
By: Senators Bromwell, Young, Dorman, and Madden

Introduced and read first time: January 22, 1996

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Experimental Medical Care Disclosure Act**

3 FOR the purpose of requiring certain health insurers to establish a certain process to
4 follow when evaluating emerging medical and surgical treatments for the purpose of
5 making coverage and payment decisions; requiring certain health insurers to make
6 certain disclosures to certain providers, enrollees, and prospective enrollees under
7 certain circumstances; specifying the provisions of the process; requiring certain
8 health insurers to identify certain local clinical experts to assist the health insurer in
9 evaluating emerging medical and surgical treatments; requiring certain health
10 insurers to file a certain report with the Insurance Commissioner; specifying the
11 contents of the report; prohibiting certain health insurers from preventing providers
12 from disclosing certain information to enrollees; prohibiting certain health insurers
13 for certain purposes from conditioning the payment of the salary of an employee or
14 provider on the number or kind of health care services denied to enrollees;
15 specifying the application of this Act; authorizing the Insurance Commissioner to
16 adopt regulations; defining certain terms; and generally relating to requiring certain
17 health insurers to establish and follow a certain process when evaluating emerging
18 medical and surgical treatments for the purpose of making certain coverage and
19 payment conditions.

20 BY adding to

21 Article 48A - Insurance Code
22 Section 490FF
23 Annotated Code of Maryland
24 (1994 Replacement Volume and 1995 Supplement)

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

27 **Article 48A - Insurance Code**

28 490FF.

29 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
30 INDICATED.

31 (2) "CARRIER" MEANS:

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- 1 (I) AN INSURER;
- 2 (II) A NONPROFIT HEALTH SERVICE PLAN;
- 3 (III) A DENTAL PLAN ORGANIZATION; OR
- 4 (IV) ANY PERSON OR ENTITY ACTING AS A THIRD PARTY
- 5 ADMINISTRATOR.

6 (3) "CONTRACT" MEANS ANY WRITTEN AGREEMENT BETWEEN A

7 PROVIDER AND A CARRIER FOR THE PROVIDER TO RENDER HEALTH CARE

8 SERVICES TO ENROLLEES OF THE CARRIER.

9 (4) "DIAGNOSTIC SERVICES" MEANS ANY MEDICAL OR SURGICAL

10 SERVICE OR PROCEDURE THAT ALLOWS A PROVIDER TO IDENTIFY OR DIAGNOSE A

11 HUMAN DISEASE OR DISORDER.

12 (5) "ENROLLEE" MEANS ANY PERSON ENTITLED TO HEALTH CARE

13 BENEFITS FROM A CARRIER.

14 (6) "HEALTH CARE SERVICES" MEANS A HEALTH OR MEDICAL CARE

15 PROCEDURE OR SERVICE RENDERED BY A PROVIDER THAT:

16 (I) PROVIDES TESTING, DIAGNOSIS, OR TREATMENT OF A HUMAN

17 DISEASE OR DYSFUNCTION; OR

18 (II) DISPENSES DRUGS, MEDICAL DEVICES, MEDICAL APPLIANCES,

19 OR MEDICAL GOODS FOR THE TREATMENT OF A HUMAN DISEASE OR

20 DYSFUNCTION.

21 (7) (I) "PROVIDER" MEANS A PERSON OR ENTITY LICENSED,

22 CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE HEALTH OCCUPATIONS

23 ARTICLE OR THE HEALTH - GENERAL ARTICLE TO PROVIDE HEALTH CARE

24 SERVICES.

25 (II) "PROVIDER" INCLUDES:

- 26 1. A HEALTH CARE FACILITY;
- 27 2. PHARMACY;
- 28 3. PROFESSIONAL SERVICES CORPORATION;
- 29 4. PARTNERSHIP;
- 30 5. LIMITED LIABILITY COMPANY;
- 31 6. PROFESSIONAL OFFICE; OR
- 32 7. ANY OTHER ENTITY LICENSED OR AUTHORIZED BY LAW
- 33 TO PROVIDE OR DELIVER PROFESSIONAL HEALTH CARE SERVICES THROUGH OR
- 34 ON BEHALF OF A PROVIDER.

