

HOUSE BILL 45

Unofficial Copy  
C3  
HB 230/97 - ECM

1998 Regular Session  
8lr0111  
CF 8lr0063

(PRE-FILED)

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By: ~~Delegates Krysiak, Kach, Barve, and Harrison~~ Harrison, Busch, Gordon, Boston, Donoghue, Exum, Frank, Fulton, Goldwater, Kirk, Love, and Pendergrass

Requested: July 15, 1997  
Introduced and read first time: January 14, 1998  
Assigned to: Economic Matters

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Committee Report: Favorable with amendments  
House action: Adopted  
Read second time: March 11, 1998

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CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Health Insurance - Medical Clinical Trial - Coverage**

3 FOR the purpose of requiring certain insurers ~~and~~ nonprofit health service plans,  
4 and health maintenance organizations to provide coverage for certain patient  
5 ~~costs~~ cost incurred as a result of a treatment being provided or studies being  
6 conducted in accordance with a clinical trial under certain circumstances;  
7 requiring certain insurers ~~and~~ nonprofit health service plans, and health  
8 maintenance organizations to provide coverage for the cost of certain drugs and  
9 devices under certain circumstances; providing for the application of this Act;  
10 providing for the construction of this Act; defining certain terms; requiring an  
11 entity seeking coverage under this Act to post electronically and keep  
12 up-to-date a certain list; requiring certain insurers, nonprofit health service  
13 plans, and health maintenance organizations to report certain information to  
14 the Insurance Commissioner; requiring the Insurance Commissioner to make a  
15 certain summary report; requiring the Insurance Commissioner to create a  
16 certain workgroup; requiring the workgroup to undertake a certain study and  
17 present a certain report; providing for the application of this Act; providing for  
18 the effective date of this Act; and generally relating to requiring certain insurers  
19 and nonprofit health service plans, and health maintenance organizations to  
20 provide coverage for certain patient ~~costs~~ cost incurred as a result of a treatment  
21 being provided or studies being conducted in accordance with a clinical trial and  
22 certain patient costs associated with certain drugs and devices under certain  
23 circumstances.

24 BY adding to

1 Article - Insurance  
2 Section 15-826  
3 Annotated Code of Maryland  
4 (1997 Volume)

5 BY adding to  
6 Article - Health - General  
7 Section 19-706(y)  
8 Annotated Code of Maryland  
9 (1996 Replacement Volume and 1997 Supplement)

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

12 **Article - Insurance**

13 15-826.

14 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS  
15 INDICATED.

16 (2) (I) "COOPERATIVE GROUP" MEANS A FORMAL NETWORK OF  
17 FACILITIES THAT COLLABORATE ON RESEARCH PROJECTS AND HAVE AN  
18 ESTABLISHED NIH-APPROVED PEER REVIEW PROGRAM OPERATING WITHIN THE  
19 GROUP.

20 (II) "COOPERATIVE GROUP" INCLUDES:

21 1. THE NATIONAL CANCER INSTITUTE CLINICAL  
22 COOPERATIVE GROUP;

23 2. THE NATIONAL CANCER INSTITUTE COMMUNITY  
24 CLINICAL ONCOLOGY PROGRAM;

25 3. THE AIDS CLINICAL TRIALS GROUP; AND

26 4. THE COMMUNITY PROGRAMS FOR CLINICAL RESEARCH IN  
27 AIDS.

28 (3) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION.

29 (4) "MEMBER" MEANS A POLICYHOLDER, SUBSCRIBER, INSURED, OR  
30 CERTIFICATE HOLDER OR A COVERED DEPENDENT OF A POLICYHOLDER,  
31 SUBSCRIBER, INSURED, OR CERTIFICATE HOLDER.

32 (5) "MULTIPLE PROJECT ASSURANCE CONTRACT" MEANS A CONTRACT  
33 BETWEEN AN INSTITUTION AND THE FEDERAL DEPARTMENT OF HEALTH AND  
34 HUMAN SERVICES THAT DEFINES THE RELATIONSHIP OF THE INSTITUTION TO THE  
35 FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SETS OUT THE

1 RESPONSIBILITIES OF THE INSTITUTION AND THE PROCEDURES THAT WILL BE USED  
 2 BY THE INSTITUTION TO PROTECT HUMAN SUBJECTS.

3           ~~(4)~~    (6)       "NIH" MEANS THE NATIONAL INSTITUTES OF HEALTH.

4           ~~(5)~~       "PATIENT" MEANS A POLICYHOLDER, SUBSCRIBER, OR CERTIFICATE  
 5 ~~HOLDER OR A COVERED DEPENDENT OF A POLICYHOLDER, SUBSCRIBER, OR~~  
 6 ~~CERTIFICATE HOLDER.~~

7           ~~(6)~~    (7)    (1)       "PATIENT COST" MEANS ~~ANY~~ THE COST OF A MEDICALLY  
 8 NECESSARY HEALTH CARE SERVICE THAT IS INCURRED AS A RESULT OF THE  
 9 TREATMENT BEING PROVIDED TO THE ~~PATIENT~~ MEMBER FOR PURPOSES OF THE  
 10 CLINICAL TRIAL.

