Unofficial Copy 1997 Regular Session
C3 7lr0844

By: Delegate Krysiak
Introduced and read first time: January 16, 1997
Assigned to: Economic Matters

A BILL ENTITLED

AN ACT concerning

Health Insurance - Medical Clinical Trials - Coverage

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

BY adding to
Article - Insurance
Section 15-822
Annotated Code of Maryland
(1995 Volume and 1996 Supplement)
(As enacted by Chapter _____ (H.B. 11) of the Acts of the General Assembly of 1997)

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

Article - Insurance

15-822.

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

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

(II) "COOPERATIVE GROUP" INCLUDES:

1. THE NATIONAL CANCER INSTITUTE CLINICAL COOPERATIVE GROUP;

2. THE NATIONAL CANCER INSTITUTE COMMUNITY CLINICAL ONCOLOGY PROGRAM;

3. THE AIDS CLINICAL TRIALS GROUP; AND

4. THE COMMUNITY PROGRAMS FOR CLINICAL RESEARCH IN AIDS.

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

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

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

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

(II) "PATIENT COST" DOES NOT INCLUDE:

1. THE COST OF AN INVESTIGATIONAL DRUG OR DEVICE;

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

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

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

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

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

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

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

(I) ONE OF THE NATIONAL INSTITUTES OF HEALTH;

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

(III) THE FDA IN THE FORM OF AN INVESTIGATIONAL NEW DRUG EXEMPTION;

(IV) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

(V) A QUALIFIED NONGOVERNMENTAL RESEARCH ENTITY THAT MEETS CRITERIA FOR NIH CENTER SUPPORT GRANT QUALIFICATIONS; OR

(VI) A PANEL OF MEDICAL EXPERTS FROM THE JOHNS HOPKINS SCHOOL OF MEDICINE AND THE UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE WHO HAVE EXPERTISE IN THE CONDITION THAT IS THE SUBJECT OF THE TREATMENT;

(3) THE PROPOSED THERAPY HAS BEEN REVIEWED AND APPROVED BY A QUALIFIED INSTITUTIONAL REVIEW BOARD;

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

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

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

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

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

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