

HOUSE BILL 45

Unofficial Copy
C3
HB 230/97 - ECM

1998 Regular Session
8r0111
CF 8r0063

(PRE-FILED)

By: **Delegates Krysiak, Kach, Barve, and Harrison**

Requested: July 15, 1997

Introduced and read first time: January 14, 1998

Assigned to: Economic Matters

A BILL ENTITLED

1 AN ACT concerning

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

3 FOR the purpose of requiring certain insurers and nonprofit health service plans to
4 provide coverage for certain patient costs incurred as a result of a treatment
5 being provided in accordance with a clinical trial under certain circumstances;
6 requiring certain insurers and nonprofit health service plans to provide
7 coverage for the cost of certain drugs and devices under certain circumstances;
8 providing for the application of this Act; providing for the construction of this
9 Act; defining certain terms; and generally relating to requiring certain insurers
10 and nonprofit health service plans to provide coverage for certain patient costs
11 incurred as a result of a treatment being provided in accordance with a clinical
12 trial and certain patient costs associated with certain drugs and devices under
13 certain circumstances.

14 BY adding to
15 Article - Insurance
16 Section 15-826
17 Annotated Code of Maryland
18 (1997 Volume)

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

21 **Article - Insurance**

22 15-826.

23 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
24 INDICATED.

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

1 (II) "COOPERATIVE GROUP" INCLUDES:

2 1. THE NATIONAL CANCER INSTITUTE CLINICAL
3 COOPERATIVE GROUP;

4 2. THE NATIONAL CANCER INSTITUTE COMMUNITY
5 CLINICAL ONCOLOGY PROGRAM;

6 3. THE AIDS CLINICAL TRIALS GROUP; AND

7 4. THE COMMUNITY PROGRAMS FOR CLINICAL RESEARCH IN
8 AIDS.

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

10 (4) "NIH" MEANS THE NATIONAL INSTITUTES OF HEALTH.

11 (5) "PATIENT" MEANS A POLICYHOLDER, SUBSCRIBER, OR CERTIFICATE
12 HOLDER OR A COVERED DEPENDENT OF A POLICYHOLDER, SUBSCRIBER, OR
13 CERTIFICATE HOLDER.

14 (6) (I) "PATIENT COST" MEANS ANY COST OF A MEDICALLY
15 NECESSARY HEALTH CARE SERVICE THAT IS INCURRED AS A RESULT OF THE
16 TREATMENT BEING PROVIDED TO THE PATIENT FOR PURPOSES OF THE CLINICAL
17 TRIAL.

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

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

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

23 3. COSTS ASSOCIATED WITH MANAGING THE RESEARCH
24 ASSOCIATED WITH THE CLINICAL TRIAL; OR

25 4. COSTS THAT WOULD NOT BE COVERED UNDER THE
26 PATIENT'S POLICY OR PLAN FOR NONINVESTIGATIONAL TREATMENTS.

27 (B) THIS SECTION APPLIES TO INSURERS AND NONPROFIT HEALTH SERVICE
28 PLANS THAT PROVIDE HOSPITAL, MEDICAL, SURGICAL, OR PHARMACEUTICAL
29 BENEFITS TO INDIVIDUALS OR GROUPS ON AN EXPENSE-INCURRED BASIS UNDER A
30 HEALTH INSURANCE POLICY OR CONTRACT ISSUED OR DELIVERED IN THE STATE.

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,

1 OR PERMANENTLY DISABLING CONDITION TO THE EXTENT SUCH COSTS WOULD BE
2 COVERED FOR NONINVESTIGATIONAL TREATMENTS IF:

3 (1) THE TREATMENT IS BEING PROVIDED WITH A THERAPEUTIC OR
4 PALLIATIVE INTENT;

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

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

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

9 (III) THE FDA IN THE FORM OF AN INVESTIGATIONAL NEW DRUG
10 APPLICATION;

11 (IV) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

12 (V) A QUALIFIED RESEARCH ENTITY THAT MEETS CRITERIA FOR
13 NIH CENTER SUPPORT GRANT ELIGIBILITY; OR

14 (VI) A PANEL OF QUALIFIED RECOGNIZED EXPERTS IN CLINICAL
15 RESEARCH WITHIN ACADEMIC HEALTH INSTITUTIONS IN THIS STATE;

16 (3) THE PROPOSED TREATMENT HAS BEEN REVIEWED AND APPROVED
17 BY TWO QUALIFIED INSTITUTIONAL REVIEW BOARDS;

18 (4) THE FACILITY AND PERSONNEL PROVIDING THE TREATMENT ARE
19 PROVIDING THE TREATMENT WITHIN THEIR SCOPE OF PRACTICE, EXPERIENCE, AND
20 TRAINING;

21 (5) THERE IS NO CLEARLY SUPERIOR, NONINVESTIGATIONAL
22 TREATMENT ALTERNATIVE; AND

23 (6) THE AVAILABLE CLINICAL OR PRECLINICAL DATA PROVIDE A
24 REASONABLE EXPECTATION THAT THE TREATMENT WILL BE AT LEAST AS
25 EFFICACIOUS AS THE ALTERNATIVE.

26 (D) IN ADDITION TO THE PROVISIONS OF SUBSECTION (C) OF THIS SECTION, A
27 POLICY OR PLAN SHALL PROVIDE COVERAGE FOR PATIENT COSTS INCURRED FOR
28 DRUGS AND DEVICES THAT HAVE BEEN APPROVED FOR SALE BY THE FDA WHETHER
29 OR NOT THE FDA HAS APPROVED THE DRUG OR DEVICE FOR USE IN TREATING THE
30 PATIENT'S PARTICULAR CONDITION.

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

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