALL THE CLINICAL AREAS AND DIAGNOSTIC AND
32 THERAPEUTIC SERVICES EVALUATED THAT WERE PART OF EMERGING MEDICAL
33 AND SURGICAL TREATMENTS, IN CONSULTATION WITH THE CLINICAL EXPERTS
34 IDENTIFIED BY THE CARRIER UNDER SUBSECTION (E)(3) OF THIS SECTION, DURING
35 THE PAST YEAR.

36 (2) THE REPORT SHALL INCLUDE:

37 (I) A SUMMARY DESCRIPTION OF EACH CLINICAL ISSUE OR
38 DIAGNOSTIC OR THERAPEUTIC SERVICE THAT WAS EVALUATED;

39 (II) FOR EACH DIAGNOSTIC OR THERAPEUTIC SERVICE, A
40 SUMMARY OF THE FINDINGS OF THE CARRIER AND THE CLINICAL EXPERTS FROM
41 THE REVIEW OF PUBLISHED, PEER-REVIEWED MEDICAL LITERATURE; AND

6

1 (III) FOR EACH DIAGNOSTIC OR THERAPEUTIC SERVICE, A
2 SUMMARY OF THE OPINIONS OF THE CLINICAL EXPERTS ON WHETHER THE
3 DIAGNOSTIC OR THERAPEUTIC SERVICE IS CONSIDERED A STANDARD OF CARE FOR
4 THE LOCAL COMMUNITY.

5 (3) THE COMMISSIONER SHALL:

6 (I) MAKE EACH CARRIER'S REPORT AVAILABLE TO THE PUBLIC
7 FOR INSPECTION AND REVIEW; AND

8 (II) PROVIDE A COPY OF A CARRIER'S REPORT TO ANY PERSON
9 UPON REQUEST IN A TIMELY MANNER AND AT A REASONABLE COST TO THE
10 PERSON.

11 (J) AN INDIVIDUAL SERVING AS A CLINICAL EXPERT FOR THE PURPOSES OF
12 THIS SECTION SHALL HAVE THE IMMUNITY FROM LIABILITY DESCRIBED UNDER §
13 5-399.8 OF THE COURTS AND JUDICIAL PROCEEDINGS ARTICLE.

14 (K) EACH CARRIER SHALL INCLUDE IN SUMMARY FORM INFORMATION ON
15 THE PROCESS THAT THE CARRIER IS REQUIRED UNDER THIS SECTION TO
16 ESTABLISH AND FOLLOW IN EVALUATING EMERGING MEDICAL AND SURGICAL
17 TREATMENTS FOR THE PURPOSE OF MAKING COVERAGE DECISIONS IN:

18 (1) THE MARKETING AND ENROLLMENT MATERIALS OF THE CARRIER
19 TO EACH CURRENT ENROLLEE AND PROSPECTIVE ENROLLEE AT THE TIME OF OPEN
20 ENROLLMENT OR POLICY OR CONTRACT RENEWAL; AND

21 (2) THE CONTRACT OR AN ATTACHMENT TO THE CONTRACT OF A
22 PROVIDER BEING OFFERED A CONTRACT BY THE CARRIER TO RENDER HEALTH
23 CARE SERVICES TO ENROLLEES OF THE CARRIER.

24 (L) AFTER NOTIFYING A CARRIER AND PROVIDING AN OPPORTUNITY FOR A
25 HEARING, THE COMMISSIONER MAY ISSUE AN ORDER UNDER § 4-113(D) OF THIS
26 ARTICLE FOR A VIOLATION OF THIS SECTION.

27 (M) (1) THE COMMISSIONER MAY WAIVE THE APPLICATION OF THIS
28 SECTION FOR A CARRIER THAT HAS IN PLACE A PROCESS FOR EVALUATING
29 EMERGING MEDICAL AND SURGICAL TREATMENTS USED FOR THE PURPOSE OF
30 MAKING COVERAGE DECISIONS, IF THE COMMISSIONER DETERMINES THAT THE
31 CARRIER'S PROCESS IS SUBSTANTIALLY EQUIVALENT TO, OR EXCEEDS, THE
32 REQUIREMENTS OF THIS SECTION.

33 (2) A CARRIER RECEIVING A WAIVER UNDER PARAGRAPH (1) OF THIS
34 SUBSECTION SHALL REPORT ANY CHANGE IN ITS PROCESS FOR EVALUATING
35 EMERGING MEDICAL AND SURGICAL TREATMENTS TO THE COMMISSIONER.

36 (3) THE COMMISSIONER MAY WITHDRAW A WAIVER GRANTED UNDER
37 PARAGRAPH (1) OF THIS SUBSECTION WHENEVER THE COMMISSIONER DETERMINES
38 THAT THE CARRIER'S PROCESS FOR EVALUATING EMERGING MEDICAL AND
39 SURGICAL TREATMENTS IS NOT SUBSTANTIALLY EQUIVALENT TO THE
40 REQUIREMENTS OF THIS SECTION.

7

1 (N) THE COMMISSIONER MAY ADOPT REGULATIONS TO CARRY OUT THIS
2 SECTION.

3 **Article - Courts and Judicial Proceedings**

4 5-399.8.

5 AN INDIVIDUAL IDENTIFIED AND SERVING AS A CLINICAL EXPERT UNDER §
6 15-121 OF THE INSURANCE ARTICLE FOR THE PURPOSE OF EVALUATING EMERGING
7 MEDICAL AND SURGICAL TREATMENTS IS IMMUNE FROM CIVIL LIABILITY FOR ANY
8 ACTION MADE IN GOOD FAITH IN CARRYING OUT THAT PURPOSE.

9 **Article - Health - General**

10 19-706.

11 (N) THE PROVISIONS OF § 15-121 OF THE INSURANCE ARTICLE SHALL APPLY
12 TO HEALTH MAINTENANCE ORGANIZATIONS.

13 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
14 October 1, 1997.