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

4 (B) (1) THIS SECTION APPLIES TO ANY CARRIER THAT PROVIDES HEALTH
5 CARE SERVICES TO ENROLLEES OR OTHERWISE MAKES HEALTH CARE SERVICES
6 AVAILABLE TO ENROLLEES THROUGH CONTRACTS WITH PROVIDERS.

7 (2) THIS SECTION DOES NOT AFFECT THE RIGHT OF AN ENROLLEE TO
8 APPEAL ANY ADVERSE DECISION BY A CARRIER THROUGH THE CARRIER'S APPEALS
9 PROCESS.

10 (C) (1) A CARRIER SHALL DISCLOSE TO PROVIDERS, ENROLLEES, AND
11 PROSPECTIVE ENROLLEES THE CARRIER'S DEFINITION OF "EXPERIMENTAL
12 MEDICAL CARE", AS REQUIRED UNDER PARAGRAPH (2) OF THIS SUBSECTION.

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

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

16 (II) MARKETING MATERIALS AND ENROLLMENT MATERIALS OF
17 THE CARRIER THAT ARE PROVIDED TO CURRENT ENROLLEES AND PROSPECTIVE
18 ENROLLEES.

19 (3) THE DEFINITION SHALL INCLUDE THE GENERAL CRITERIA AND
20 PROCESS THAT THE CARRIER FOLLOWS FOR INDIVIDUAL ENROLLEES OR FOR THE
21 ENTIRE ENROLLED POPULATION IN EVALUATING WHETHER EMERGING MEDICAL
22 AND SURGICAL TREATMENTS WILL BE COVERED OR PAID FOR BY THE CARRIER.

23 (4) THE DEFINITION SHALL BE BINDING ON THE CARRIER, ENROLLEES,
24 AND PROVIDERS FOR THE PURPOSE OF RESOLVING DISPUTES THAT ARISE OVER
25 WHETHER A MEDICAL OR SURGICAL TREATMENT IS OR IS NOT EXPERIMENTAL,
26 AND THEREFORE, COVERED AND PAID FOR BY THE CARRIER.

27 (D) (1) EACH CARRIER SHALL ESTABLISH A SYSTEMATIC, SCIENTIFIC
28 PROCESS TO FOLLOW FOR EVALUATING EMERGING MEDICAL AND SURGICAL
29 TREATMENTS TO ENSURE THAT PROVIDERS AND ENROLLEES HAVE ACCESS TO THE
30 LATEST APPROPRIATE TREATMENTS.

31 (2) THE PROCESS SHALL INCLUDE:

32 (I) ONGOING ANALYSES BY THE MEDICAL DIRECTOR OF THE
33 CARRIER AND THE MEDICAL POLICY STAFF OF THE CARRIER OF PUBLISHED,
34 PEER-REVIEWED MEDICAL LITERATURE, AND THE FINDINGS AND PUBLICATIONS
35 OF STATE AND FEDERAL AGENCIES; AND

36 (II) ONGOING DIALOGUE WITH EXPERTS IN THE LOCAL MEDICAL
37 COMMUNITY FOR THE PURPOSE OF EVALUATING WHETHER NEW MEDICAL OR
38 SURGICAL TREATMENTS HAVE BECOME AN APPROPRIATE STANDARD OF CARE FOR
39 SPECIFIED HUMAN DISEASES OR DISORDERS.

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1 (3) (I) THE CARRIER SHALL IDENTIFY LEADING LOCAL CLINICAL
2 EXPERTS IN RECOGNIZED MEDICAL AND SURGICAL SPECIALTIES AND
3 SUBSPECIALTIES FOR THE PURPOSE OF HAVING THE CLINICAL EXPERTS PROVIDE
4 THE CARRIER WITH DIALOGUE ON AND ANALYSES OF THE STATUS OF EMERGING
5 MEDICAL AND SURGICAL TREATMENTS.

6 (II) THE CLINICAL EXPERTS SHALL BE DRAWN FROM:

- 7 1. THE UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE;
- 8 2. THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE;
- 9 3. THE NATIONAL INSTITUTES OF HEALTH;
- 10 4. LOCAL PROVIDERS WHO ARE GENERALLY RECOGNIZED
11 AS AUTHORITATIVE RESOURCES ON CERTAIN HUMAN DISEASES AND DISORDERS;
12 AND

13 5. LOCAL CHAPTERS OF MEDICAL AND SURGICAL
14 SPECIALTY SOCIETIES AND PROFESSIONAL ASSOCIATIONS, AS RECOGNIZED BY THE
15 AMERICAN BOARD OF MEDICAL SPECIALTIES AND THE U.S. COUNCIL ON MEDICAL
16 SPECIALTIES.