11                           (II)       "PATIENT COST" DOES NOT INCLUDE:

12                                       1.       THE COST OF AN INVESTIGATIONAL DRUG OR DEVICE;

13                                       2.       THE COST OF NONHEALTH CARE SERVICES THAT A  
 14 PATIENT MAY BE REQUIRED TO RECEIVE AS A RESULT OF THE TREATMENT BEING  
 15 PROVIDED FOR PURPOSES OF THE CLINICAL TRIAL;

16                                       3.       COSTS ASSOCIATED WITH MANAGING THE RESEARCH  
 17 ASSOCIATED WITH THE CLINICAL TRIAL; OR

18                                       4.       COSTS THAT WOULD NOT BE COVERED UNDER THE  
 19 PATIENT'S POLICY ~~OR PLAN, PLAN, OR CONTRACT~~ FOR NONINVESTIGATIONAL  
 20 TREATMENTS.

21    (B)       THIS SECTION APPLIES TO:

22           (1)       INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE  
 23 HOSPITAL, MEDICAL, SURGICAL, OR PHARMACEUTICAL BENEFITS TO INDIVIDUALS  
 24 OR GROUPS ON AN EXPENSE-INCURRED BASIS UNDER A HEALTH INSURANCE  
 25 POLICY OR CONTRACT ISSUED OR DELIVERED IN THE STATE; AND

26           (2)       HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE HOSPITAL,  
 27 MEDICAL, SURGICAL, OR PHARMACEUTICAL BENEFITS TO INDIVIDUALS OR GROUPS  
 28 UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

29    (C)       THIS SECTION DOES NOT APPLY TO A POLICY, PLAN, OR CONTRACT PAID  
 30 FOR UNDER TITLE XVIII OR TITLE XIX OF THE SOCIAL SECURITY ACT.

31    ~~(C)~~       ~~A POLICY OR PLAN SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE~~  
 32 ~~FOR ALL PATIENT COSTS INCURRED AS A RESULT OF A TREATMENT BEING PROVIDED~~  
 33 ~~IN ACCORDANCE WITH A CLINICAL TRIAL FOR A LIFE-THREATENING,~~  
 34 ~~DEGENERATIVE, OR PERMANENTLY DISABLING CONDITION OR A CONDITION~~  
 35 ~~ASSOCIATED WITH OR A COMPLICATION OF A LIFE-THREATENING, DEGENERATIVE,~~  
 36 ~~OR PERMANENTLY DISABLING CONDITION TO THE EXTENT SUCH COSTS WOULD BE~~  
 37 ~~COVERED FOR NONINVESTIGATIONAL TREATMENTS IF:~~

1 ~~(1) THE TREATMENT IS BEING PROVIDED WITH A THERAPEUTIC OR~~  
2 ~~PALLIATIVE INTENT;~~

3 (D) A POLICY, PLAN, OR CONTRACT SUBJECT TO THIS SECTION SHALL  
4 PROVIDE COVERAGE FOR PATIENT COST TO A MEMBER IN A CLINICAL TRIAL, AS A  
5 RESULT OF:

6 (1) TREATMENT PROVIDED FOR A LIFE-THREATENING CONDITION; OR

7 (2) PREVENTION, EARLY DETECTION, AND TREATMENT STUDIES ON  
8 CANCER.

9 (E) THE COVERAGE UNDER SUBSECTION (D) OF THIS SECTION SHALL BE  
10 REQUIRED IF:

11 (1) (I) THE TREATMENT IS BEING PROVIDED OR THE STUDIES ARE  
12 BEING CONDUCTED IN A PHASE I, PHASE II, PHASE III, OR PHASE IV CLINICAL TRIAL  
13 FOR CANCER; OR

14 (II) THE TREATMENT IS BEING PROVIDED IN A PHASE II, PHASE III,  
15 OR PHASE IV CLINICAL TRIAL FOR ANY OTHER LIFE-THREATENING CONDITION;

16 (2) THE TREATMENT IS BEING PROVIDED IN ACCORDANCE WITH A  
17 CLINICAL TRIAL APPROVED BY:

18 (I) ONE OF THE NATIONAL INSTITUTES OF HEALTH;

19 (II) AN NIH COOPERATIVE GROUP OR AN NIH CENTER;

20 (III) THE FDA IN THE FORM OF AN INVESTIGATIONAL NEW DRUG  
21 APPLICATION;

22 (IV) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

23 ~~(V) A QUALIFIED RESEARCH ENTITY THAT MEETS CRITERIA FOR~~  
24 ~~NIH CENTER SUPPORT GRANT ELIGIBILITY; OR~~

25 ~~(VI) A PANEL OF QUALIFIED RECOGNIZED EXPERTS IN CLINICAL~~  
26 ~~RESEARCH WITHIN ACADEMIC HEALTH INSTITUTIONS IN THIS STATE;~~

