

HOUSE BILL 45

Unofficial Copy
C3
HB 230/97 - ECM

1998 Regular Session
8lr0111
CF 8lr0063

(PRE-FILED)

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

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

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 ~~(4) 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 ~~(5)~~ (4) THERE IS NO CLEARLY SUPERIOR, NONINVESTIGATIONAL
2 TREATMENT ALTERNATIVE; AND

3 ~~(6)~~ (5) THE AVAILABLE CLINICAL OR PRECLINICAL DATA PROVIDE A
4 REASONABLE EXPECTATION THAT THE TREATMENT WILL BE AT LEAST AS
5 ~~EFFICACIOUS~~ EFFECTIVE AS THE NONINVESTIGATIONAL ALTERNATIVE.

6 (F) THE COVERAGE UNDER SUBSECTION (D) OF THIS SECTION MAY BE
7 PROVIDED ON A CASE BY CASE BASIS IF THE TREATMENT IS BEING PROVIDED IN A
8 PHASE I CLINICAL TRIAL FOR ANY LIFE-THREATENING CONDITION OTHER THAN
9 CANCER.

10 ~~(D)~~ (G) IN ADDITION TO CONJUNCTION WITH THE PROVISIONS OF
11 SUBSECTION ~~(E)~~ (D) OF THIS SECTION, A ~~POLICY OR PLAN~~ POLICY, PLAN, OR
12 CONTRACT SHALL PROVIDE COVERAGE FOR PATIENT ~~COSTS~~ COST INCURRED FOR
13 DRUGS AND DEVICES THAT HAVE BEEN APPROVED FOR SALE BY THE FDA WHETHER
14 OR NOT THE FDA HAS APPROVED THE DRUG OR DEVICE FOR USE IN TREATING THE
15 PATIENT'S PARTICULAR CONDITION, TO THE EXTENT THAT THE DRUGS OR DEVICES
16 ARE NOT PAID FOR BY THE MANUFACTURER, DISTRIBUTOR, OR PROVIDER OF THAT
17 DRUG OR DEVICE.

18 (H) (1) AN ENTITY SEEKING COVERAGE FOR TREATMENT IN A CLINICAL
19 TRIAL APPROVED BY AN INSTITUTIONAL REVIEW BOARD UNDER SUBSECTION
20 (E)(2)(V) OF THIS SECTION SHALL POST ELECTRONICALLY AND KEEP UP-TO-DATE A
21 LIST OF THE CLINICAL TRIALS MEETING THE REQUIREMENTS OF SUBSECTIONS (D)
22 AND (E) OF THIS SECTION.

23 (2) THE LIST SHALL INCLUDE, FOR EACH CLINICAL TRIAL:

24 (I) THE PHASE FOR WHICH THE TRIAL IS APPROVED;

25 (II) THE ENTITY APPROVING THE TRIAL;

26 (III) WHETHER THE TRIAL IS FOR TREATMENT OF CANCER OR
27 ANOTHER LIFE-THREATENING DISEASE AND, IF NOT CANCER, THE PARTICULAR
28 DISEASE; AND

29 (IV) THE ESTIMATED NUMBER OF PARTICIPANTS IN THE TRIAL.

30 ~~(E)~~ (I) THIS SECTION MAY NOT BE CONSTRUED TO AFFECT COMPLIANCE
31 WITH § 15-804 OF THIS SUBTITLE REGARDING COVERAGE FOR OFF-LABEL USE OF
32 DRUGS.

33 **Article - Health - General**

34 19-706.

35 (Y) THE PROVISIONS OF § 15-826 OF THE INSURANCE ARTICLE SHALL APPLY
36 TO HEALTH MAINTENANCE ORGANIZATIONS.

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.