17 (4) THE LOCAL CLINICAL EXPERTS IDENTIFIED BY THE CARRIER SHALL
18 BE:

19 (I) ACTIVELY INVOLVED IN THE PROVISION OF DIRECT HEALTH
20 CARE SERVICES TO PATIENTS WITH THE HUMAN DISEASES OR DISORDERS BEING
21 EVALUATED WHETHER OR NOT THE PATIENTS ROUTINELY TREATED BY THE
22 PROVIDER ARE ENROLLEES OF THE CARRIER;

23 (II) BOARD-CERTIFIED IN THE PERTINENT OR APPROPRIATE
24 SPECIALTY OR SUBSPECIALTY AREA; AND

25 (III) GENERALLY RECOGNIZED BY THEIR PEERS TO BE
26 AUTHORITATIVE RESOURCES IN THE CLINICAL AREA BEING EVALUATED, AS
27 EVIDENCED BY FACULTY APPOINTMENTS, AUTHORSHIP OF A SIGNIFICANT BODY OF
28 PEER-REVIEWED CLINICAL LITERATURE IN THE RELEVANT SPECIALTY AREA, AND
29 A DEMONSTRATED HISTORY OF LEADERSHIP IN LOCAL, STATE, AND NATIONAL
30 PROFESSIONAL ASSOCIATIONS AND NONPROFIT PATIENT AND COMMUNITY
31 ADVOCACY ORGANIZATIONS THAT ADDRESS THE DISEASES AND SPECIALTY AREAS
32 IN QUESTION.

33 (5) THE CARRIER SHALL IDENTIFY THE LOCAL CLINICAL EXPERTS
34 WITH WHOM IT CONSULTS:

35 (I) UPON THE REQUEST OF AN ENROLLEE, PROVIDER, OR STATE
36 OFFICIAL; AND

37 (II) ANNUALLY IN ITS DISCLOSURE FILING WITH THE
38 COMMISSIONER.

1 (6) THE CARRIER SHALL DISCLOSE IN ITS FILING WITH THE
2 COMMISSIONER ANY HONORARIA OR OTHER FEES PAID TO CLINICAL EXPERTS FOR
3 THEIR SERVICES.

4 (E) A CARRIER'S DECISION TO PAY FOR EMERGING MEDICAL AND SURGICAL
5 TREATMENTS SHALL RESULT FROM THE CONSENSUS OF OPINION FROM ITS OWN
6 ANALYSIS AND THE KNOWLEDGE PROVIDED TO THE CARRIER FROM LOCAL
7 CLINICAL EXPERTS.

8 (F) (1) EACH CARRIER AND THE LOCAL CLINICAL EXPERTS IDENTIFIED BY
9 THE CARRIER SHALL JOINTLY DECIDE THE APPROPRIATE PATIENT SELECTION
10 CRITERIA FOR EMERGING MEDICAL AND SURGICAL TREATMENTS FOR THE
11 CARRIER'S AND THE LOCAL EXPERT'S REVIEW AND FOR WHICH COVERAGE AND
12 PAYMENT IS EXTENDED.

13 (2) A CARRIER MAY USE THE PATIENT SELECTION CRITERIA AND
14 OTHER GUIDELINES JOINTLY AGREED ON WITH THE LOCAL CLINICAL EXPERTS TO
15 APPROVE OR DENY COVERAGE AND PAYMENT FOR EMERGING MEDICAL AND
16 SURGICAL TREATMENTS FOR ENROLLEES.

17 (G) (1) A CARRIER'S MEDICAL DIRECTOR AND MEDICAL POLICY STAFF
18 MAY NOT MAKE COVERAGE AND PAYMENT DECISIONS ON LIFESAVING EMERGING
19 MEDICAL AND SURGICAL TREATMENTS WITHOUT FIRST CONSULTING THE LOCAL
20 CLINICAL EXPERTS IDENTIFIED BY THE CARRIER.