27 ~~(3) THE PROPOSED TREATMENT HAS BEEN REVIEWED AND APPROVED~~  
28 ~~BY TWO QUALIFIED INSTITUTIONAL REVIEW BOARDS; OR~~

29 (V) AN INSTITUTIONAL REVIEW BOARD OF AN INSTITUTION IN THE  
30 STATE THAT HAS A MULTIPLE PROJECT ASSURANCE CONTRACT APPROVED BY THE  
31 OFFICE OF PROTECTION FROM RESEARCH RISKS OF THE NIH;

32 ~~(4) (3) THE FACILITY AND PERSONNEL PROVIDING THE TREATMENT~~  
33 ~~ARE PROVIDING THE TREATMENT WITHIN THEIR SCOPE OF PRACTICE, EXPERIENCE,~~  
34 ~~AND TRAINING CAPABLE OF DOING SO BY VIRTUE OF THEIR EXPERIENCE, TRAINING,~~  
35 ~~AND VOLUME OF PATIENTS TREATED TO MAINTAIN EXPERTISE;~~



1 ~~SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect~~  
2 ~~October 1, 1998.~~

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

4 (a) On or before June 1 of each year, each insurer, nonprofit health service  
5 plan, and health maintenance organization subject to the requirements of this Act  
6 shall submit to the Insurance Commissioner, on the form the Insurance  
7 Commissioner requires, a report that describes the clinical trials covered during the  
8 previous year.

9 (b) The Insurance Commissioner shall compile an annual summary report  
10 based on the information provided under subsection (a) of this section and provide  
11 copies of the summary report to the Senate Finance Committee and the House  
12 Economic Matters Committee in accordance with § 2-1246 of the State Government  
13 Article.

14 SECTION 3. AND BE IT FURTHER ENACTED, That:

15 (a) The Insurance Commissioner shall create a Workgroup on Insurance  
16 Coverage for Patient Care Cost in Clinical Trials.

17 (b) The purpose of the Workgroup is to assess the costs and benefits of  
18 insurance coverage for patient care cost incurred in clinical trials.

19 (c) At a minimum, the Workgroup shall:

20 (1) Develop a methodology for assessing the economic and clinical impact  
21 of the health insurance coverage required by this Act for patient care cost in clinical  
22 trials;

23 (2) Request and collect from health care providers and payers pertinent  
24 aggregate clinical and financial data on patient treatment to assess differences in  
25 patient care costs and clinical outcomes between patients treated in clinical trials and  
26 patients treated outside of clinical trials; and

27 (3) Review any other issues the Workgroup considers appropriate to  
28 assess and on which to make recommendations pertaining to coverage for patient care  
29 cost in clinical trials.

30 (d) The Workgroup shall be comprised of 11 members, appointed by the  
31 Commissioner:

32 (1) One representative of the University of Maryland School of Medicine;

33 (2) One representative of The Johns Hopkins University School of  
34 Medicine;

35 (3) The president of the Maryland Society of Clinical Oncology;

36 (4) One representative of the Maryland State Cancer Council;

- 1           (5)     One representative of the National Institutes of Health;
- 2           (6)     Four representatives, including two health plan medical directors  
3 licensed to practice medicine in this State, of health insurers, nonprofit health service  
4 plans, or health maintenance organizations licensed to do business in this State;
- 5           (7)     One member of the general public; and
- 6           (8)     The Insurance Commissioner or the Commissioner's designee.
- 7     (e)     The Workgroup shall select a chairman from among its members.
- 8     (f)     Staffing for the Workgroup shall be provided by the Maryland Insurance  
9 Administration.
- 10    (g)     The Workgroup shall present a preliminary report on the results of its  
11 study, including findings and recommendations, to the Senate Finance Committee  
12 and the House Economic Matters Committee, and, in accordance with § 2-1246 of the  
13 State Government Article, the General Assembly, on or before July 1, 2000. If the  
14 Workgroup requests an additional year to complete its work, the Workgroup shall  
15 present a final report on or before July 1, 2001.
- 16    SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall apply to all  
17 new policies, contracts, or health benefit plans issued or delivered in the State on or  
18 after January 1, 1999 and to the renewal of all policies, contracts, or health benefit  
19 plans in effect before that date, except that any policy, contract, or health benefit plan  
20 in effect before January 1, 1999 shall comply with the provisions of this Act no later  
21 than January 1, 2000.
- 22    SECTION 5. AND BE IT FURTHER ENACTED, That Section 3 of this Act shall  
23 take effect July 1, 1998.
- 24    SECTION 6. AND BE IT FURTHER ENACTED, That, subject to Section 5 of  
25 this Act, this Act shall take effect January 1, 1999.