21 (2) WHENEVER A CARRIER'S MEDICAL DIRECTOR OR MEDICAL POLICY
22 STAFF AND THE LOCAL CLINICAL EXPERTS IDENTIFIED BY THE CARRIER DISAGREE
23 ON COVERAGE AND PAYMENT DECISIONS, THE OPINION OF THE LOCAL CLINICAL
24 EXPERTS SHALL PREVAIL.

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

30 (H) (1) EACH YEAR EACH CARRIER SHALL FILE WITH THE COMMISSIONER
31 A DETAILED REPORT ON ALL THE CLINICAL AREAS AND DIAGNOSTIC AND
32 THERAPEUTIC SERVICES THAT WERE EVALUATED IN CONSULTATION WITH LOCAL
33 CLINICAL EXPERTS IDENTIFIED BY THE CARRIER DURING THE PAST YEAR.

34 (2) THE REPORT SHALL INCLUDE:

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

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

40 (III) FOR EACH DIAGNOSTIC OR THERAPEUTIC SERVICE, A
41 SUMMARY OF THE OPINIONS OF THE LOCAL CLINICAL EXPERTS ON WHETHER THE

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1 DIAGNOSTIC OR THERAPEUTIC SERVICE IS CONSIDERED A STANDARD OF CARE FOR
2 THE LOCAL COMMUNITY;

3 (IV) THE NAMES AND AFFILIATIONS OF EACH LOCAL CLINICAL
4 EXPERT WHO WORKED WITH THE CARRIER TO EVALUATE THE DIAGNOSTIC OR
5 THERAPEUTIC SERVICE AND THE FEES OR HONORARIA, IF ANY, THE EXPERT WAS
6 PAID;

7 (V) THE NAMES AND TITLES OF EACH OF THE CARRIER'S
8 EMPLOYEES WHO EVALUATE EMERGING MEDICAL AND SURGICAL TREATMENTS TO
9 DETERMINE WHETHER THESE SERVICES OR PROCEDURES SHOULD BE COVERED
10 AND PAID FOR BY THE CARRIER;

11 (VI) THE NAMES AND AFFILIATIONS OF ANY OUTSIDE
12 CONSULTANTS WHO WORKED WITH THE MEDICAL POLICY STAFF OF THE CARRIER
13 DURING THE PAST YEAR TO EVALUATE WHETHER EMERGING MEDICAL AND
14 SURGICAL TREATMENTS SHOULD BE COVERED BY AND PAID FOR BY THE CARRIER;
15 AND

16 (VII) THE NAMES OF EACH STATE AND FEDERAL AGENCY AND
17 EACH FOR-PROFIT OR NONPROFIT ORGANIZATION, TRADE GROUP, OR
18 TECHNOLOGY COUNCIL THAT CONTRIBUTED TO THE CARRIER'S EVALUATION OF
19 EMERGING MEDICAL AND SURGICAL TREATMENTS TO DETERMINE WHETHER
20 THESE TREATMENTS SHOULD BE COVERED AND PAID FOR BY THE CARRIER.

21 (3) THE COMMISSIONER SHALL:

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

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

27 (I) A CARRIER MAY NOT CONDITION THE SALARY OR BONUS OF AN
28 EMPLOYEE OR CONTRACTED PROVIDER ON THE NUMBER OR KIND OF HEALTH
29 CARE SERVICES THE EMPLOYEE OR CONTRACTED PROVIDER DENIES TO AN
30 ENROLLEE FOR THE PURPOSE OF SAVING MONEY FOR THE CARRIER OR TO MEET
31 THE FINANCIAL GOALS OF THE CARRIER.

32 (J) A CARRIER MAY NOT PREVENT A PROVIDER IT EMPLOYS OR A PROVIDER
33 WITH WHICH THE CARRIER CONTRACTS TO RENDER HEALTH CARE SERVICES TO
34 ENROLLEES FROM:

35 (1) PROVIDING ENROLLEES WITH FULL AND OPEN DISCLOSURE OF ALL
36 THE DIAGNOSTIC OR THERAPEUTIC SERVICES THAT MAY BE APPROPRIATE FOR THE
37 ENROLLEE'S PARTICULAR DISEASE OR DYSFUNCTION;

38 (2) PROVIDING ENROLLEES WITH INFORMATION ON WHETHER THE
39 CARRIER COVERS AND PAYS FOR EMERGING MEDICAL AND SURGICAL
40 TREATMENTS AND THE BASIS FOR THE CARRIER'S POSITION; AND

41 (3) INFORMING ENROLLEES OF:

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1 (I) THE PROCESS THAT THE CARRIER IS REQUIRED TO ESTABLISH
2 AND FOLLOW UNDER THIS SECTION IN EVALUATING EMERGING MEDICAL AND
3 SURGICAL TREATMENTS FOR THE PURPOSE OF DETERMINING WHETHER THE
4 TREATMENTS WILL BE COVERED AND PAID FOR BY THE CARRIER; AND

5 (II) INFORMATION THAT THE CARRIER IS REQUIRED TO DISCLOSE
6 AS REQUIRED UNDER THIS SECTION.

7 (K) (1) WHENEVER A CARRIER CONSULTS WITH OTHER CONSULTANTS OR
8 ORGANIZATIONS OTHER THAN THE LOCAL CLINICAL EXPERTS IDENTIFIED BY THE
9 CARRIER IN SUBSECTION (D) OF THIS SECTION TO EVALUATE EMERGING MEDICAL
10 OR SURGICAL TREATMENTS FOR THE PURPOSE OF DETERMINING WHETHER THE
11 TREATMENTS SHOULD BE COVERED AND PAID BY THE CARRIER, THE CARRIER
12 SHALL DISCLOSE IMMEDIATELY THE NAMES, AFFILIATIONS, AND ADDRESSES OF
13 THESE PERSONS TO THE COMMISSIONER AND THE LOCAL CLINICAL EXPERTS
14 IDENTIFIED BY THE CARRIER IN THE PERTINENT CLINICAL AREA.

15 (2) THE INFORMATION REQUIRED TO BE DISCLOSED IN PARAGRAPH (1)
16 OF THIS SUBSECTION SHALL BE MADE AVAILABLE TO AN ENROLLEE UPON THE
17 REQUEST OF THE ENROLLEE TO THE COMMISSIONER OR THE CARRIER.

18 (3) IN ADDITION TO THE INFORMATION REQUIRED TO BE DISCLOSED
19 UNDER PARAGRAPH (1) OF THIS SUBSECTION, THE CARRIER SHALL PROVIDE THE
20 FEES OR SALARIES, IF ANY, PAID BY THE CARRIER TO EACH CONSULTANT OR
21 ORGANIZATION.

22 (L) THIS SECTION DOES NOT APPLY TO ANY COSMETIC OR MEDICALLY
23 UNNECESSARY SERVICE OR PROCEDURE THAT TYPICALLY WOULD BE EXCLUDED
24 FROM COVERAGE BY THE CARRIER OR OTHER CARRIERS THAT ISSUE OR DELIVER
25 CONTRACTS OR POLICIES OF HEALTH INSURANCE IN THE STATE.

26 (M) EACH CARRIER SHALL INCLUDE IN SUMMARY FORM INFORMATION ON
27 THE PROCESS THAT THE CARRIER IS REQUIRED UNDER THIS SECTION TO
28 ESTABLISH AND FOLLOW IN EVALUATING EMERGING MEDICAL AND SURGICAL
29 TREATMENTS FOR THE PURPOSE OF MAKING COVERAGE AND PAYMENT DECISIONS
30 IN:

31 (1) THE MARKETING AND ENROLLMENT MATERIALS OF THE CARRIER
32 TO EACH CURRENT ENROLLEE AND PROSPECTIVE ENROLLEE AT THE TIME OF OPEN
33 ENROLLMENT OR RENEWAL; AND

34 (2) THE CONTRACT OR AN ATTACHMENT TO THE CONTRACT OF A
35 PROVIDER BEING OFFERED A CONTRACT BY THE CARRIER TO RENDER HEALTH
36 CARE SERVICES TO ENROLLEES OF THE CARRIER.

37 (N) AFTER NOTICE AND AN OPPORTUNITY FOR A HEARING, A CARRIER THAT
38 VIOLATES THIS SECTION IS SUBJECT TO A CIVIL FINE OF \$10,000 FOR A FIRST
39 VIOLATION AND \$25,000 FOR EACH SUBSEQUENT VIOLATION.

40 (O) THE COMMISSIONER MAY ADOPT REGULATIONS TO CARRY OUT THIS
41 SECTION.

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
2 October 1, 1996.